# MINUTES OF 360TH MEETING OF REGISTRATION BOARD HELD ON 07TH JULY, 2026


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

360th meeting of Registration Board was held on 07th July, 2026 in the Committee Room, Drug Regulatory Authority of Pakistan, Prime Minister's National Health Complex Park Road, Chak Shehzad, Islamabad.

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

The meeting was attended by the following:

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

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

## Item No. I Confirmation of minutes of 359th meeting of Registration Board.

359th meetings of Registration Board were held on 09th June, 2026. Accordingly, draft minutes of the 359th 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 358th meeting were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 359th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

**Decision: Registration Board confirmed the minutes of 359th meeting.**

# Item No. II Division of Pharmaceutical Evaluation & Registration

**Registration-I Section**

**Case No.01. Suspended Registrations of Cephalosporin Containing Products of M/s Hicon Pharmaceuticals, Peshawar**

Registration Board in its 297th meeting (held on 12th -15th January, 2021) considered the request of M/s Hicon Pharmaceuticals, Peshawar for suspension of registrations of their 'Cephalosporin containing products' and decided as under:

| Sr. No. | Reg. No. | Product Name and Composition |
|---|---|---|
| 1. | 041504 | Podomax Tablets<br>Each Tablet contains:<br>Cefpodoxime Proxetil Eq. to<br>Cefpodoxime……..100mg |
| 2. | 041507 | Podomax Dry Suspension<br>Each 5ml contains:<br>Cefpodoxime Proxetil Eq. to Cefpodoxime….40mg |
| 3. | 041508 | Duxima Dry Suspension<br>Each 5ml contains:<br>Cefixime ……..……100mg |
| 4. | 041509 | Duxima Capsules<br>Each capsules contains:<br>Cefixime Axitel …….... 400mg |
| 5. | 041510 | Concef Dry Suspension<br>Each 5ml contains:<br>Cephradine ……...125mg |
| 6. | 041511 | Concef Dry Suspension<br>Each 5ml contains:<br>Cephradine …….…...250mg |
| 7. | 041512 | Concef Capsules<br>Each Capsule contains:<br>Cephradine …….. 250mg |
| 8. | 041513 | Concef Capsules<br>Each Capsule contains:<br>Cephradine ……..500mg |
| 9. | 041514 | Foxil Dry Suspension<br>Each 5ml contains:<br>Cefadroxil ……..……..125mg |
| 10. | 041515 | Foxil Dry Suspension<br>Each 5ml contains:<br>Cefadroxil ……..…….250mg |
| 11. | 041516 | Foxil Capsules<br>Each Capsule contains:<br>Cefadroxil …….……500mg |

Decision of M-297:

*Registration Board acceded to the request of M/s Hicon Pharmaceuticals, Peshawar for suspension of registration of above-mentioned cephalosporin products subject to following:*

*i. The firm shall submit timelines for completion of dedicated cephalosporin facility.*

*ii. The firm shall continue to submit renewal applications of above-mentioned products throughout the duration of suspension.*

In line with the above-mentioned decision, registrations of above-mentioned products were suspended on 06.04.2021.

Later on, the firm applied for fresh registration of 'Duxima Dry Suspension & Capsule' (mentioned at S.No.3-4 of above table) by way of contract manufacturing at M/s Biogen Life Sciences, Rawalpindi. Accordingly, PRV approval has been issued in compliance with the decision taken by the RB in its 349th & 358th meetings.

However, for rest of the products the Board reconsidered the case in its 353rd meeting and decided as under:

Decision of M-353:

> *Registration Board noted that despite the lapse of almost 5 years, M/s Hicon, Peshawar has neither established dedicated cephalosporin facility nor submitted any timeline for completion.*
>
> *Therefore, the Board decided to issue show cause notice to the firm under section 7(11)(b)&(c) of the Drugs Act, 1976 read with section 42 thereof that why the registrations of their cephalosporin containing products may not be cancelled.*

In compliance with the above-mentioned decision, the firm was issued show-cause notice on 20.02.2026 vide e-Application TID PLX-8B1-1VEJ.

The firm responded the show cause notice as under:

> *"We humbly submit that due to financial and operational constraints, it has not been feasible for us to establish a separate building for cephalosporin manufacturing facility.*

The case was reconsidered in 358th meeting and *inter-alia* decided as under:

Decision of M-358:

*Under section 42 of the Drugs Act, 1976, M/s Hicon Pharmaceuticals, Peshawar shall be called for personal hearing with respect to following products which were suspended on 06.04.2021*

| Sr. No. | Reg. No. | Product Name and Composition |
|---|---|---|
| 1. | 041504 | Podomax Tablets<br>Each Tablet contains:<br>Cefpodoxime Proxetil Eq. to<br>Cefpodoxime……..100mg |
| 2. | 041507 | Podomax Dry Suspension<br>Each 5ml contains:<br>Cefpodoxime Proxetil Eq. to Cefpodoxime….40mg |
| 3. | 041510 | Concef Dry Suspension<br>Each 5ml contains:<br>Cephradine ……...125mg |
| 4. | 041511 | Concef Dry Suspension<br>Each 5ml contains:<br>Cephradine …….…...250mg |
| 5. | 041512 | Concef Capsules<br>Each Capsule contains:<br>Cephradine …….. 250mg |
| 6. | 041513 | Concef Capsules<br>Each Capsule contains:<br>Cephradine ……..500mg |
| 7. | 041514 | Foxil Dry Suspension<br>Each 5ml contains:<br>Cefadroxil ……..……..125mg |

| | | |
|---|---|---|
| 8. | 041515 | Foxil Dry Suspension<br>Each 5ml contains:<br>Cefadroxil ……..…….250mg |
| 9. | 041516 | Foxil Capsules<br>Each Capsule contains:<br>Cefadroxil …….……..……500mg |

In compliance with the decision of 358th meeting, the firm has been called for personal hearing on 07th July 2026 at 12:00 P.M.

Proceedings of 360th Meeting:

Mst. Anum appeared before the Board on behalf of M/s Hicon Pharmaceuticals, Peshawar. She informed that the firm intends to change the manufacturing status of above-mentioned products from self-manufacturing to contract manufacturing. Therefore, the Board is requested to allow the firm to proceed under contract manufacturing. In this context, she also confirmed that in compliance with the decision of 297th meeting of the Board, the firm has submitted renewal applications of above mentioned products throughout the duration of suspension.

**Decision: Registration Board acceded to request of the firm and directed to submit applications for change in manufacturing site of above-mentioned products within one month w.e.f 07th July, 2026.**

**Case No.02. Cancellation of Drug Manufacturing License of M/s. Alson Pharmaceutical Pvt. Ltd, Peshawar**

Deputy Director, QA&LT Division, DRAP has communicated vide letter No.F.3-21/2026-QALT(317-CLB) dated 14-05-2026 that CLB in its 317th meeting held on 27th April 2026 cancelled the Drug Manufacturing License of M/s Alson Pharmaceutical Pvt. Ltd., Plot No.169, 7-B Road, Industrial Estate, Hayatabad, Peshawar (DML No. 000522).

*Grounds of Cancellation:*

*Keeping in view the facts and proceedings of the case, after thorough deliberations and recommendations of FID that no necessary equipment related to manufacturing and quality control are available with the firm and the firm doesn't comply with Good Manufacturing Practices as per law and provision of SRO. 1460(I)/2019 dated 27-11-2019,*

**Decision: Keeping in view the decision taken by the Central Licensing Board, in its 317th meeting, regarding cancellation of DML of M/s Alson Pharmaceutical Pvt. Ltd., Plot No.169, 7-B Road, Industrial Estate, Hayatabad, Peshawar (DML No. 000522), Registration Board cancelled all registered products of the firm w.e.f. 14.05.2026. Furthermore, all under process and approved applications (if any) of the firm shall also stand disposed of.**

**Case No.03. Request of M/s Bosch Pharmaceuticals Pvt. Ltd., Karachi for Registration of Cefbac Injection 0.5gm Approved in 214th Meeting of Registration Board**

Registration Board in its 214th meeting (held on 28th - 29th Oct, 2008 ) approved the following product in favor of M/s Bosch Pharmaceuticals Pvt. Ltd., as per details given below:

| Name of Indentor /Manufacturer | Name of drug(s)/Composition & Therapeutic Group | Demanded Pack | Demanded Price | Remarks |
|---|---|---|---|---|
| M/s Bosch Pharmaceuticals, Karachi | Cebac 0.5gm Injection<br>Each vial contains:<br>Cefoperazone (as sodium)….250mg<br>Sulbactam (as Sodium) 250mg | Per Vial | Rs.130/- | Approved. |

| | | | | |
|---|---|---|---|---|
| | (Semi synthetic Broad-spectrum Cephalosporin) | | | |

Now the firm has requested for issuance of registration letter vide tracking Id: 9AX-NHM-8HSW and provided following details/documents.

1. Copy of initial registration dated 29.04.2008. (the **application does not bear any endorsement from DRAP/MOH**).
2. Fresh registration fee of Rs.38700/-(Slip#83766816009)
3. Copy of Form-5 with relevant annexures.
4. Copy of GMP Inspection Report dated 25-04-2024.
5. Copy of letter (dated 17-11-2025) issued by Licensing Division, DRAP for approval of 'Dry Powder Injectable (Ceph)' Section.

**Decision:** **The Board deferred the case and directed the firm to submit data of:**

**1. Development of 03 trial batches of the applied product.**
**2. Stability studies including accelerated and real time till 3rd month time point.**
**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**
**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**
**5. Analytical method of drug product and its verification/validation.**

**Furthermore, the Board decided that all such applications which were approved by the Board in its previous meetings (i.e., before 238th meeting) shall only be reconsidered after submission of above-mentioned studies by the applicant along-with confirmation of requisite manufacturing facility and GMP status of the firm.**

## Registration-II Section

**Case No.1 Registration of M/s. N.B.S Pharma, Lahore**

Following products of M/s N.B.S Pharma, Lahore considered in 215th meeting of Registration Board and decision is as follows.

| Sr. No | Name of Drug | Decision |
|---|---|---|
| 1. | Povidone-1 Solution<br>Each 100ml contains:-<br>Povidone Iodine USP 7.5gm equivalent to 0.75% available iodine (USP) | Approved subject to the submission of the last Inspection report. |

It is submitted that the above cases were discussed in 215th meeting of registration board and decision of the board has been reflected in the above table. The firm has now submitted the differential free of Rs. 12000/- and submitted the inspection report dated 12.11.2014. which shows details of the section as under:-

External Preparation Section:-

This section comprised of preparation and filling rooms, equipped with preparation vessels of different sizes. Silver san mixer and filling machines was installed HVAC system was provided in this area and was functional at the time of inspection. Re-packing area was equipped with filling machine and different size vessels. HVAC system was installed production area furnish with epoxy.

Registration Board in its 260th meeting deferred the case for GMP status of the firm and confirmation of section either from Licensing division or from panel / renewal inspection report.

The firm has submitted copy of inspection report 20-09-2019 with conclusion that the firm has rectified most of the shortcomings pointed out during last inspection. The panel recommends that M/s. N.B.S Pharma, Lahore may be allowed to resume the production in all sections.

Mr. Ajmal Sohail Asif Area FID vide letter No. 15075/2016-DRAP (L-II) dated 17-10-2016 clarified that the firm has approved external preparation section and is already manufacturing Povidone I

Solution, (Povidone Iodine SP. 10gm eq. to 1% Iodine) under Reg. No. 025552

**Decision of 296th meeting of Registration Board:**

**Registration Board deferred the case for confirmation of section approval from Licensing division.**

Now firm has submitted DML renewal letter wherein it is mentioned that firm has approval of following sections;

1. External Preparation - General (Human)
2. Liquid Repacking - General (Human)

**Decision: The Board deferred the case and directed the firm to submit data of:**

**1. Development of 03 trial batches of the applied product.**
**2. Stability studies including accelerated and real time till 3rd month time point.**
**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**
**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**
**5. Analytical method of drug product and its verification/validation.**

**RRR Section**

**Case No.1. M/s. Medasia Pharmaceuticals Plot No.07 Nowshwra industrial estate Riasalpur.**

M/s Medasia Pharmaceuticals submit the Form 5 Application with requisite fee and documents of already registered products of the previously under DML No. 000690, as per the following details, DML No. 000690 was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal.

The Central Licensing Board, 312th meeting held on 04 November 2025, considered the application for approval of Regrant the DML (by way of formulation) and DML has been received with issuance dated is. 14-11-2025.

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

Following applications are submitted in the light of above-mentioned decision:

| | | |
|---|---|---|
| 1. | **Brand Name + Dosage Form and Strength** | Estasia 10mg Tablet |
| | **Composition** | Each film coated tablet contains:<br>Escitalopram oxalate equivalent to<br>Escitalopram……10mg |
| | **Dairy No. date of R &I fee** | Rs.38700/- (Tracking ID: **6JU-J8X-S4U7)** |
| | **Type of form** | Fom-5 |
| | **Finished product specifications** | USP Specifications |
| | **Pack size and Demand Price** | 14's<br>As per SRO. |
| | **RRA Status** | USFDA Approved<br>Lexapro (escitalopram oxalate) |
| | **GMP Status** | Renewal of DML Inspection report dated 11.10.2021<br><br>Tablet (General) section is approved. |
| | **Remark of the Renewal section** | Registration of Estasia 10mg Tablet (064127) is invalid due to non-submission of renewal application within prescribe time period. |
| 2. | Brand Name + Dosage Form and Strength | Moxasia 400mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Moxifloxacin as HCl …….400mg |

| | | |
|---|---|---|
| | Dairy No. date of R &I fee | Rs.38700/- (Tracking ID: **QH8-NJL-JJ4Q)** |
| | Type of form | Fom-5 |
| | Finished product specifications | USP Specifications |
| | Pack size and Demand Price | ----- |
| | Me-too status | Moksi 400 mg Tablet ABBOTT LABORATORIES |
| | RRA Status | USFDA approved |
| | GMP Status | Renewal of DML Inspection report dated 11.10.2021<br><br>Tablet (General) section is approved. |
| | Remark of the Renewal section | Registration of Moxasia 400mg Tablet (064406) is invalid due to non-submission of renewal application within prescribe time period. |
| 3. | Brand Name + Dosage Form and Strength | IRO-P Tablet |
| | Composition | **Each chewable tablet contains: -**<br>Iron (III) hydroxide Polymaltose Complex eq. to Elemental Iron ……100mg<br>Folic Acid…….0.35mg |
| | Dairy No. date of R &I fee | Rs.38700/- (Tracking ID: **Q4E-79Z-WG9P)** |
| | Type of form | Form 5 |
| | Finished product specifications | Manufacturer's specifications |
| | Pack size and Demand Price | 10's |
| | Me-too status | IROTON-F BY SHAIGAN |
| | RRA Status | -- |
| | GMP Status | Renewal of DML Inspection report dated 11.10.2021<br>Tablet (General) section is approved |
| | Remark of the Renewal section | Registration of IRO-P Tablet (064128) is invalid due to non-submission of renewal application within prescribe time period. |
| 4. | **Brand Name + Dosage Form and Strength** | ANIFEN 100mg SR CAPSULE |
| | **Composition** | Each Capsule contains:<br>Diclofenac sodium (as SR pellets)…100mg |
| | **Dairy No. date of R &I fee** | Rs.38700/- **(Tracking ID: NPZ-XTG-QG73)** |
| | **Type of form** | Form 5 |
| | **Finished product specifications** | (BP Specification) |
| | **Pack size and Demand Price** | 20 's |
| | **Me-too status** | Phlogin SR-100 Brookes Pharma |
| | **RRA Status** | MHRA Approved |
| | **GMP Status** | DML Inspection report dated:11.10.2021<br>Capsule (General) section is approved. |
| | **Remark of the Renewal section** | Registration of ANIFEN 100mg SR CAPSULE (064116) is invalid due to non-submission of renewal application within prescribe time period. |
| 5. | Brand Name + Dosage Form and Strength | F-Pain SR 100mg Tablet |
| | Composition | Each sustained release tablet contains: -<br>Diclofenac sodium ……100mg |
| | Dairy No. date of R &I fee | Rs 38700/- (Tracking ID: **RYJ-LJQ-G1QW)** |
| | Type of form | Form 5 |
| | Finished product specifications | USP Specification |
| | Pack size and Demand Price | ------ |
| | Me-too status | Voltral SR 100 by Novartis |
| | RRA Status | USFDA approved |
| | GMP Status | DML Inspection report dated:11.10.2021<br>Tablet (General) section is approved. |

| | | |
|---|---|---|
| | Remark of the Renewal section | Registration of F-Pain tablet Tablet (064117) is invalid due to non-submission of renewal application within prescribed time period. |

**Decision: The Board deferred above cases and directed the firm either to submit data of:**

**1. Development of 03 trial batches of the applied product.**
**2. Stability studies including accelerated and real time till 3rd month time point.**
**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**
**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**
**5. Analytical method of drug product and its verification/validation.**

**Or**

1. **Testing method and record.**
2. **Long term stability testing upto the shelf life.**

**Case No.2. M/s. Welmed Pharmaceuticals industries (Pvt) Ltd. Plot No.108/1 Road No.R-2 I.E. Gadoon.**

| | | |
|---|---|---|
| 1. | **Brand Name + Dosage Form and Strength** | Micotrex Oral Gel 2% w/w |
| | **Composition** | Each gram contains:<br>Miconazole…….....20mg |
| | **Dairy No. date of R &I fee** | Rs.38700/- (Tracking ID: **74L-T14-QMLG)** |
| | **Type of form** | Fom-5 |
| | **Finished product specifications** | BP Specification |
| | **Pack size and Demand Price** | 20gm As per SRO. |
| | **Me-too status** | Daktarin 20mg/gram Oral Gel (Aspin Pharma) |
| | **RRA Status** | |
| | **GMP Status** | ……. |
| | **Remark of the Renewal section** | Registration of Micotrex Oral Gel 2% w/w (087460) is invalid due to non-submission of renewal application within prescribed time period. |

**Decision: The Board deferred above cases and directed the firm either to submit data of:**

**1. Development of 03 trial batches of the applied product.**
**2. Stability studies including accelerated and real time till 3rd month time point.**
**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**
**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**
**5. Analytical method of drug product and its verification/validation.**

**Or**

1. **Testing method and record.**
2. **Long term stability testing upto the shelf life.**

**Case No.3. M/s. Wnsfield Pharmaceuticals, Plot No. 122 Block-A Phase-V Industrial Estate, Hattar.**

| | | |
|---|---|---|
| 1. | Brand Name + Dosage Form and Strength | **Navix 40mg Capsule** |
| | Composition | Each Capsule Contains: -<br>Enteric Coated Pellets of Esomeprazole Magnesium Trihydrate eq. to Esomeprazole.....40mg |
| | Dairy No. date of R &I fee | Rs.38700/- (Tracking ID: **73U-EAS-7LEB**) |
| | Type of form | Form-5 |
| | Finished product specifications | As per Requirement of Importing Country |
| | Pack size and Demand Price | As per Requirement of Importing Country |
| | Me-too status | Lesomep 40mg Capsules<br>Reg# 054935 by Lawari International |
| | RRA Status | USFDA |

| | | |
|---|---|---|
| | GMP Status | GMP certificate issued on 08/08/2025 |
| | Remark of the Renewal section | Registration of Navix 40mg Capsule (Reg No. 008048-Ex) is invalid due to non-submission of renewal application within prescribed time period. |
| 2. | Brand Name + Dosage Form and Strength | **Colwincine 1mg Tablet** |
| | Composition | Each Film Coated Tablet contains:-<br>Colchicine ….....1mg |
| | Dairy No. date of R &I fee | Rs.38700/- (Tracking ID: **73U-EAS-7LEB**) |
| | Type of form | Form-5 |
| | Finished product specifications | As per Requirement of Importing Country |
| | Pack size and Demand Price | As per Requirement of Importing Country |
| | Me-too status | Acefen 100mg Tablet (0558813) of-Semos Pharmaceuticals PVT LTD |
| | RRA Status | UK MHRA |
| | GMP Status | GMP certificate issued on 08/08/2025 |
| | Remark of the Renewal section | Registration of Colwincine 1mg Tablet (Reg No. 008038-Ex) is invalid due to non-submission of renewal application within prescribed time period. |

**Decision: The Board deferred above cases and directed the firm either to submit data of:**

**1. Development of 03 trial batches of the applied product.**
**2. Stability studies including accelerated and real time till 3rd month time point.**
**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**
**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**
**5. Analytical method of drug product and its verification/validation.**

**Or**

1. **Testing method and record.**
2. **Long term stability testing upto the shelf life.**

**Case No.04: M/s AZ Pharmaceuticals Co. Ltd., address 4-KM, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338)**

M/s AZ Pharmaceuticals Co. Ltd., submit the Form 5 Application with requisite fee and documents of already registered products of the previously under DML No. 000338, as per the following details, DML No. 000338 was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal.

The Central Licensing Board, 312th meeting held on 04 November 2025, considered the application for approval of Regrant the DML (by way of formulation) and DML has been received with issuance dated is. 14-11-2025.

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

Following applications are submitted in the light of above-mentioned decision. These applications were also considered in 354th and 358th meeting wherein firm had applied for fill volume of 500ml and 1000ml as firm already possess registrations of both voles against single registration. Registration Board decided to ask firm to select one fill volume and accordingly, registrations of 1000ml fill volume were granted. Now firm has submitted separate application for registration of 500ml pack size in light of above decision of the Authority.

| | | |
|---|---|---|
| **1.** | Brand Name + Dosage Form and Strength | Immunasol 5 % IV Infusion |

| | | |
|---|---|---|
| | Composition | Each 1000ml contains:-<br>Dextrose Anhydrous….....50gm |
| | Tracking ID and fee details | Challan No. 92504153205 Rs. 38700 &<br>Tracking ID: **SX9-EHP-PE8X** |
| | Type of form | IV Infusion |
| | Finished product specifications | BP Specification |
| | Pack size and Demand Price | 500ml |
| | GMP Status | DML (afresh) granted dated 14th November 2025<br>Large volume parenteral (infusion) section is approved. |
| | RRA status | MHRA Approved |
| | Remarks: | Immunasol 5% IV Infusion (014233) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, |
| | | due to the late submission of the application for DML renewal |
| | | |
| **2.** | Brand Name + Dosage Form and Strength | Immunasol 10% Intravenous Infusion |
| | Composition | Each 1000ml contains:-<br>Dextrose Anhydrous….....100gm |
| | Tracking ID and fee details | Challan No. 15282677 Rs. 38700 &<br>Tracking ID: **9HW-L2G-BDN3** |
| | Type of form | IV Infusion |
| | Finished product specifications | BP Specification |
| | Pack size and Demand Price | 500ml |
| | GMP Status | DML (afresh) granted dated 14th November 2025<br>Large volume parenteral (infusion) section is approved. |
| | RRA status | MHRA Approved |
| | Remarks: | Immunasol 10% Intravenous Infusion (014234) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal |
| | | |
| **3.** | Brand Name + Dosage Form and Strength | Immunasol NS IV Infusion |
| | Composition | Each 1000ml contains:-<br>Sodium Chloride….....9gm |
| | Tracking ID and fee details | Challan No. 36516731112 Rs. 38700 &<br>Tracking ID: **E85-SAL-XVUG** |
| | Type of form | IV Infusion |
| | Finished product specifications | BP Specification |
| | Pack size and Demand Price | 500ml |
| | GMP Status | DML (afresh) granted dated 14th November 2025<br>Large volume parenteral (infusion) section is approved |
| | RRA status | MHRA Approved |

| | | |
|---|---|---|
| | Remarks: | Immunasol NS IV Infusion (014235) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, |
| | | due to the late submission of the application for DML renewal |
| | | |
| **4.** | Brand Name + Dosage Form and Strength | Immunasol DN Intravenous Infusion |
| | Composition | Each 1000ml contains:-<br>Dextrose Anhydrous….....50gm<br>Sodium Chloride….....9gm |
| | Tracking ID and fee details | Challan No. 730073300702 Rs. 38700 &<br>Tracking ID: **LU4-7HB-AVZE** |
| | Type of form | IV Infusion |
| | Finished product specifications | BP Specification |
| | Pack size and Demand Price | 500ml |
| | GMP Status | DML (afresh) granted dated 14th November 2025<br>Large volume parenteral (infusion) section is approved |
| | RRA status | MHRA Approved |
| | Remarks: | Immunasol DN Intravenous Infusion (014236) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal |
| | | |
| **5.** | Brand Name + Dosage Form and Strength | Immunasol-H IV Infusion |
| | Composition | Each 100ml contains:-<br>Sodium Chloride .....0.6gm<br>Potassium Chloride.....0.04gm<br>Sodium Lactate.....0.32gm<br>Calcium Chloride $2H_2O$.....0.027gm |
| | Tracking ID and fee details | Challan No. 15934906089 Rs. 38700 &<br>Tracking ID: **UVZ-ZJH-9E4X** |
| | Type of form | IV Infusion |
| | Finished product specifications | BP Specification |
| | Pack size and Demand Price | 500ml |
| | GMP Status | DML (afresh) granted dated 14th November 2025<br>Large volume parenteral (infusion) section is approved |
| | RRA status | MHRA Approved |
| | Remarks: | Immunasol-H IV Infusion (015329) M/s AZ Pharmaceutical, Manga Road, Raiwind, District Kasur Lahore (DML No. 000338), was declared invalid vide letter No. F.1-13/93-Lic (Vol-V) dated 11 August 2025, due to the late submission of the application for DML renewal 1 volume/pack size to be chosen by the firm (either 500ml or 1000ml) |

| | | |
|---|---|---|
| | | |

**Decision: The Board deferred above cases and directed the firm either to submit data of:**

**1. Development of 03 trial batches of the applied product.**
**2. Stability studies including accelerated and real time till 3rd month time point.**
**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**
**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**
**5. Analytical method of drug product and its verification/validation.**

**Or**

1. **Testing method and record.**
2. **Long term stability testing upto the shelf life.**

**Post-Registration-I Section**

**Case No. 01: Decision of USFDA to withdraw approval of Makena (Hydroxyprogesterone Caproate Injection) and its Generics.**

On April, 06, 2023, U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

2. In 2011, FDA approved Makena to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. This accelerated approval was based on a trial that showed the drug reduced deliveries before 37 weeks of pregnancy, an intermediate clinical endpoint that FDA determined was reasonably likely to predict clinical benefit to the newborn.

3. As a condition of Makena's accelerated approval, the sponsor was required to conduct a confirmatory clinical trial to verify and describe the predicted clinical benefit to newborns. This trial, which was nearly four times larger than the trial that supported Makena's approval, did not show improvement in the health of the babies born to mothers who were treated with Makena. Makena and its generics (i.e., generic versions of Makena) are not shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Nor have Makena and its generics been shown to be effective for any subgroup of this population, including in women at high risk of preterm birth. In addition, there are known risks associated with Makena. Accordingly, these drugs do not have benefits that outweigh their risks to patients.

4. Registration Board while considering the approval of Hydroxyprogesterone Injection in USFDA registered following drug products:-

| Sr. No. | Reg. No. | Product Name & Composition | Registration Holder / Manufacturer | Renewal Status |
|---|---|---|---|---|
| 1. | 096479 | Nandrosol 250mg Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate.....250mg | Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore | Renewal is not yet due |

| | | | | |
|---|---|---|---|---|
| 2. | 094205 | Hygest Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate....……250mg | Shaigan Pharmaceuticals (Pvt) Ltd | Renewal is not yet due |
| 3. | 003531 | Hydroxyprogesterone Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate....……250mg | M/s. Zafa Pharmaceutical, Karachi. | Renewal is valid |
| 4. | 030526 | Globinan 2Ml Injection<br>Hydroxy Progesterone Caproate…. 250mg | Global Pharmaceuticals Pvt Ltd | Renewal Not Submitted |
| 5. | 030525 | Globinan 1Ml Injection<br>Hydroxy Progesterone | Global Pharmaceuticals Pvt Ltd | Renewal Not Submitted |
| 6. | 013624 | VIO-DEPOT INJ<br>Each ml contains:<br>Hydroxyprogesterone caproate....……250mg | Venus Pharma, 23 Km Multan Road Lahore. , Lahore | Renewal Not Submitted |
| 7. | 003746 | HYDROXYPROGESTRONE INJECTION<br>Each ml contains:<br>Hydroxyprogesterone caproate....……250mg | Haji Medicines, Rawalpindi | Renewal Not Submitted |
| 8. | 003833 | HYDROXYPROGESTRONE<br>Each ml contains:<br>Hydroxyprogesterone caproate....……250mg | | Renewal Not Submitted |

5. Following combination drug products containing Hydroxyprogesterone were also registered by the Registration Board:-

| Sr. No. | Reg. No. | Product Name & Composition | Registration Holder / Manufacturer | Renewal Status |
|---|---|---|---|---|
| 1. | 103324 | Kevi Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate_ 250 mg<br>Estradiol valerate _ 5 mg | Hansel Pharmaceuticals (Pvt) Ltd., Plot No 2 Pharma City 30-Km Multan Road Lahore. , Lahore | Renewal is not yet due |
| 2. | 084375 | Contrex Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate_ 250 mg<br>Estradiol valerate _ 5 mg | Shaigan Pharmaceuticals (Pvt) Ltd | Renewal is valid |
| 3. | 077108 | Z-Bron Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate_ 250 mg<br>Estradiol valerate _ 5 mg | Pharma Health Pakistan (Pvt) Ltd. | Renewal is valid |
| 4. | 011155 | VIO-DEPOT INJ<br>HYDROXYPROGESTERONE CARPOATE 250MG<br>QUESTRADIOL VALERATE | Wilson's Pharmaceuticals | Renewal Not Submitted |

| | | | | |
|---|---|---|---|---|
| | | 5MG SESAME OIL 693MG | | |
| 5. | 000798 | GRAVIBINON INJECTION HYDROXY PROGESTERONE CAPROATE 250MG, , OESTRADIOL VALERATE IN OILY SOLUTION | Medipharm (Private) Limited,, 7-A, Gulberg II, Lahore, Lahore | Last renewal was submitted dated 02-10-2018 |

6. Sub-rule 10 (a) of Rule 30 of Drugs (L, R & A) Rules, 1976 narrates as under:

***"(a) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentors, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;"***

**7. Decision of 327th Meeting:**

**Registration Board decided to issue show-cause notice to all registration holders having valid registration of Hydroxyprogesterone containing drug products under section 7(11)(d) of the Drug Act, 1976 read with section 42 thereof that why the registration of their products may not be cancelled in the public interest. For products having in-valid registration, RRR-Section is advised to proceed for cancellation of registration.**

9. **(Hydroxyprogesterone Caproate)** With reference to above decision of 327th meeting of the Board, M/s. Bayer has submitted a request for reconsideration of Drug Registration Board (327th Meeting) decision for Proluton Depot Injection (Hydroxyprogesterone Caproate) in response of withdrawal of Makena by USFDA. Request of the firm is as under:

*i. Proluton Depot is Bayer's innovator product, registered in Pakistan since 1988. However, Makena was first approved by USFDA in 2012 under the accelerated approval pathway.*

*ii. It is important to note that approval of Makena was Withdrawn by USFDA due to lack of efficacy in approved indication i.e. To reduce the risk of preterm birth which is entirely different from approved indication of Proluton Depot i.e., Habitual and imminent abortion, infertility due to corpus luteum insufficiency, primary and secondary amenorrhea but not due to quality or safety reasons.*

*iii. Bayer is the manufacturer of Drug Substance i.e., Hydroryprogesterone caproate) used for the manufacturing of Proluton Depot.*

*iv. Proluton Depot is available in many countries across the World including Austria (SRA), Bahrain, Malaysia, Afghanistan, lran, Turkey, Qatar, Yemen, Lebanon, Oman, Thailand Argentina and Singapore.*

*v. Firm has also submitted snapshot of Austria's Official Health Authority Website confirming the approval of Proluton Depot indication which are reproduced as under:*

*"After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.*

*lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.*

*Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.*

*Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus luteum deficiency."*

9. Firm has further submitted a justification provided by Bayer AG, Germany, their ultimate parent company which outlines the differences between the products further and clearly sets out that the USFDA's Makena decision does not have any implication for Proluton Depot. Thus recall is not applicable.

10. **(Hydroxyprogesterone caproate + Estradiol valerate)** With reference to above decision of 327th meeting of the Board, M/s. Bayer has also submitted a request for reconsideration of Drug Registration Board (327th Meeting) decision for Gravibinan Injection (Estradiol Valerate + Hydroxyprogesterone Caproate) in response of withdrawal of Makena (Hydroryprogesterone caproate) and its generics by USFDA stating that Gravibinan, a combination product comprising Estradiol valerate and Hydroxyprogesterone caproate, should not be encompassed in the recent proceedings of the Drug Registration Board meeting regarding the decision of the USFDA to withdraw the approval of Makena (Hydroryprogesterone Caproate) and its generics due to lack of efficacy, i.e. Makena's, approved indication is to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

11. They have further submitted that Gravibinan should be excluded from the scope of this decision, and presented following points:

i. *Regarding Therapeutic Indication of Gravibinan Injection firm has submitted that Gravibinan is not only a distinct product as it is a combination of Estradiol valerate and Hydroxyprogesterone caproate but is also indicated for the prophylaxis of abortion and threatened abortion. Hence, its therapeutic use differs significantly from that of Makena. Furthermore, they have also enclosed a justification provided by Bayer AG, their parent company based in Germany, which outlines the differences between the products and stablishes that the USFDA's decision regarding Makena does not impact Gravibinan.*

ii. *Regarding need for Gravibinan Injection in Pakistan firm has submitted as under:*
   a. *Currantly there are no alternative options available in injectable form for the prophylaxis of abortion and threatened abortion.*
   b. *The prevalence of prophylaxis of abortion and threatened abortion is considerably high within our country.*
   c. *Gravibinan alone serves an annual patient turnover of 630,417.*

12. They have requested to reconsider the decision of 327th meeting of the Board regarding Hydroxyprogesterone caproate and Estradiol valerate + Hydroxyprogesterone caproate.

13. In USFDA, an NDA product DELALUTIN (Hydroxyprogesterone caproate) is discontinued with remarks that "***Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons***". Furthermore, one generic approval of Hydroxyprogesterone caproate Injection 250mg/ml is available as a status of prescription [Abbreviated New Drug Application (ANDA): 200271] with following indication and usage:

> **Hydroxyprogesterone Caproate Injection USP is indicated in non-pregnant women: for the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); in the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as sub mucous fibroids or uterine cancer; as a test for endogenous estrogen production and for the production of secretory**

**endometrium and desquamation.**

14. Moreover, approved indications of Makena (Hydroxyprogesterone Caproate) are as under:

**Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.**

15. Indication approved by Austria as claimed by M/s. Bayer are as under:

**After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.**
**lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.**
**Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.**
**Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus luteum deficiency.**

**16. Decision of 330th Meeting of the Board:**

**Registration Board decided that M/s Bayer shall be provided an opportunity of personal hearing in the next meeting to present their stance and brief the Board regarding approval status of their products in reference regulatory authorities.**

As per decision of the Board firm was called for personal hearing.

**17. Proceedings of 331st Meeting:**

Dr. Aftab Ahned Khan, Head of Regulatory Affairs and Dr Masroor Ahmed, Sr. Medcal Advisor appeared on behalf of M/s. Bayer and submitted that withdrawal of Makena is linked with its indication which are different than that of Prolutin of M/s. Bayer. Prolution is also available in Austria which was also confirmed from website https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx;jsessionid=MBTSW0JJJ6ihyhL8nRipVJit Ty-3qEb7-xNnE54qIcZaCU5sSJMr!2098280154?_adf.ctrl-state=11ajcl0qd9_4.
Firm has also submitted Austria approved indication of Prolutin which is as under:
*After the ovulation of the woman, the follicles are transformed into the corpus luteum. The corpus luteum produces the hormone progesterone and inhibits thus the premature reduction of the endometrium and causes furthermore a thickening of the cervic mucus. Thus an implantation of the fertilized egg is possible and favorable conditions for the maintenance of the pregnancy are secured.*
*lf your body is not producing enough progesterone (corpus luteum hormone) due to a low functioning during pregnancy, a miscarriage (abortion) may occur.*
*Proluton Depot contains the hormone hydroxyprogesterone caproate, comparable to the naturally produced corpus luteum, which the female body produces during pregnancy.*
*Proluton is used in case of repeated miscarriage (habitual abortion) due to corpus*

*luteum deficiency.*

Furthermore, firm has also submitted that Gravibinan Injection contains Estradiol valerate + Hydroxyprogesterone caproate which is not generic of Makena.

**18. Decision of 331st Meeting:**

***Keeping in view the submissions of M/s Bayer Pakistan Limited and the approval of the indications of their product i.e. Proluton Depot Injection by the Austrian Federal Office for Safety in Healthcare BASG, Registration Board withdraws its earlier show cause approved in 327th meeting.***

***Moreover, the show cause, approved in 327th meeting, to the products containing combination of Hydroxyprogesterone Caproate and Estradiol Valerate is also hereby withdrawn considering the fact that the aforesaid formulations have not been reported to be withdrawn in any reference regulatory authorities.***

19. On 26 June 2024, the Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) endorsed the recommendation from EMA's safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), to suspend the marketing authorizations for medicines containing 17-Hydroxyprogesterone caproate (17-OHPC) in the European Union (EU). A review by the PRAC concluded that there is a possible but unconfirmed risk of cancer in people exposed to 17-OHPC in the womb. In addition, the review considered new studies which showed that 17-OHPC is not effective in preventing premature birth; there are also limited data on its effectiveness in other authorized uses.

In some EU countries, 17-OHPC medicines are authorized as injections to prevent pregnancy loss or premature birth in pregnant women. They are also authorized for the treatment of various gynecological and fertility disorders, including disorders caused by a lack of a hormone called progesterone. The study, which involved over 1,700 pregnant women with a history of preterm delivery, found that 17-OHPC is no more effective than placebo (a dummy treatment) in preventing recurrent premature birth or medical complications due to prematurity in newborns.

In view of the concern raised by the possible risk of cancer in people exposed to 17-OHPC in the womb, together with the data on the effectiveness of 17-OHPC in its authorized uses, the PRAC considered that the benefits of 17-OHPC do not outweigh its risks in any authorized use. The Committee therefore recommended the suspension of the marketing authorizations for these medicines. Alternative treatment options are available. Detail of drug products is as under:

| Sr. No. | Reg. No. | Product Name & Composition | Registration Holder / Manufacturer |
|---|---|---|---|
| 1. | 000899 | Proluton Depot 250mg Injection<br>Hydroxyprogesterone caproate....250mg | M/s. Bayer |
| 2. | 096479 | Nandrosol 250mg Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate....250mg | Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore |
| 3. | 094205 | Hygest Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate....250mg | Shaigan Pharmaceuticals (Pvt) Ltd |
| 4. | 003531 | Hydroxyprogesterone Injection<br>Each ml contains:<br>Hydroxyprogesterone caproate....250mg | M/s. Zafa Pharmaceutical, Karachi. |
| 5. | 030526 | Globinan 2Ml Injection<br>Hydroxy Progesterone Caproate…. 250mg | Global Pharmaceuticals Pvt |

| | | | |
|---|---|---|---|
| | | | Ltd |
| 6. | 030525 | Globinan 1Ml Injection<br>Hydroxy Progesterone | Global Pharmaceuticals Pvt Ltd |
| 7. | 013624 | VIO-DEPOT INJ<br>Each ml contains:<br>Hydroxyprogesterone caproate....……250mg | Venus Pharma, 23 Km Multan Road Lahore. , Lahore |
| 8. | 003746 | HYDROXYPROGESTRONE INJECTION<br>Each ml contains:<br>Hydroxyprogesterone caproate....……250mg | Haji Medicines, Rawalpindi |

**19. Decision of 343rd meeting of Registration Board:**

***Registration Board decided to issue show-cause notice to all registration holders having registration of Hydroxyprogesterone containing drug products under section 7(11) (d) read with section 42 of Drug Act 1976.***

**20. Proceedings of 346th meeting of Registration Board:**

In light of above decision of the Board, showcause letters have been issued to firms and firm have also been called for personal hearing. In response to show cause notice, following firms submitted their responses which is as under:

| Sr. No. | Name of Firm | Brief Response |
|---|---|---|
| 1. | **M/s Bayer Pakistan (Pvt) Limited Karachi.** | We, Bayer Pakistan (Pvt) Ltd, would like to highlight that based on the recommendations of EMS's Pharmacovigilance Risk Assessment Committee (PRAC), we have already informed DRAP via letter no. BPPL-DRAP-24-039 dated 01st Aug 2024 stating that registration of Proluton Depot is no longer valid and has lapsed following the divestment of the licensed facility to OBS Pakistan. |
| 2. | **M/s. Global Pharmaceutical (Pvt) Ltd, Islamabad.** | In accordance with the esteemed registration board's guidance, we have decided to withdraw the registration of our product. |

**21. Decision of 346th meeting of Registration Board:**

***Registration Board considered the below mentioned decision of Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) of European Medicine Agency (EMA):***

> ***"On 26 June 2024, the Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) endorsed the recommendation from EMA's safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), to suspend the marketing authorizations for medicines containing 17-Hydroxyprogesterone caproate (17-OHPC) in the European Union (EU). A review by the PRAC concluded that there is a possible but unconfirmed risk of cancer in people exposed to 17-OHPC in the womb. In addition, the review considered new studies which showed that 17-OHPC is not effective in preventing premature birth; there are also limited data on its effectiveness in other authorized uses."***

***In light of above decision of European Medicine Agency for suspension of medicines***

***containing 17-Hydroxyprogesterone caproate (17-OHPC), Registration Board under Section 7 (11)(b), (c) and (d) of the Drugs Act, 1976 read with rule 30(10) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 decided as under:***

***i. To suspend the registration of following products containing 17-Hydroxyprogesterone caproate (17-OHPC):***

| *Sr. No.* | *Reg. No.* | *Product Name & Composition* | *Registration Holder / Manufacturer* |
|---|---|---|---|
| *1.* | *096479* | *Nandrosol 250mg Injection*<br>*Each ml contains:*<br>*Hydroxyprogesterone caproate....250mg* | *Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore* |
| *2.* | *094205* | *Hygest Injection*<br>*Each ml contains:*<br>*Hydroxyprogesterone caproate....250mg* | *Shaigan Pharmaceuticals (Pvt) Ltd* |
| *3.* | *003531* | *Hydroxyprogesterone Injection*<br>*Each ml contains:*<br>*Hydroxyprogesterone caproate....250mg* | *M/s. Zafa Pharmaceutical, Karachi.* |
| *4.* | *030526* | *Globinan 2Ml Injection*<br>*Hydroxy Progesterone Caproate…. 250mg* | *Global Pharmaceuticals Pvt Ltd* |
| *5.* | *030525* | *Globinan 1Ml Injection*<br>*Hydroxy Progesterone* | *Global Pharmaceuticals Pvt Ltd* |
| *6.* | *013624* | *VIO-DEPOT INJ*<br>*Each ml contains:*<br>*Hydroxyprogesterone caproate.....250mg* | *Venus Pharma, 23 Km Multan Road Lahore. , Lahore* |
| *7.* | *003746* | *HYDROXYPROGESTRONE INJECTION*<br>*Each ml contains:*<br>*Hydroxyprogesterone caproate.....250mg* | *Haji Medicines, Rawalpindi* |

***ii. Registration of Proluton Depot bearing Registration No. 000899 in name of M/s Bayer Pakistan (Pvt) Limited 108 Kot Lakpat Industrial Estate Lahore is no longer valid as it was not divested to any company in Pakistan after acquisition of of aforesaid facility by M/s OBS Pakistan.***

***iii. Decision of suspension of 17-Hydroxyprogesterone caproate (17-OHPC) shall be placed again before the Registration Board once matter is further proceeded by the Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) of EU.***

***iv. To issue show cause and personal hearing notice to the companies having registration of 17-Hydroxyprogesterone caproate (17-OHPC) in combination with other drugs.***

In line with the point **iv** of above-mentioned decision, show cause notices were issued to following firms on 27.06.2025.

| **Sr. No.** | **Reg. No.** | **Product Name & Composition** | **Registration Holder / Manufacturer** | **Renewal Status** |
|---|---|---|---|---|
| 1. | 103324 | Kevi Injection<br>Each ml contains:<br>Hydroxyprogesterone Caproate…….250mg<br>Estradiol valerate……..5mg | Hansel Pharmaceuticals (Pvt) Ltd., Plot No 2 Pharma City 30-Km Multan Road Lahore. , Lahore | Renewal is not yet due |

| | | | | |
|---|---|---|---|---|
| 2. | 084375 | Contrex Injection<br>Each ml contains:<br>Hydroxyprogesterone Caproate…….250mg<br>Estradiol Valerate……5mg | Shaigan Pharmaceuticals (Pvt) Ltd | Renewal is valid |
| 3. | 077108 | Z-Bron Injection<br>Each ml contains:<br>Hydroxyprogesterone Caproate……..250mg<br>Estradiol Valerate……..5mg | Pharma Health Pakistan (Pvt) Ltd. | Renewal is valid |
| 4. | 011155 | Vio-Depot Injection<br>Hydroxyprogesterone Carpoate…… 250mg<br>Estradiol Valerate……..5mg<br>Sesame Oil…….693mg | Wilson's Pharmaceuticals | Renewal Not Submitted |
| 5. | 000798 | Gravibinon Injection<br>Hydroxy Progesterone Caproate…… 250mg<br>Oestradiol Valerate in Oily Solution | Medipharm (Private) Limited,, 7-A, Gulberg II, Lahore, Lahore | Last renewal was submitted dated 02-10-2018 |

Subsequently, above-mentioned firms have also been called for personal hearing before the Board on 24.09.2025 at 10:00 AM (vide notices issued on 04.09.2025).

**Proceeding of the 351st meeting of the Board**

Mr. Humayoun Mughal on behalf of M/s. OBS Pharma (Pvt) Ltd., Lahore appeared before the Registration Board and requested to grant four months time for submission of safety and efficacy data of under question product. He informed that Agha Khan Hospital, Karachi has the data of the use of this product in local population since year 2001 and they have signed an agreement with Agha Khan Hospital, Karachi for sharing this data. Data sharing and its compilation will take time. The Registration Board may decide the case on the basis of actual data of safety and efficacy in local population.

**Decision of 351st meeting of Registration Board:**

The Registration Board acceded to the request of the firm for granting four months time for sharing data of local use of the Gravibinon Injection with the condition that agreement be shared immediately with PE&R Division after signing with Agha Khan Hospital.

**In reply to the decision of the Registration Board, the firm has submitted following study conducted by the Agha Khan University Karachi:**

**Project Title:**

Efficacy and Safety of Gravibinan in High-Risk Pregnancies: A Retrospective Cohort Study on Long-Term Child Health Outcomes

Report Period: 1 November 2025 to 22nd December 2025

**Project Overview:**

This retrospective cohort study aims to assess the effectiveness and safety of Gravibinan (hydroxyprogesterone caproate) in high-risk pregnancies and to evaluate the long-term health outcomes among children born to mothers who received Gravibinan during pregnancy. Data has been retrieved from multiple Aga Khan University Hospital sites, including the main campus and secondary hospitals in Garden, Karimabad, Kharadar, and Hyderabad.

**Current Report Status:**

This report presents maternal and pregnancy outcome data for 266 women enrolled from Aga Khan University Hospital (AKU) Main Campus and affiliated secondary hospitals in Garden and Karimabad. Of these pregnancies, 209 (78.57%) resulted in live births, comprising 196 singleton, 9 twin, and 4 triplet pregnancies. Immediate neonatal information for a total of 226 live-born infants was included in the analysis. Follow-up data were extracted for 178 (78.76%) of the 226 live-born children, while follow-up for the remaining cases is ongoing. Among the 178 children, 12 (6.74%) were confirmed to have been deceased, 10 (5.62%) had an unknown survival status, and 156 (87.64%) were alive. Long-term outcome data were subsequently extracted for the 156 surviving children. Missing information

was primarily attributable to pending medical record retrievals and scheduled telephonic interviews, which are being conducted as part of the study's longitudinal follow-up framework

**Strengths and Limitations**

This study is longitudinal in nature. It enrolled pregnant women who were prescribed Gravibinan during pregnancy and subsequently delivered at Aga Khan University Hospital (AKUH). The offspring of these women were followed up during 2025 to assess late-onset adverse outcomes. A key strength of the study is its long exposure assessment window (2007 2024), which allowed comprehensive identification of Gravibinan use during pregnancy. In addition, late-onset adverse effects among offspring were assessed through structured telephonic follow-up. The study also benefited from a universal sampling approach, as records of all eligible women meeting the inclusion criteria were included, minimizing selection bias. However, several limitations should be considered. Certain maternal and child variables were subject to recall bias, as pregnancy history and child developmental outcomes relied partly on self-reported information. Data on total dose and dosing frequency of Hydroxyprogesterone (Gravibinan) may be incomplete or underestimated because analyses were based solely on AKU pharmacy records; participants may have obtained medication from external pharmacies, introducing potential misclassification and compliance bias. Additionally, a small number of variables remain under refinement due to incomplete reporting or pending validation.

**Submitted for consideration of the Board**

**Decision:- The Board decided to call the firm for personal hearing along with Principle Investigator.**

## Import & Vet-I Section

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| **1.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Ismisole 50% Oral Powder |
| | Composition | Each Kg contains:<br>Levamisole HCl…500gm |
| | Diary No. Date of R& I & fee | Dy.No 27494 dated 23-11-2023 Rs 30,000/- dated 12-10-2023 (slip No. 0598922673) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg; Decontrolled |
| | Me-too status | Arch Lev 50% Powder of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK. (Reg. No. 122001) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |
| | Remarks of the Evaluator | **Target species:**<br>Cattle, calves, sheep, goats, poultry<br>**Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>• **fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024dated 30-08-2024**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of Dry Powder suspension (Veterinary) vide letter dated 15-06-2021, fee challan** 1134996926 | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |

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| **2.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Ismisole 1.5% Oral Solution |
| | Composition | Each ml contains:<br>Levamisole…15mg |
| | Diary No. Date of R& I & fee | Dy.No 27492 dated 23-11-2023 Rs 30,000/- dated 12-10-2023 (slip No. 5108558653) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled |
| | Me-too status | Arch Leva 1.5% Drench of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK. (Reg. No. 121894) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |
| | Remarks of the Evaluator | **Target species:**<br>Cattle, buffaloes, sheep, goats, pets<br>**Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 37,000/- for correction/standardization of composition as per reference regulatory authority/innovator's product (Generic Drug local manufacture) and FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>• **fee Rs. 37,000/- for correction/standardization of composition as per reference regulatory authority/innovator's product (Generic Drug local manufacture) and FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024.**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of liquid syrup veterinary vide letter dated 15-06-2021. And fee is submitted vide challan no.** 6992810528. | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| **3.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Ismisole 15% Oral Solution |
| | Composition | Each ml contains:<br>Levamisole…150mg |
| | Diary No. Date of R& I & fee | Dy.No 27495 dated 23-11-2023 Rs 30,000/- dated 12-10-2023 (slip No. 7381636014) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled |
| | Me-too status | **Could not be confirmed in the applied strength** |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |

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| | Remarks of the Evaluator | **Target species:**<br>Cattle, buffaloes, sheep, goats, pets, poultry<br>**Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.<br>• Firm shall submit fee Rs. 37,000/- for correction/standardization of composition as per reference regulatory authority/innovator's product (Generic Drug local manufacture) and FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)along with registration number, brand name and name of firm.**<br>• **fee Rs. 37,000/- for correction/standardization of composition as per reference regulatory authority/innovator's product (Generic Drug local manufacture) and FPP specifications asper SRO 1324(I)/2024 dated 30-08-2024.**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of liquid syrup veterinary vide letter dated 15-06-2021, generic is not confirmed.** | |
| **Decision: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)along with registration number, brand name and name of firm.** | | |
| **4.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Ismisole 15% Oral Powder |
| | Composition | Each Kg contains:<br>Levamisole HCl…150gm |
| | Diary No. Date of R& I & fee | Dy.No 27493 dated 23-11-2023 Rs 30,000/- dated 12-10-2023 (slip No. 62635008720) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg; Decontrolled |
| | Me-too status | Arch Lev 15% Powder of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK. (Reg. No. 121999) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |
| | Remarks of the Evaluator | **Target species:**<br>Cattle, calves, sheep, goats, poultry<br>**Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | Decision: (M-340) Deferred for submission of following:<br>• Confirmation of relevant manufacturing facility<br>• fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024dated 30-08-2024<br>Remarks:<br>Manufacturing facility is confirmed via section of Dry Powder suspension (Veterinary) vide letter dated 15- | |

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| | 06-2021, fee challan 17415634139 | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(I)12025 dated 01-08- 2025.** | | |
| **5.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Isfezole-SC Oral Solution |
| | Composition | Each ml contains:<br>Oxfendazole…22.65mg<br>Cobalt Sulphate…3.82mg<br>Sodium Selenite…0.5mg |
| | Diary No. Date of R& I & fee | Dy.No 25265 dated 17-10-2023 Rs.30,000/- dated 11-09-2023 (slip No. 92715682417) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled |
| | Me-too status | Fandavetz SC Oral Liquid of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No. 079277) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |
| | Remarks of the Evaluator | **Target species:**<br>Cattle, sheep, goats<br>**Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>• **Fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024dated 30-08-2024**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of liquid syrup veterinary vide letter dated 15-06-2021.**<br>**Fee via challan** 6059641316 submitted | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(I)12025 dated 01-08- 2025.** | | |
| **06.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Isgocin-NF Oral Powder |
| | Composition | Each gram contains:<br>Oxytetracycline HCl…300mg<br>Florfenicol…100mg<br>Neomycin Sulphate…150mg |
| | Diary No. Date of R& I & fee | Dy.No 25267 dated 17-10-2023 Rs.30,000/- dated 11-09-2023 (slip No. 02501997161) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |

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| | Pack size & Demanded Price | 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg; Decontrolled |
| | Me-too status | AR Nfcole Oral Powder of M/s Medpharm Research Lab, Lahore. (Reg. No. 122022) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |
| | Remarks of the Evaluator | **Target species:**<br>Calves, goats, poultry<br>**Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>• **Fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024dated 30-08-2024**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of Dry Powder suspension (Veterinary) vide letter dated 15-06-2021, fee via challan** 4616842680 submitted | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| **07.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Istrifon 98% Oral Powder |
| | Composition | Each gram contains:<br>Trichlorfon…980mg |
| | Diary No. Date of R& I & fee | Dy.No 25263 dated 17-10-2023 Rs.30,000/- dated 11-09-2023 (slip No. 385815648) |
| | Pharmacological Group | Antiparasitic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg; Decontrolled |
| | Me-too status | Stone Fon 98 Powder of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK (Reg. No. 121904) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |
| | Remarks of the Evaluator | **Target species:**<br>Sheep, goats, calves, cattle, buffaloes, camel, poultry<br>**Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of Dry Powder suspension (Veterinary) vide letter dated 15-06-2021, fee challan via 88739109** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| **08.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Isfenide-SC Oral Solution . |

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| | Composition | Each ml contains:<br>Oxfendazole…22.65mg<br>Oxyclozanide…62.50mg<br>Cobalt Sulphate…1.67mg<br>Sodium Selenite…0.5mg |
| | Diary No. Date of R& I & fee | Dy.No 25264 dated 17-10-2023 Rs.30,000/- dated 11-09-2023 (slip No. 5134428183) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled |
| | Me-too status | Clofen Drench of M/s Archard Pharmaceuticals Pvt Ltd., Bhimber, AJK. (Reg. No. 121892) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |
| | Remarks of the Evaluator | **Target species:**<br>Cattle, sheep, goats<br>**Shortcomings:**<br>• **"Oral powder**" instead of "oral solution" is mentioned on fee challan.<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>• **Full fee of registration Rs. 37,000/- as per SRO 1324(I)/2024 dated 30-08-2024.**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of liquid syrup veterinary vide letter dated 15-06-2021. Fee not submitted.** | |
| **Decision: Deferred for submission of fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08-2025.** | | |
| **09.** | Name and address of manufacturer / Applicant | M/s ISIS Pharmaceuticals & Chemical Works, 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Trimisole Oral Solution |
| | Composition | Each ml contains:<br>Triclabendazole…50mg<br>Levamisole…37.50mg<br>Cobalt Sulphate…1.67mg<br>Sodium Selenite…0.35mg |
| | Diary No. Date of R& I & fee | Dy.No 25266 dated 17-10-2023 Rs.30,000/- dated 11-09-2023 (slip No. 258597964064) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 250ml, 500ml, 1000ml, 2500ml, 5000ml; Decontrolled |
| | Me-too status | TL-Nix Forte Suspension of M/s Pharmonix Pharmaceuticals, Rawat (Reg. No. 122117) |
| | GMP status | Inspection conducted on 03-02-2022 concluded good level of GMP compliance. |

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| | Remarks of the Evaluator | **Shortcomings:**<br>• Confirmation of **relevant manufacturing facility**<br>• Firm shall submit fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024 dated 30-08-2024 before issuance of registration letter. |
| | **Decision: (M-340) Deferred for submission of following:**<br>• **Confirmation of relevant manufacturing facility**<br>• **Fee Rs. 9000/- for pre-approval correction in FPP specifications as per SRO 1324(I)/2024dated 30-08-2024**<br>**Remarks:**<br>**Manufacturing facility is confirmed via section of liquid syrup veterinary vide letter dated 15-06-2021.**<br>**Fee via challan** 969884883103 submitted | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 10. | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Ak-Nag Liquid |
| | Composition | Each 100ml contains:<br>Norfloxacin…20gm<br>Guaiphenesin…20gm<br>Aminophylline…8gm |
| | Diary No. Date of R& I & fee | Dy.No 22094 dated 01-09-2020 Rs.20,000/- dated 01-09-2020 |
| | Pharmacological Group | Antibiotic/ Bronchodilator |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 30ml, 60ml, 100ml, 150ml, 200ml, 250ml, 300ml, 500ml, 1000ml, 2.5L, 5L, 10L, 25L: Decontrolled |
| | Me-too status | Noramin-G Liquid of M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg. No. 044976) |
| | GMP status | |
| | Remarks of the Evaluator [X] | • **Oral Liquid (General) section** confirmed vide panel inspection report for renewal of DML based on inspection dated 09-11-2018.<br>**Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of last three years) |
| | **Decision: (M-326) Referred to EWG on veterinary drugs.**<br>**Remarks:**<br>**Sub-committee recommended Norfloxacin containing formulation.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 11. | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Akflox Injection 100ml |
| | Composition | Each 100ml Contains:<br>Levofloxacin as Hemihydrate…500mg |
| | Diary No. Date of R& I & fee | Dy.No 26591 dated 09-10-2020 Rs.20,000/- dated 09-10-2020 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml vial: Decontrolled |
| | Me-too status | **Could not be confirmed** |
| | GMP status | |
| | Remarks of the Evaluator [X] | • **Liquid injectable (General) section** confirmed vide panel inspection report for renewal of DML based on inspection |

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| | | dated 09-11-2018.<br>**Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of last three years).<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: (M-326) Deferred for following:**<br>• **Latest GMP inspection report conducted within the period of last three years.**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>**Remarks:**<br>**Generic status is not confirmed. And firm inform than no generic is available.** | |
| **Decision: Rejected as the applied product has not me-too/generic registration.** | | |
| **12.** | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Coolant Oral Powder |
| | Composition | Each 100gm contains:<br>Paracetamol…20gm<br>Vitamin C…5gm<br>Potassium Carbonate…12.5gm<br>Sodium Bicarbonate…12.5gm<br>Vitamin E…12.5gm |
| | Diary No. Date of R& I & fee | Dy.No 12025 dated 16-07-2019 Rs.20,000/- dated 16-07-2019 |
| | Pharmacological Group | Analgesic, Stress controller |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10gm, 30gm, 100gm sachet, 250gm, 500gm, 1000gm white plastic jar with sealed cap, 2.5Kg, 5Kg, 10Kg, 25Kg Bag; Decontrolled |
| | Me-too status | Para CE Oral Powder of M/s Biogen Pharma, Rawat Chak Beli Road, Rawat (Reg. No. 063812) |
| | GMP status | Not submitted |
| | Remarks of the Evaluator [X] | • **Oral Dry Powder General (Vet) section** confirmed from panel inspection report for renewal of DML based on inspection dated 09-11-2018<br>• Firm has revised finished product specification from inhouse to "**as per innovator's specifications**" along with the fee of Rs. 7,500/- via deposit slip no 60066419.<br>**Shortcomings:**<br>• Latest cGMP inspection report (conducted within the period of last three years) |
| | **Decision: (M-323) Referred to Expert working Group to review therapeutic requirement keeping in view safety, efficacy and quality parameters.**<br>**Remarks:**<br>**Sub-committee on veterinary drugs recommended such formulation containing paracetamol and vitamin C.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 13. | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Ectin 0.01gm/ml Injection |
| | Composition | Each ml Contains:<br>Ivermectin…0.01Gm |

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| | Diary No. Date of R& I & fee | Dy.No 23551 dated 12-11-2019 Rs.20,000/- dated 12-11-2019 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | **500ml**: Decontrolled |
| | Me-too status | Ivobak Injection (500ml) of M/s Attabak Pharmaceuticals Islamabad (Reg. No. 053908) |
| | GMP status | |
| | Remarks of the Evaluator [X] | **Shortcomings:**<br>• **Liquid injectable (General) LVP section** approval<br>• Latest GMP inspection report (conducted within the period of last three years). |
| | **Decision: (M-324) Registration Board deferred the case for submission evidence of availability of required manufacturing facility for the applied fill volume.**<br>**Firm has submitted inspection report(Inspection report (dated 14-12-2023) showing manufacturing facility upto 500ml.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 14. | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Calci-Dex Injection 300ml |
| | Composition | Each 100ml contains:<br>Calcium Gluconate…20.83gm<br>Magnesium Hypophosphite…5.33gm<br>Calcium D Saccharate…1gm<br>Magnesium Chloride…2gm<br>Boric Acid…4.33gm<br>Dextrose…20gm |
| | Diary No. Date of R& I & fee | Dy.No 22080 dated 01-09-2020 Rs.20,000/- dated 01-09-2020 |
| | Pharmacological Group | Restorative, Minerals, Electrolytes |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 300ml: Decontrolled |
| | Me-too status | Dicalfon-C Injection (300ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912) |
| | GMP status | |
| | Remarks of the Evaluator [X] | **Shortcomings:**<br>• Approval of **manufacturing facility (LVP)**<br>• Latest GMP inspection report (conducted within the period of last three years). |
| | **Decision: (M-326) Deferred for following:**<br>• **Confirmation of relevant manufacturing facility (LVP)**<br>• **Latest GMP inspection report (conducted within the period of last three years).**<br>**Firm has submitted inspection report(Inspection report (dated 14-12-2023) showing manufacturing facility upto 500ml.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 15. | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Calci-Dex Injection 500ml |
| | Composition | Each 100ml contains:<br>Calcium Gluconate…20.83gm<br>Magnesium Hypophosphite…5.33gm |

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|---|---|---|
| | | Calcium D Saccharate…1gm<br>Magnesium Chloride…2gm<br>Boric Acid…4.33gm<br>Dextrose…20gm |
| | Diary No. Date of R& I & fee | Dy.No 22081 dated 01-09-2020 Rs.20,000/- dated 01-09-2020 |
| | Pharmacological Group | Restorative, Minerals, Electrolytes |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 500ml: Decontrolled |
| | Me-too status | Dicalfon-C Injection (500ml) of M/s Mylab (Pvt) Ltd. Khanqah Sharif, Bahawalpur (Reg. No. 073912) |
| | GMP status | |
| | Remarks of the Evaluator [X] | **Shortcomings:**<br>• Approval of **manufacturing facility (LVP)**<br>• Latest GMP inspection report (conducted within the period of last three years). |
| | **Decision: (M-326) Decision: Deferred for following:**<br>• **Confirmation of relevant manufacturing facility (LVP)**<br>• **Latest GMP inspection report (conducted within the period of last three years).**<br>**Firm has submitted inspection report(Inspection report (dated 14-12-2023) showing manufacturing facility upto 500ml.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 16. | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Ak-MD Complex Injection |
| | Composition | Each 100ml contains:<br>Calcium Gluconate…20.83gm<br>Magnesium Hypophosphite…5.33gm<br>Calcium D Saccharate…1gm<br>Magnesium Chloride…2gm<br>Boric Acid…4.33gm<br>Vitamin B1…100mg<br>Vitamin B6…70mg<br>Vitamin 12…3000mcg<br>Nicotinamide…200mg<br>Dextrose…20gm |
| | Diary No. Date of R& I & fee | Dy.No 22082 dated 01-09-2020 Rs.20,000/- dated 01-09-2020 |
| | Pharmacological Group | Restorative, Minerals, Electrolytes |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 250ml: Decontrolled |
| | Me-too status | Calphovit Injection (300ml, 450ml) of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore (Reg. No. 032205)<br>**Could not be confirmed in the applied pack size/ fill volume** |
| | GMP status | |
| | Remarks of the Evaluator [X] | **Shortcomings:**<br>• Approval of **manufacturing facility (LVP)**<br>• Latest GMP inspection report (conducted within the period of last three years).<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) **with the applied fill volume/pack size** alongwith registration number, brand name and name of firm. |
| | **Decision: (M-326) Deferred for following:** | |

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| | • **Approval of manufacturing facility (LVP)**<br>• **Latest GMP inspection report conducted within the period of last three years.**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) with the applied fill volume/pack size alongwith registration number, brand name and name of firm.**<br>**Firm has submitted generic Reg.** 007629 MIL-D FORTE INJECTION and **inspection report (Inspection report (dated 14-12-2023) showing manufacturing facility upto 500ml.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 17. | Name and address of manufacturer / Applicant | M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Meta-Amino Injection 250ml |
| | Composition | Each 100ml Contains:<br>L-Carnitine…500mg<br>Thioctic Acid…20mg<br>Pyridoxine HCl…15mg<br>Cyanocobalamin…3mg<br>DL-Acetylmethionine…2000mg<br>L-Arginine…240mg<br>L-Ornithine…120mg<br>L-Citruline…120mg<br>L-Lysine…50mg<br>Glycine...150mg<br>Taurine...150mg<br>Aspartic Acid...150mg<br>Glutamic Acid...150mg<br>Fructose...5000mg<br>Sorbitol...8000mg |
| | Diary No. Date of R& I & fee | Dy.No 26603 dated 09-10-2020 Rs.20,000/- dated 09-10-2020 |
| | Pharmacological Group | Restorative |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 250ml vial: Decontrolled |
| | Me-too status | Vetzpower Injection (250ml) of M/s Vetz Pharmaceuticals (Private) Limited., Kotri Sindh. (Reg. No.088074) |
| | GMP status | |
| | Remarks of the Evaluator [X] | **Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of last three years).<br>• Approval of **Liquid injectable (LVP) (General) section** by CLB |
| | **Decision: (M-326) Deferred for following:**<br>• **Latest GMP inspection report (conducted within the period of last three years).**<br>• **Approval of Liquid injectable (LVP) (General) section by CLB**<br>**Firm has submitted inspection report(Inspection report (dated 14-12-2023) showing manufacturing facility upto 500ml.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 18. | Name and address of manufacturer / Applicant | M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura. |
| | Brand Name +Dosage Form + Strength | Necosin Powder |
| | Composition | Each Kg contains:-<br>Neomycin Sulphate……..….200gm<br>Oxytetracycline HCL……200gm<br>Colistin Sulphate……..12.631gm |

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| | Diary No. Date of R& I & fee | Dy.No 31826 dated 30-11-2020 Rs.20,000/- dated 30-11-2020 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100gm, 500gm, 1000gm: Decontrolled |
| | Me-too status | **Could not be confirmed in the applied strength** |
| | GMP status | |
| | Remarks of the Evaluator [X] | **General Powder section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.<br>**Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of last three years).<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following: (M-326)**<br>• **Latest GMP inspection report (conducted within the period of last three years).**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>**Reply from the firm:**<br>**Latest inspection report for renewal of DML conducted on 31-05-2024**<br>Submitted RRA is not confirmed | |
| **Decision: Deferred for following:**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | | |
| 19. | Name and address of manufacturer / Applicant | M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura. |
| | Brand Name +Dosage Form + Strength | Clomet Suspension |
| | Composition | Each ml contains:-<br>Closantel……..…50mg<br>Ivermectin……..2mg |
| | Diary No. Date of R& I & fee | Dy.No 24538 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 44684944172) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 500ml and 1000ml: Decontrolled |
| | Me-too status | **Could not be confirmed** |
| | GMP status | |
| | Remarks of the Evaluator [X] | **General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.<br>**Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of last three years).<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following: (M-330)**<br>• **latest GMP inspection report conducted within the period of last three years.**<br>• **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>**The applicant shall submit the response within 1 month after publication of the minutes.**<br>**Reply from the firm:**<br>**Latest inspection report for renewal of DML conducted on 31-05-2024**<br>Submitted RRA is not confirmed. | |

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| **Decision: Deferred for following:**<br>**Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | | |
| 20. | Name and address of manufacturer / Applicant | M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura. |
| | Brand Name +Dosage Form + Strength | Piperacena Suspension |
| | Composition | Each ml contains:-<br>Piperazine……..10mg |
| | Diary No. Date of R& I & fee | Dy.No 24537 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 3900451398) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1000ml: Decontrolled |
| | Me-too status | **Could not be confirmed in the applied strength** |
| | GMP status | |
| | Remarks of the Evaluator [X] | **General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.<br>**Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of last three years).<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following: (M-330)**<br>• **Latest GMP inspection report conducted within the period of last three years.**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>**The applicant shall submit the response within 1 month after publication of the minutes,**<br>**<u>Reply from the firm:</u>**<br>**Latest inspection report for renewal of DML conducted on 31-05-2024**<br>Submitted RRA is not confirmed | |
| **Decision: Deferred for following:**<br>**Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | | |
| 21. | Name and address of manufacturer / Applicant | M/s Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura |
| | Brand Name +Dosage Form + Strength | Triclacina Suspension |
| | Composition | Each ml contains:-<br>Triclabendazole……..…120mg<br>Albendazole……..…100mg<br>Ivermectin…….2mg |
| | Diary No. Date of R& I & fee | Dy.No 24543 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 38525948118) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml, 500ml, and 1000ml: Decontrolled |
| | Me-too status | **Could not be confirmed** |
| | GMP status | |
| | Remarks of the Evaluator [X] | **General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.<br>**Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of |

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| | | last three years).<br>• **Ivermectin …2gm** is mentioned on cover letter while **Ivermectin …0.2gm /100ml** is mentioned in label claim on Form-5; clarification regarding applied strength is required.<br>• Accordingly provide evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following: (M-330)**<br>• **Latest GMP inspection report conducted within the period of last three years.**<br>• **Clarification regarding applied strength since varied composition si mentione in coveing letter and submitted Form 5.**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>**The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**<br>**<u>Reply from the firm:</u>**<br>**Latest inspection report for renewal of DML conducted on 31-05-2024**<br>Submitted RRA is not confirmed | |
| **Decision: Deferred for following:**<br>**Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | | |
| 22. | Name and address of manufacturer / Applicant | M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura |
| | Brand Name +Dosage Form + Strength | Avifen Plus Suspension |
| | Composition | Each ml contains:-<br>Fenbendazole……..…25mg<br>Selenium Sulphide……..…0.40mg<br>Cobalt Sulphate……...…0.94mg |
| | Diary No. Date of R& I & fee | Dy.No 24545 dated 06-09-2021 Rs.30,000/- dated 06-09-2021 (slip No. 636927857) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 500ml, and 1000ml: Decontrolled |
| | Me-too status | **Could not be confirmed** |
| | GMP status | |
| | Remarks of the Evaluator [X] | **General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.<br>• The firm has submitted list of equipments for confirmation of testing facility (HPLC, FTIR, Flame photometer, UV spectrophotometer)<br>**Shortcomings:**<br>• Latest GMP inspection report (conducted within the period of last three years).<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following:**<br>• **latest GMP inspection report conducted within the period of last three years.**<br>• **evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>**The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes.**<br><br>**<u>Reply from the firm:</u>** | |

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| | **Latest inspection report for renewal of DML conducted on 31-05-2024**<br>Submitted RRA is not confirmed | |
| **Decision: Deferred for following:**<br>**Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | | |
| 23. | Name and address of manufacturer / Applicant | M/s. Avicenna Laboratories, 14-Km Sheikhupura Faisalabad Road Bhikki, Sheikhupura. |
| | Brand Name +Dosage Form + Strength | Faciozan 1.5% Oral Liquid |
| | Composition | Each 1000ml contains:-<br>Rafoxanide……15gm<br>Levamisole HCl……15gm |
| | Diary No. Date of R& I & fee | Dy.No 32809 dated 15-11-2022 Rs.30,000/- dated 04-11-2022 (slip No. 05425667) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form-5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 30ml, 50ml, 100ml, 500ml, 1000ml; Decontrolled |
| | Me-too status | **Not provided** |
| | GMP status | |
| | Remarks of the Evaluator | **General Liquid section** confirmed from panel inspection report for renewal of DML based on inspection conducted on 22-10-2018.<br>**Shortcomings:**<br>Evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for submission of following: (M-336)**<br>• **latest GMP inspection report conducted within period of last three years**<br>• **evidence of applied formulation/drug, in the applied strength, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>**Reply from the firm:**<br>**Latest inspection report for renewal of DML conducted on 31-05-2024**<br>Submitted RRA is not confirmed | |
| **Decision: Deferred for following:**<br>**Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | | |
| 24. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur |
| | Brand Name +Dosage Form + Strength | Dicox Forte Water Soluble Powder |
| | Composition | Each gram contains:<br>Amprolium as HCl…175mg<br>Sulphaquinoxaline as Sodium…175mg<br>Vitamin A (Retinol concentrate powder) …15000IU Vitamin K3 (Menadiol Sodium phosphate)…5mg |
| | Diary No. Date of R& I & fee | Dy.No 27638 dated 29-09-2022 Rs.30,000/- dated 20-09 2022 (slip No. 048234188) |
| | Pharmacological Group | Anti-protozoal and vitamins |
| | Type of Form | Form 5 |
| | Finished product Specifications | As per innovator's specifications |
| | Pack size & Demanded Price | 100gm, 250gm, 500gm, 1Kg, 5Kg; Decontrolled |
| | Me-too status | Dicox Forte Water Soluble Powder of M/s Prix Pharmaceutica (Pvt) Ltd., Lahore. (Reg. No. 049529) |
| | GMP status | Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | Oral powder General Veterinary section confirmed from panel inspection report for renewal of DML based on inspection conducted on 13-09-2018 to 14-09-2018. Shortcomings: |

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| | | Stability of instant formulation along with master formula |
| | Decision: **(M-336)**<br>Deferred for submission of stability of instant formulation along with master formula and latest GMP inspection report conducted within the period of last three years indicating the required testing facility.<br>**Reply from the firm:**<br>**Latest inspection report for renewal of DML conducted on 13.02.2026.** | |
| **Decision: Approved** | | |
| 25. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur |
| | Brand Name +Dosage Form + Strength | Oxycart spray |
| | Composition | Each ml Contains:<br>Oxytetracyclin….. 750 mg<br>Oxycartisone 240 mg |
| | Diary No. Date of R& I & fee | Dy.No 44228 dated 28-12-2018 Rs. 20,000 (26/12/2018) |
| | Pharmacological Group | Antibiotic/steroidal solution |
| | Type of Form | Form 5 |
| | Finished product Specifications | In house |
| | Pack size & Demanded Price | 250 ml / As per brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too status | NA |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator VII | Me too not available |
| | Previous decision | Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. |
| | Remarks of the Evaluator VII | The Me too Oxycort spray by star lab Registration # 014143. With composition EACH 300ML Contains: - Oxytetracycline HCL 1500MG Which is not same as applied |
| | Decision: Deferred for following **(M-336)**<br>• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.<br>• Confirmation of manufacturing facility of spray section from licencing division.<br>**Reply from the firm:**<br>**Latest inspection report for renewal of DML conducted on 13.02.2026. Submitted generic is not confirmed.** | |
| **Decision: Approved with innovator's specifications. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.** | | |
| 26. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur |
| | Brand Name +Dosage Form + Strength | Apoderm Cutaneous Spray Solution |
| | Composition | Each ml contains:<br>Chlortetracycline HCl eq. to Chlortetracycline…20mg |
| | Diary No. Date of R& I & fee | Dy.No 9441 dated 13-04-2022 Rs.30,000/- dated 28-02 2022 (slip No. 2545666619) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specifications | As per innovator's specifications |
| | Pack size & Demanded Price | 100ml,: Decontrolled |
| | Me-too status | Apoderm Cutaneous Spray Solution of M/s Lachman Pharmaceuticals, Lahore. (Reg. No. 095644) |
| | GMP status | Inspection conducted on 24-02-2021 to 25-02-2021 concluded satisfactory level of GMP compliance except aerosol and Oral Liquid (General) II section. |
| | Remarks of the Evaluator | Shortcomings:<br>• Approval of Aerosol (Veterinary) section from CLB. |

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| | | • Latest GMP inspection report conducted within the period of last three years. |
| | Decision: Deferred for following: **(M-331)**<br>• Approval of Aerosol (Veterinary) section from CLB.<br>• Latest relevant GMP inspection report conducted within the period of last three years<br>**Reply from the firm:**<br>**Latest inspection report for renewal of DML conducted on 13.02.2026.** | |
| **Decision: Approved** | | |
| 27. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif, Bahawalpur (DML No. 000747) Aerosol (Veterinary) Section |
| | Brand Name +Dosage Form + Strength | Frontline Spray |
| | Composition | Each 100ml Contains:<br>Fipronil…0.25gm |
| | Diary No. Date of R& I & fee | Dy.No 34221 dated 31-12-2021; Rs.30,000/- vide Deposit Slip No.34466944993 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specifications | As per innovator's specifications |
| | Pack size & Demanded Price | 100ml, 250ml; Decontrolled |
| | Me-too status | Not verified from database |
| | GMP status | GMP inspection was conducted on 25-02-21. Liquid Injectable (Steroid) section was found to be operating at a satisfactory level of GMP compliance. However, the Aerosol section was under maintenance and not functional at the time of inspection. |
| | Remarks of the Evaluator | • Latest GMP inspection report conducted within a period of last three years is required for assessing the GMP compliance of Aerosol section. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm is required. |
| | Decision: Deferred for submission of following: **(M-331)**<br>• Latest GMP inspection report for Aerosol section conducted within a period of last three<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me too status) along with registration number, brand name and name of firm. The Board further decided that the applicant shall submit response within 1 month after publication of the minutes,<br>**Reply from the firm:**<br>**Latest inspection report for renewal of DML conducted on 13.02.2026.** | |
| **Decision: Approved subject to change of brand name.** | | |

**Import Product**

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| **1.** | Name and address of Applicant | M/s. Vety Care Pvt Ltd., Plot # 77, Street No. 6, I-10/3, Islamabad. |
| | Detail of Drug Sale License | Not provided |
| | Name and address of manufacturer | M/s. Intervet International B.V.<br>Wim De Korversaraat 35, 5831 AN Boxmeer, Netherlands. |
| | Name and address of marketing authorization holder | M/s. Intervet International B.V.<br>Wim De Korversaraat 35, 5831 AN Boxmeer, Netherlands. |
| | Name of exporting country | **Netherlands** |
| | Type of Form | Form-5A |
| | Diary No. & Date of R& I | Dy.No 6612 Dated 01-03-2021 |
| | Fee including differential fee | Rs : 1,00,000 Dated 26-02-2021 |
| | Brand Name +Dosage Form + Strength | Mastijet Forte Intramammary Suspension |

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| | Composition | Each 8gram contains:-<br>Tetracycline HCl……..……200mg<br>Neomycin Base as Sulphate....…250mg<br>Bacitracin……..2000 IU<br>Prednisolone…….10mg |
| | Finished Product Specification | Inhouse |
| | Pharmacological Group | Antibacterial and Corticosteroid |
| | Shelf life | 2 years |
| | Demanded Price | Decontrolled |
| | Pack size | Not demanded |
| | International availability | N/A |
| | Me-too status | MASTIJET Syringe of M/s Progressive Associate, Karachi.<br>(Reg. No. 014162) |
| | Detail of certificates attached | **1.** Original legalized CoPP BD/2020/No. of Certificate 254273 dated 12-11-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands **does not confirm free sale status of the product in country of origin**<br>**2.** Original legalized GMP certificate No. NL/V 20/0012 based on inspection conducted on 16-07-2020 issued by Ministry of Agriculture, Nature and Food Quality of the Netherlands. (**scope of provided GMP certificate does not cover manufacturing lines of steroids**)<br>**3.** Letter of authorization not provided |
| | Remarks of the Evaluator X | 4. Provide valid copy of DSL<br>5. CoPP is provided which **does not confirm free sale status of the product in country of origin;** Submit legalized original valid FSC.<br>6. The **scope of provided GMP certificate does not cover manufacturing lines of steroids;** Submit legalized original relevant GMP certificate.<br>7. Provide legalized original valid Letter of authorization/sole agency agreement between product license holder and distributor.<br>8. In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and<br>(iii) Instruction is missing. Submit label in accordance with The Drugs (Labeling and Packing) Rules, 1986.<br>9. Demanded Pack size is not mentioned in form-5A.<br>**1. The initial stability studies of Mastijet Forte were performed at 25ºC/60% RH covering 24 months. However, when a decrease in the content of Bacitracin and Prednisolone was observed the storage conditions were finally changed to "store at 2-8ºC". Consequently, only 24 months study results for storage at 5ºC (±3ºC) are presented.** |
| | **Decision: Referred to EWG on veterinary drugs to review therapeutic requirement keeping in view safety, efficacy and quality parameters** | |

**Recommendation of Sub-committee:**

**After deliberation, the Sub-committee on Veterinary Drugs recommended the above formulation for veterinary use.**

**Reply from the firm:**

**Firm has submitted RRA evidence (France) of same product from same manufacturer.**

**Decision: Approved with innovator's specifications as per policy of inspection of manufacturer abroad. Firm shall submit fee for pre-registration variation as per S.R.O. 1399(l)12025 dated 01-08- 2025.**

**Case.No.01:** **REQUEST OF M/S SEARLE PAKISTAN LIMITED FOR DE-REGISTRATION OF REGISTERED PRODUCTS.**

M/s Searle Pakistan Limited, One IBL Center, 2nd Floor, Plot No.1, Block 7&8, DMCHS, Tipu Sultan Road, Off Shahra-e-Faisal, Karachi has submitted request for de-registration of following registered imported products as per details mentioned alongside.

| S. No | Product(s) Name | Reg. No. | Reason for De-Reg. (stated by firm) | Alternate Brands |
|---|---|---|---|---|
| 1. | Janumet tablets<br>Each tablet contains:-<br>Sitagliptin phosphate 50.00mg.<br>Metformin Hcl 500.00mg. | 059084 | Due to some business decision, it has been decided to discontinue the registered product | Sitamet 50mg+500mg Tablets<br>Treviamet 50mg+500mg Tablets<br>Sitaglumet 50mg+500mg Tablets<br>Tagipmet 50mg+500mg Tablets<br>Inosita Plus 50mg+500mg Tablets |
| 2. | Janumet tablet<br>Each tablet contains: -<br>Sitagliptin phosphate…50mg<br>Metformin hcl…1000mg | 066172 | -do- | Sitamet 50mg+1000mg Tablets<br>Treviamet 50mg+1000mg Tablets<br>Sitaglumet 50mg+1000mg Tablets<br>Tagipmet 50mg+1000mg Tablets<br>Inosita Plus 50mg+1000mg Tablets |

Firm has submitted following supporting documents:

**Janumet tablets 50/500 Reg. No.059084**

a. Copy of Registration letter issued on 20-10-2009.
b. Change of manufacturing site on 04-04-2014.
c. Change of source of manufacturer on 18-08-2016.
d. Last renewal submitted on 06-05-2021.
e. Fee of Rs.12500/- for above product.
f. Justification as mentioned above.
g. An Undertaking.

**Janumet tablets 50/1000 Reg. No. 066172**

a. Copy of Registration letter issued on 01-12-2010.
b. Change of manufacturing site on 04-04-2014.
c. Change of source of manufacturer on 18-08-2016.
d. Last renewal submitted on 06-05-2021.
e. Fee of Rs.12500/- for above product.
f. Justification as mentioned above.
g. An Undertaking.

**Decision: Registration Board acceded the firm's request for de-registration of following imported products:**

| S. No | Product(s) Name | Reg. No. |
|---|---|---|
| **1.** | Janumet tablets<br>Each tablet contains:-<br>Sitagliptin phosphate 50.00mg.<br>Metformin Hcl 500.00mg. | 059084 |
| **2.** | Janumet Tablet<br>Each tablet contains: -<br>Sitagliptin phosphate…50mg<br>Metformin hcl…1000mg | 066172 |

**Case.No.02:** **REQUEST OF M/S FEROZSONS LABORATORIES LTD, FOR DE-REGISTRATION OF REGISTERED PRODUCTS.**

M/s Searle Pakistan Limited, One IBL Center, 2nd Floor, Plot No.1, Block 7&8, DMCHS, Tipu Sultan Road, Off Shahra-e-Faisal, Karachi has submitted request for de-registration of following registered

imported products as per details mentioned alongside.

| S. No | Product(s) Name | Reg. No. | Reason for De-Reg. (stated by firm) | Alternate Brands |
|---|---|---|---|---|
| 1. | Viread 300mg tablets<br>Each tablets contains:-<br>Tenofovir DF……300mg which is equivalent to tenofovir disoproxil……245mg | 072522 | Gilead Sciences, the marketing authorization holder of the product, hereby notifies our request to withdraw the Marketing Authorization in Pakistan and cease all further regulatory activity related to this marketing authorization. Gilead Sciences would like to confirm that this is a voluntary withdrawal and does not pertain to any safety, efficacy or quality issue. | Tenvir of M/s AJM Pharma<br>Tenovir of M/s Amson Vaccine & Pharma.<br>Tenovir of M/s CCL Pharma.<br>Tenofo-B of M/s Getz Pharma.<br>Viro-B of M/s Global Pharma.<br>Hifovir of M/s Hilton Pharma.<br>Tendi of M/s LCI Pharma.<br>Vireof of Macter International.<br>Fovirox-AF of M/s Nabiqasim<br>Tenova of M/s Pharmevo.<br>Scifovir of M/s Scilife.<br>Sefovir of M/s Scilife.<br>Lixpro of M/s Tabroz Pharma<br>Devire of M/s Wilshire Labs.<br>Tenfavir of M/s Crystolite. |
| 2. | Harvoni Tablet<br>Each film coated tablet contains:-<br>Ledipasvir……90mg<br>Sofosbuvir.....400mg | 085250 | -do- | Ledvir of M/s AGP Limited.<br>Lesof Plus of M/s Bio-Labs.<br>Syneget-LS of M/s Getz Pharma<br>Tenofo-B of M/s Getz Pharma.<br>Cure-C plus of M/s Global Pharma.<br>Fosbir M/s Novamed Phamra Pakistan.<br>Sofaldi-L of M/s Saffron Pharma.<br>Twinvir M/s Scilife Pharma.<br>Vebuvir-L of M/s Shaigan Pharma. |

Firm has submitted following supporting documents:

**Viread 300mg tablets Reg. No.072522.**

a. Copy of Registration letter issued on 19-08-2011.
b. Last renewal submitted on 14-04-2021.
c. Fee of Rs.12500/- for above product.
d. Justification as mentioned above.

**Harvoni Tablet Reg. No. 085250**

a. Copy of Registration letter issued on 22-11-2017.
b. Last renewal submitted on 05-09-2022.
c. Fee of Rs.12500/- for above product.
d. Justification as mentioned above.

**Decision: Registration Board acceded the firm's request for de-registration of following imported product:**

| S. No | Product(s) Name | Reg. No. |
|---|---|---|
| 1. | Viread 300mg tablets<br>Each tablets contains:-<br>Tenofovir DF 300mg which is equivalent to tenofovir disoproxil..245mg | 072522 |
| 2. | Harvoni Tablet<br>Each film coated tablet contains:-<br>Ledipasvir……90mg<br>Sofosbuvir.....400mg | 085250 |

**Cases of Form 5 (deferred in various meetings) not requiring stability data:**

As per notification No.F.15.1/2022-PEC dated 18-10-2024, the replies of applications of Form-5 and Form-5A of Human Drugs deferred in various Registration Board meetings shall be submitted in R&I section of DRAP till **31st December 2024**. Replies of such applications submitted after said date shall not be entertained and all such applications shall be considered as disposed off and the applicant firm may submit fresh application on Form-5F which will be considered on its turn in queue of Form 5F.

Below are the applications submitted on Form 5 with the reply which deferred in various meeting of Registration Board and for which stability data is not required.

| | | |
|---|---|---|
| 1. | **Name and address of manufacturer / Applicant** | **M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan** |
| | Brand Name +Dosage Form + Strength | Angitrin SR 2.6mg tablet |
| | Composition | Each Tablet Contains:<br>Glyceryl Trinitrate …2.6mg |
| | Diary No. Date of R& I & fee | Dy No. 17267: 07-03-2019<br>PKR 20,000/-: 06-03-2019 |
| | Pharmacological Group | Organic nitrates |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in-house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Angitryl 2.6mg Tablet by Saffron Pharma |
| | GMP status | The firm have submitted cGMP certificate issued on 14-12- 2020<br>based on inspection conducted on 23-09-2020. |
| | Remarks of the Evaluator3. | Latest GMP inspection report conducted within a period of last three years.<br>Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| **Decision of 329th RB held on 6-8th June, 2023:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed<br>in the upcoming meeting of the Board for final decision. | | |
| **Firm's response:** The firm has submitted the reply dated 19-09-2023 (R&I receiving attached).<br>The applied product is MHRA Approved.<br>Sustac Tablet 2.6 mg prolonged released tablet<br>https://mhraproducts4853.blob.core.windows.net/docs/fb0ae981276da5edfae2372a47e44875bea22747 | | |

| | | |
|---|---|---|
| Last inspection report dated 07-10-2025 is submitted. | | |
| Evaluation by PEC: However, as per decision of Board, the reply should have been submitted within 01 month after publication of minutes. The reply is received on 19-09-2023. Date of publication of minutes I s18-08-2023 as per DRAP's official website. | | |
| **Decision: The Board deferred the case and directed the firm to submit data of:**<br>**1. Development of 03 trial batches of the applied product.**<br>**2. Stability studies including accelerated and real time till 3rd month time point.**<br>**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**<br>**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**<br>**5. Analytical method of drug product and its verification/validation.** | | |
| 2. | **Name and address of manufacturer / Applicant** | **M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan** |
| | Brand Name +Dosage Form + Strength | Angitrin SR 6.4mg tablet |
| | Composition | Each Tablet Contains:<br>Glyceryl Trinitrate …6.4mg |
| | Diary No. Date of R& I & fee | Dy No. 17271: 07-03-2019<br>PKR 20,000/-: 06-03-2019 |
| | Pharmacological Group | Organic nitrates |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in-house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Niglys SR 6.4mg Tablets by Uni-Mark Pharma |
| | GMP status | The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020. |
| | Remarks of the Evaluator[3]. | Latest GMP inspection report conducted within a period of last three years.<br>Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Decision of 329th RB 6-8th June, 2023:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. | |
| | **Firm's response:** The firm has submitted the reply dated 19-09-2023 (R&I receiving attached).<br>The applied product is MHRA Approved.<br>Sustac Tablet 6.4 mg prolonged released tablet | |

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|---|---|---|
| | https://mhraproducts4853.blob.core.windows.net/docs/6b0557147367af72dd9a347a0b75af1675fe7e58<br>Last inspection report dated 07-10-2025 is submitted. | |
| | Evaluation by PEC: However, as per decision of Board, the reply should have been submitted within 01 month after publication of minutes. The reply is received on 19-09-2023. Date of publication of minutes I s18-08-2023 as per DRAP's official website. | |
| | **Decision: The Board deferred the case and directed the firm to submit data of:**<br>**1. Development of 03 trial batches of the applied product.**<br>**2. Stability studies including accelerated and real time till 3rd month time point.**<br>**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**<br>**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**<br>**5. Analytical method of drug product and its verification/validation.** | |
| 3. | **Name and address of manufacturer / Applicant** | **M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan** |
| | Brand Name +Dosage Form + Strength | Prednicort 0.1% w/w Cream |
| | Composition | Each Gram Contains:<br>Methylprednisolone Aceponate…1mg/Gm |
| | Diary No. Date of R& I & fee | Dy No. 17269: 07-03-2019<br>PKR 20,000/-: 06-03-2019 |
| | Pharmacological Group | Corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Depomax Cream by shaigan Pharma |
| | GMP status | The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020. |
| | Remarks of the Evaluator[3]. | Latest GMP inspection report conducted within a period of last three years.<br>Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Decision of 329th RB 6-8th June, 2023:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. | |
| | **Firm's response:** The firm has submitted the reply dated 19-09-2023 (R&I receiving attached). | |

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|---|---|---|
| | The applied product is CIMA Spain Approved.<br>Adventan Cream 1mg/g<br>https://cima.aemps.es/cima/dochtml/p/60137/P_60137.html<br>Last inspection report dated 07-10-2025 is submitted. | |
| | **Evaluation by PEC:** However, as per decision of Board, the reply should have been submitted within 01 month after publication of minutes. The reply is received on 19-09-2023. Date of publication of minutes I s18-08-2023 as per DRAP's official website. | |
| | **Decision: The Board deferred the case and directed the firm to submit data of:**<br>**1. Development of 03 trial batches of the applied product.**<br>**2. Stability studies including accelerated and real time till 3rd month time point.**<br>**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**<br>**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**<br>**5. Analytical method of drug product and its verification/validation.** | |
| 4. | **Name and address of manufacturer / Applicant** | **M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan** |
| | Brand Name +Dosage Form + Strength | Prednicort 0.1% w/w Ointment |
| | Composition | Each Gram Contains:<br>Methylprednisolone Aceponate…1mg/Gm |
| | Diary No. Date of R& I & fee | Dy No. 17264: 07-03-2019<br>PKR 20,000/-: 06-03-2019 |
| | Pharmacological Group | Corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Methlepred Ointment by Jaens Pharma |
| | GMP status | The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020. |
| | Remarks of the Evaluator[3]. | Latest GMP inspection report conducted within a period of last three years.<br>Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Decision of 329th RB 6-8th June, 2023:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. | |

| | | |
|---|---|---|
| | **Firm's response:** The firm has submitted the reply dated 19-09-2023 (R&I receiving attached).<br>The applied product is CIMA Spain Approved.<br>Adventan Ointment 1mg/g<br>https://cima.aemps.es/cima/dochtml/p/60139/P_60139.html<br>Last inspection report dated 07-10-2025 is submitted. | |
| | **Evaluation by PEC:** However, as per decision of Board, the reply should have been submitted within 01 month after publication of minutes. The reply is received on 19-09-2023. Date of publication of minutes I s18-08-2023 as per DRAP's official website. | |
| | **Decision: The Board deferred the case and directed the firm to submit data of:**<br>**1. Development of 03 trial batches of the applied product.**<br>**2. Stability studies including accelerated and real time till 3rd month time point.**<br>**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**<br>**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**<br>**5. Analytical method of drug product and its verification/validation.** | |
| 5. | **Name and address of manufacturer / Applicant** | **M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan** |
| | Brand Name +Dosage Form + Strength | Seboderm 1.5% w/v Liquid |
| | Composition | Each Gram Contain:<br>Ciclopirox Olamine…1.5%W/V |
| | Diary No. Date of R& I & fee | Dy No. 17266: 07-03-2019<br>PKR 20,000/-: 06-03-2019 |
| | Pharmacological Group | Antifungal for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Stieprox Shampoo by GSK<br>**(Health Canada Approved)** |
| | Me-too status | Stieprox liquid by GSK |
| | GMP status | The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020. |
| | Remarks of the Evaluator[3]. | Latest GMP inspection report conducted within a period of last three years.<br>Evidence of required manufacturing facility / section approval letter from Licensing Division. |
| | **Decision of 329th RB 6-8th June, 2023:**<br>Deferred for submission of evidence of approval of required manufacturing facility of "Lotion section" from CLB. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. | |
| | **Firm's response:** The firm has submitted the reply dated 19-09-2023 (R&I receiving attached).<br>Section approval letter dated 17-11-2025 for Lotion General Section is submitted. | |

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|---|---|---|
| | **Evaluation by PEC:** However, as per decision of Board, the reply should have been submitted within 01 month after publication of minutes. The reply is received on 19-09-2023.<br>Moreover, at the time of deferment, the firm was not having the required section. The firm has stated in reply submitted on 19-09-2023 "Location section approved in recent GMP report".<br>Date of publication of minutes I s18-08-2023 as per DRAP's official website. | |
| | **Decision: The Board deferred the case and directed the firm to submit data of:**<br>**1. Development of 03 trial batches of the applied product.**<br>**2. Stability studies including accelerated and real time till 3rd month time point.**<br>**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**<br>**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**<br>**5. Analytical method of drug product and its verification/validation.** | |
| 6. | **Name and address of manufacturer / Applicant** | **M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan** |
| | Brand Name +Dosage Form + Strength | Synaroid 0.1% w/w ointment |
| | Composition | Each Gram Contains:<br>Diflurocortolone Valerate…0.1% W/W |
| | Diary No. Date of R& I & fee | Dy No. 17261: 07-03-2019<br>PKR 20,000/-: 06-03-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Could not be confirmed |
| | GMP status | The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020. |
| | Remarks of the Evaluator[3]. | Latest GMP inspection report conducted within a period of last three years.<br>Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm |
| | **Decision of 329th RB 6-8th June, 2023:**<br>Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. | |
| | **Firm's response:** The firm has submitted the reply dated 19-09-2023 (R&I receiving attached).<br>The applied product is MHRA Approved.<br>Nerison Ointment (100g ointment contains 0.1g diflucortolone valerate) | |

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|---|---|---|
| | https://mhraproducts4853.blob.core.windows.net/docs/2cffd2594875a60142b59399da08412634d956b1<br>Last inspection report dated 07-10-2025 is submitted.<br>Me-too could not be confirmed. | |
| | **Evaluation by PEC:** However, as per decision of Board, the reply should have been submitted within 01 month after publication of minutes. The reply is received on 19-09-2023. Date of publication of minutes I s18-08-2023 as per DRAP's official website. | |
| | **Decision: Rejected due to non-availability of me-too/generic reference.** | |
| 7. | **Name and address of manufacturer / Applicant** | **M/s Mass Pharma Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan** |
| | Brand Name +Dosage Form + Strength | Synaroid Forte Fatty 0.3% w/w Ointment |
| | Composition | Each Gram Contains:<br>Diflurocortolone Valerate…0.3% W/W |
| | Diary No. Date of R& I & fee | Dy No. 17260: 07-03-2019<br>PKR 20,000/-: 06-03-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Nerisone Forte Fatty Ointment 0.3% by Medipharm |
| | GMP status | The firm have submitted cGMP certificate issued on 14-12- 2020 based on inspection conducted on 23-09-2020. |
| | Remarks of the Evaluator[3]. | Latest GMP inspection report conducted within a period of last three years.<br>Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Decision of 329th DRB:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. | |
| | **Firm's response:** The firm has submitted the reply dated 19-09-2023 (R&I receiving attached).<br>The applied product is MHRA Approved.<br>Nerison Forte Ointment (100g ointment contains 0.3g diflucortolone valerate.) fatty ointment<br>https://mhraproducts4853.blob.core.windows.net/docs/7f8014067dccfb3eb4bd8940029f5baae1df83ba | |

| | | |
|---|---|---|
| | Last inspection report dated 07-10-2025 is submitted. | |
| | **Evaluation by PEC:** However, as per decision of Board, the reply should have been submitted within 01 month after publication of minutes. The reply is received on 19-09-2023. Date of publication of minutes I s18-08-2023 as per DRAP's official website. | |
| | **Decision: The Board deferred the case and directed the firm to submit data of:**<br>**1. Development of 03 trial batches of the applied product.**<br>**2. Stability studies including accelerated and real time till 3rd month time point.**<br>**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**<br>**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**<br>**5. Analytical method of drug product and its verification/validation.** | |
| 8. | **Name and address of manufacturer / Applicant** | **M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore** |
| | Brand Name +Dosage Form + Strength | Hepcon Infusion |
| | Composition | Each Vial Contains:<br>L-Ornithine L-Aspartate…5g/10ml |
| | Diary No. Date of R& I & fee | General Request Form Tracking R9G-H6U-ZSMS<br><br>Dy No. 13436: 07-03-2019<br>PKR 20,000/-: 05-03-2019 |
| | Pharmacological Group | Amino Acid (Hepato Protective Lipotropic) |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in-house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Hepa-Merz 5 g / 10 ml infusion solution concentrate (Austria Approved) as 10ml ampoule |
| | Me-too status | Hepanil Infusion Concentrate 5gm/10ml by Medicraft |
| | GMP status | Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | • Evidence of required manufacturing facility / section approval letter from Licensing Division.<br>• The RRA approved product is available in 10ml ampoule while you have applied the formulation in 10ml vial, clarification is required in this regard. |
| | **Decision of 327th Meeting:**<br><br>**Deferred for following submissions:**<br><br>• Evidence of required manufacturing facility / section approval letter from Licensing Division.<br>• Clarification, since the reference product is available in 10ml ampoule while you have applied the formulation in 10ml vial.<br>• Evidence of requisite testing facility. | |

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<tr><td></td><td colspan="2">

- Latest GMP inspection report conducted within a period of last three years.

**Firm's response:**

The firm has submitted the reply vide general request ID no. R9G-H6U-ZSMS. The firm has submitted R&I receiving dated 02-08-2023.

Evaluation by PEC: sent back

<table>
<tr><th>observation</th><th>Reply</th></tr>
<tr><td>Evidence of required manufacturing facility section approval letter from Licensing Division.</td><td>Liquid Ampoule General Section is approved as per letter for DML renewal No. N31-ZHT-Z7EY dated 21st January, 2026.</td></tr>
<tr><td>Clarification, since the reference product is available in 10ml ampoule while you have applied the formulation in 10ml vial.</td><td>The firm has submitted revised label claim.<br>Each ampoule (10mL) contains:<br>L-Ornithine L-Aspartate…5g</td></tr>
<tr><td>Evidence of requisite testing facility</td><td>Details of HPLC method for analysis is submitted.</td></tr>
<tr><td>Latest GMP inspection report conducted within a period of last three years</td><td>GMP certificate issued on the basis of inspection conducted on 12-12-2025.</td></tr>
</table>

**Decision: The Board deferred the case and directed the firm to submit data of:**
**1. Development of 03 trial batches of the applied product.**
**2. Stability studies including accelerated and real time till 3rd month time point.**
**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**
**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**
**5. Analytical method of drug product and its verification/validation.**
</td></tr>
<tr><td>9.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Standpharm Pakistan Pvt. Ltd. 20-km, Ferozepur Road, Lahore</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Hepcon 5g Sachet</td></tr>
<tr><td></td><td>Composition</td><td>Each Sachet Contains:<br>L-Ornithine L-Aspartate…3g</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>General Request Form Tracking LJ1-GV8-GSZX<br><br>Dy No. 13437: 07-03-2019<br>PKR 20,000/-: 05-03-2019</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Amino Acid (Hepato Protective Lipotropic)</td></tr>
<tr><td></td><td>Type of Form</td><td>Form 5</td></tr>
<tr><td></td><td>Finished Product Specification</td><td>Firm has claimed in-house specifications</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>As per SRO</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities.</td><td>Hepa-Merz 3g Granules by Austria Approved</td></tr>
<tr><td></td><td>Me-too status</td><td>Hepa Merz Sachet by Brookes</td></tr>
<tr><td></td><td>GMP status</td><td>Panel inspection conducted on 18-02-2020 wherein the panel recommended the renewal of DML.</td></tr>
<tr><td></td><td>Remarks of the Evaluator.</td><td>• Evidence of required manufacturing facility / section approval letter from Licensing Division.<br>• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted</td></tr>
</table>

| | | |
|---|---|---|
| | | by the Registration Board in its 275th meeting.<br>• Submit complete label claim as per RRA approved product along with submission of full fee. |
| | **Decision of 329th Meeting held on 6-8th June 2023:**<br><br>Deferred for clarification since the applied brand name is 5g sachet, while the applied composition specifies 3g strength. The Board further decided that the applicant shall submit the response within 1 month after publication of the minutes, otherwise the application shall be placed in the upcoming meeting of the Board for final decision. | |
| | Firm's response: The firm has submitted R&I receiving dated 31-08-2023. The firm has submitted 5g written with brand name was a typographical error. The correct brand name is Hepacon 3g granules. | |
| | Evaluation by PEC:<br>The qualitative composition of the reference product is as follows:<br><br>2. QUALITATIVE AND QUANTITATIVE COMPOSITION<br><br>One 5g sachet contains 3g of ornithine aspartate.<br>Other ingredients with known effects: 1 sachet of 5 g contains 1.135 g fructose and 0.001 g Dye Sunset Yellow FCF (E 110) | |
| | **Decision: The Board deferred the case and directed the firm to submit data of:**<br>**1. Development of 03 trial batches of the applied product.**<br>**2. Stability studies including accelerated and real time till 3rd month time point.**<br>**3. Pharmaceutical equivalence studies against reference/innovator's/comparator's product by performing all the quality tests.**<br>**4. Comparative dissolution profile against reference/innovator's/comparator's (where applicable).**<br>**5. Analytical method of drug product and its verification/validation.** | |
| 10. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi" |
| | Brand Name + Dosage Form + Strength | Ikra Syrup 100mg/ml Suspension |
| | Composition | Each ml of syrup contains:<br>Levetiracetam…100mg |
| | Diary No. Date of R&I & Fee | Dy.No 5937 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019 |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | :As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | Tamlev 100mg/ml oral Solution of Medisure Lab. Karachi |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |

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| | Remarks of the Evaluator | Reference product is solution you have applied for syrup, clarify. |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 11. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi" |
| | Brand Name + Dosage Form + Strength | Ikra 250mg Tablet |
| | Composition | Each Film Coated Tablet Contains: Levetiracetam…250mg |
| | Diary No. Date of R&I & Fee | Dy.No 9040 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Anti epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | L-Epsi Tablet 250mg of M/s Akson Pharmaceuticals |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 12. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi" |

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|---|---|---|
| | Brand Name + Dosage Form + Strength | Ikra 500mg Tablet |
| | Composition | Each Film Coated Tablet Contains: Levetiracetam…500mg |
| | Diary No. Date of R&I & Fee | Dy.No 9039 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | L-Epsi Tablet 500mg of M/s Akson Pharmaceuticals |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 13. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Nermox 500mg Tablet |
| | Composition | Each Tablet Contains: Mebendazole…500mg |
| | Diary No. Date of R&I & Fee | Dy.No 9072 dated 28-02-2019 Rs.20,000/- 25-02-2019 |
| | Pharmacological Group | ANTINEMATODAL AGENTS |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Leukiban Tablets 100mg of Rakaposhi Pharmaceuticals |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |

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| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 14. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Rosulip 20mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Rosuvastatin as calcium…20mg |
| | Diary No. Date of R&I & Fee | Dy.No 9058 dated 28-02-2019 Rs.20,000/- 25-02-2019 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | 10,s: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Rosocard Tablets of M/s Himont |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 15. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Rosulip 40mg Tablet |

| | | |
|---|---|---|
| | Composition | Each Film Coated Tablet Contains:<br>Rosuvastatin as calcium…40mg |
| | Diary No. Date of R&I & Fee | Dy.No 9059 dated 28-02-2019 Rs.20,000/- 25-02-2019 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Rosocard Tablets of M/s Himont |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 16. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Gabreg 100mg Capsules |
| | Composition | Each Capsule Contains:<br>Pregabalin…100mg |
| | Diary No. Date of R&I & Fee | Dy.No 9044 dated 28-02-2019 Rs.20,000/- 25-02-2019 |
| | Pharmacological Group | antiepileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | 14's, 28's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | Nurica 100mg Capsule of Macter Int. Karachi |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:** | |

| | | |
|---|---|---|
| | The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 17. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Gabreg 300mg Capsules |
| | Composition | Each Capsule Contains:<br>Pregabalin…300mg |
| | Diary No. Date of R&I & Fee | Dy.No 9046 dated 28-02-2019 Rs.20,000/- 25-02-2019 |
| | Pharmacological Group | antiepileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | 14's, 28's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | Nurica 300mg Capsule of Macter Int. Karachi |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 18. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Gabreg 75mg Capsules |
| | Composition | Each Capsule Contains:<br>Pregabalin…75mg |
| | Diary No. Date of R&I & Fee | Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | antiepileptic |

| | | |
|---|---|---|
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | 14's, 28's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Regab of Caraway pharmaceuticals |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 19. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Gabreg 50mg Capsules |
| | Composition | Each Capsule Contains:<br>Pregabalin…50mg |
| | Diary No. Date of R&I & Fee | Dy.No 9042 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | antiepileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | 14's, 28's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | Dygab 25mg Capsules of M/s. Dyson Research Laboratories |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted. | |

| | | |
|---|---|---|
| | The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 20. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Aliprid 25mg Tablet |
| | Composition | Each Tablet Contains: Levosulpiride…25mg |
| | Diary No. Date of R&I & Fee | Dy.No 9050 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | ANTIPSYCHOTICS |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | 10's, 20's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in AIFA |
| | Me-too status | Sulpeol tablet of Danas Pharmaceuticals |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 21. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Aliprid 100mg Tablet |
| | Composition | Each Tablet Contains: Levosulpiride…100mg |
| | Diary No. Date of R&I & Fee | Dy.No 9052 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | ANTIPSYCHOTICS |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |

| | | |
|---|---|---|
| | Pack size & Demanded Price | :As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in AIFA |
| | Me-too status | Lipride tablet 100mg of Polyfine chemicals |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 22. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Amlogyl Suspension 200mg/5ml |
| | Composition | Each 5ml of suspension contains: Metronidazole as benzoate…200mg |
| | Diary No. Date of R&I & Fee | Dy.No 9074 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Anti-infective and antiseptics for local oral treatment |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | 60ml, 120ml: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Mogel 200mg Suspension of M/s Metro Pharmaceuticals |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted. | |

| | | |
|---|---|---|
| | The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 23. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Inezon 400mg Tablet |
| | Composition | Each Tablet Contains:<br>Linezolid…400mg |
| | Diary No. Date of R&I & Fee | Dy.No 9053 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | antibacterials |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in USFDA( zyvox tablet 400mg)<br>(but discontinued, however it is written that Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**) |
| | Me-too status | Barizold tablet 400mg of Barrett Hodgson(Reg #076342) |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 24. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Inezon 600mg Tablet |
| | Composition | Each Tablet Contains:<br>Linezolid…600mg |

| | | |
|---|---|---|
| | Diary No. Date of R&I & Fee | Dy.No 9054 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | antibacterials |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | LinzolTablet 600 mg of M/s Regal Pharmaceuticals, |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | Reference product is film coated tablet |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 25. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Temisart 20mg Tablet |
| | Composition | Each Tablet Contains:<br>Telmisartan…20mg |
| | Diary No. Date of R&I & Fee | Dy.No 9065 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | Velmon tablets 20mg of Martin Dow |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:** | |

| | | |
|---|---|---|
| | The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 26. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Temisart 40mg Tablet |
| | Composition | Each Tablet Contains:<br>Telmisartan…40mg |
| | Diary No. Date of R&I & Fee | Dy.No 9066 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | Velmon tablets 40mg of Martin Dow |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. NG9-LZH-452U dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 27. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Temisart 80mg Tablet |
| | Composition | Each Tablet Contains:<br>Telmisartan…80mg |
| | Diary No. Date of R&I & Fee | Dy.No 9067 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |

| | | |
|---|---|---|
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | As Per SRO |
| | Approval status of product in reference regulatory authorities | Approved in USFDA |
| | Me-too status | Velmon tablets 80mg of Martin Dow |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted.<br>The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 28. | Name and address of manufacturer / Applicant | M/s Alina Combine Pharmaceuticals Pvt Ltd<br>A-127, S.I.T.E Super Highway, Karachi |
| | Brand Name + Dosage Form + Strength | Viredo B Tablet 300mg |
| | Composition | Each Film Coated Tablet Contains:<br>Tenofovir Disoproxil as Fumarate…300mg |
| | Diary No. Date of R&I & Fee | Dy.No 9061 dated 28-02-2019 Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Antiviral |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg Specification |
| | Pack size & Demanded Price | 10's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | |
| | Me-too status | |
| | GMP status | GMP inspection conducted on 08-01-18 of Alina Pharmaceuticals concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision of 296 meeting (8-10th Sep, 2020):** Deferred for updated status of GMP from QA & LT Division.<br>**Reply:**<br>The firm has submitted the reply vide General Request ID No. **NG9-LZH-452U** dated 11-06-2026. Last inspection report for renewal of DML dated 02-02-2026 is submitted. | |

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|---|---|
| | The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period. |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** |

**Cases of Form 5 (deferred in various meetings) requiring stability data:**

As per notification No.F.15.1/2022-PEC dated 18-10-2024, all those registration applications requiring stability study data (applied on Form5/Form 5D) for which the requisite data has not been submitted till **30th June, 2023**, shall be considered as disposed off and the applicant firms may apply afresh on Form-5F which will be considered on its turn in queue of Form 5F.

Below are the applications submitted on Form 5 with the reply which deferred in various meeting of Registration Board and for which stability data is required.

| | | |
|---|---|---|
| 29. | Name and address of manufacturer / Applicant | M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313,<br>Industrial Triangle, Kahuta road, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitalip DS 50/1000 mg Tablet |
| | Composition | Each Film Coated Extended Release Tablet Contains:<br>Sitagliptin Phosphate Monohydrate…50mg<br>Metformin HCl…1000mg |
| | Diary No. Date of R& I & fee | General Request Form Tracking ID PQ9-EJ3-6YP5<br>Dy No. 16021: 07-03-2019<br>PKR 20,000/-: 07-03-2019 |
| | Type of Form | Form 5 |
| | Pharmacological Group | Antidiabetic |
| | Finished product Specification | Firm has claimed in house specifications |
| | Pack size & Demanded Price | As per SRO |
| | RRA Status | USFDA Approved |
| | Me-too status | Treivamet Tablet by Getz |
| | GMP status | |
| | Remarks of the Evaluator [IV] | • Latest GMP inspection report conducted within a period of last three years.<br>• Revise your label claim as per the innovator's product along with submission of full fee of registration.<br>• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. |
| | **Decision of 326th meeting:**<br>Deferred for following:<br>• Latest GMP inspection report conducted within a period of last three years.<br>• Revision of the label claim as per the innovator's product along with submission of full fee of registration. | |

| | | |
|---|---|---|
| | • Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. | |
| | **Firm's response:** The firm has submitted the response for submission of stability data on 31-12-2024 (R&I receiving is attached), however, as per notification NF.15-1/2022-PEC dated 18-10-2024 the last date for submission of stability data for form 5/5D was 30-06-2023. | |
| | Evaluation by PEC: | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 30. | Name and address of manufacturer / Applicant | M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313,<br>Industrial Triangle, Kahuta road, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitalip DS 50/500 mg Tablet |
| | Composition | Each Film Coated Extended Release Tablet Contains:<br>Sitagliptin Phosphate Monohydrate…50mg<br>Metformin HCl…500mg |
| | Diary No. Date of R& I & fee | General Request Form Tracking ID PQ9-EJ3-6YP5<br>Dy No. 16022: 07-03-2019<br>PKR 20,000/-: 07-03-2019 |
| | Type of Form | Form 5 |
| | Pharmacological Group | Antidiabetic |
| | Finished product Specification | Firm has claimed in house specifications |
| | Pack size & Demanded Price | As per SRO |
| | RRA Status | USFDA Approved |
| | Me-too status | Treivamet Tablet by Getz |
| | GMP status | |
| | Remarks of the Evaluator [IV] | • Latest GMP inspection report conducted within a period of last three years.<br>• Revise your label claim as per the innovator's product along with submission of full fee of registration.<br>• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. |
| | **Decision of 326th meeting:**<br>Deferred for following:<br>• Latest GMP inspection report conducted within a period of last three years.<br>• Revision of the label claim as per the innovator's product along with submission of full fee of registration.<br>• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. | |
| | **Firm's response:** The firm has submitted the response for submission of stability data on 31-12-2024 (R&I receiving is attached), however, as per notification NF.15- | |

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|---|---|---|
| | 1/2022-PEC dated 18-10-2024 the last date for submission of stability data for form 5/5D was 30-06-2023. | |
| | | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 31. | Name and address of manufacturer / Applicant | M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313,<br>Industrial Triangle, Kahuta road, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitazan XR 50/850 mg Tablet |
| | Composition | Each Film Coated Extended Relase Tablet Contains:<br>Sitagliptin Phosphate Monohydrate…50mg<br>Metformin HCl…850mg |
| | Diary No. Date of R& I & fee | General Request Form Tracking ID PQ9-EJ3-6YP5<br>Dy No. 16286: 07-03-2019<br>PKR 20,000/-: 07-03-2019 |
| | Type of Form | Form 5 |
| | Pharmacological Group | Antidiabetic |
| | Finished product Specification | Firm has claimed in house specifications |
| | Pack size & Demanded Price | As per SRO |
| | RRA Status | USFDA Approved |
| | Me-too status | Treivamet Tablet by Getz |
| | GMP status | |
| | Remarks of the Evaluator [IV] | • Latest GMP inspection report conducted within a period of last three years.<br>• Revise your label claim as per the innovator's product along with submission of full fee of registration.<br>• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. |
| | **Decision of 326th meeting:**<br>Deferred for following:<br>• Latest GMP inspection report conducted within a period of last three years.<br>• Revision of the label claim as per the innovator's product along with submission of full fee of registration.<br>• Submission of stability study data of three batches as per the guidelines and checklist approved by Registration Board in its 293rd meeting. | |
| | **Firm's response:** The firm has submitted the response for submission of stability data on 31-12-2024 (R&I receiving is attached), however, as per notification NF.15-1/2022-PEC dated 18-10-2024 the last date for submission of stability data for form 5/5D was 30-06-2023. | |
| | | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases** | |

| | | |
|---|---|---|
| | **which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 32. | Name and address of manufacturer / Applicant | M/s Mega Pharmaceuticals Limited.<br>27-km, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Profamed 5/500 XR Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Dapagliflozin…5mg<br>Metformin Hcl…500mg |
| | Diary No. Date of R& I & fee | Dy.No 8428 dated 26-02-2019<br>Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA(as extended release tablet) |
| | Me-too status | Could not be confirmed |
| | GMP status | Panel inspection conducted on 09-07-2018 recommended issuance of GMP. |
| | Remarks of the Evaluator. | • Please submit stability studies plus correct composition in line with reference product & in line with brand name of applied drug product that is extended release tablet. |
| | **Decision of 297th Meeting:**<br><br>Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 293rd meeting of registration Board. | |
| | **Firm's response:** The firm had submitted stability data dated 31-12-2024 (R&I receiving is attached), however, as per notification NF.15-1/2022-PEC dated 18-10-2024 the last date for submission of stability data for form 5/5D was 30-06-2023. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 33. | Name and address of manufacturer / Applicant | M/s Mega Pharmaceuticals Limited.<br>27-km, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Profamed 10/500 XR Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Dapagliflozin…10mg<br>Metformin Hcl…500mg |
| | Diary No. Date of R& I & fee | Dy.No 8429 dated 26-02-2019<br>Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |

| | | |
|---|---|---|
| | Finished Product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA(as extended release tablet) |
| | Me-too status | Could not be confirmed |
| | GMP status | Panel inspection conducted on 09-07-2018 recommended issuance of GMP. |
| | Remarks of the Evaluator. | • Please submit stability studies plus correct composition in line with reference product & in line with brand name of applied drug product that is extended release tablet. |
| | **Decision of 297th Meeting:**<br><br>Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 293rd meeting of registration Board. | |
| | **Firm's response:** The firm had submitted stability data dated 31-12-2024 (R&I receiving is attached), however, as per notification NF.15-1/2022-PEC dated 18-10-2024 the last date for submission of stability data for form 5/5D was 30-06-2023. | |
| | Evaluation by PEC: | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 34. | Name and address of manufacturer / Applicant | M/s Mega Pharmaceuticals Limited.<br>27-km, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Profamed 10/1000 XR Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Dapagliflozin…10mg<br>Metformin Hcl…1000mg |
| | Diary No. Date of R& I & fee | Dy.No 8430 dated 26-02-2019<br>Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA(as extended release tablet) |
| | Me-too status | Could not be confirmed |
| | GMP status | Panel inspection conducted on 09-07-2018 recommended issuance of GMP. |
| | Remarks of the Evaluator. | • Please submit stability studies plus correct composition in line with reference product & in line with brand name of applied drug product that is extended release tablet. |

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|---|---|---|
| | **Decision of 297th Meeting:**<br><br>Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 293rd meeting of registration Board. | |
| | Firm's response: | |
| | **Firm's response:** The firm had submitted stability data dated 31-12-2024 (R&I receiving is attached), however, as per notification NF.15-1/2022-PEC dated 18-10-2024 the last date for submission of stability data for form 5/5D was 30-06-2023. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 35. | Name and address of manufacturer / Applicant | M/s Mega Pharmaceuticals Limited.<br>27-km, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Profazin Tablet 5mg |
| | Composition | Each Film Coated Tablet Contains:<br>Dapagliflozin propanediol monohydrate eq to Dapagliflozin…5mg |
| | Diary No. Date of R& I & fee | Dy.No 8427 dated 26-02-2019<br>Rs.20,000/- Dated 25-02-2019 |
| | Pharmacological Group | ANTIPSYCHOTICS |
| | Type of Form | Form 5 |
| | Finished Product Specification | Mfg Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA(as extended release tablet) |
| | Me-too status | Could not be confirmed |
| | GMP status | Panel inspection conducted on 09-07-2018 recommended issuance of GMP. |
| | Remarks of the Evaluator. | |
| | **Decision of 297th Meeting:**<br><br>Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 293rd meeting of registration Board. | |
| | **Firm's response:** The firm had submitted stability data dated 31-12-2024 (R&I receiving is attached), however, as per notification NF.15-1/2022-PEC dated 18-10-2024 the last date for submission of stability data for form 5/5D was 30-06-2023. | |
| | | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP** | |

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| | **Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** |

**Cases of Form 5/Form 5D (deferred for shortcomings in stability data):**

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|---|---|---|
| 36. | Name and address of manufacturer / Applicant | M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan |
| | Brand Name +Dosage Form + Strength | Onset 4mg Tablet |
| | Composition | Each Orodispersible Tablet Contains:<br>Ondansetron As Hcl…4mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 59 dated 01-01-2019<br>Rs.20,000/- dated 01-01-2019 |
| | Pharmacological Group | ANTIEMETICS AND ANTINAUSEANTS |
| | Type of Form | Form 5. |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | |
| | Approval status of product in Reference Regulator Authorities | Zofran Melt 4mg tablet USFDA Approved |
| | Me-too status | |
| | GMP status | |
| | Remarks of the Evaluator | |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Onset 4mg Tablet | | |
| Manufacturer of API | **Anugraha chemicals (As per COA)** | | |
| API Lot No. | | | |
| Description of Pack (Container closure system) | Alu-Alu foil | | |
| Stability Storage Condition | Real time: 30°C ± 2° C / 65% ± 5% RH<br>Accelerated: 40 °C ± 2 °C / 75% ± 5% | | |
| Time Period | Real time: 09 months<br>Accelerated: 06 months | | |
| Frequency | Accelerated: 0, 1, 2, 3,4, 6 (months)<br>Real Time: 0, 3, 6, 9 (months) | | |
| Batch No. | OND4-TR002 | OND4-TR003 | OND4-TR004 |
| Batch Size | 1000 | 1000 | 1000 |
| Manufacturing Date | 12-2018 | 06-2019 | 06-2019 |
| Date of Initiation | 19-12-2018 | 30-07-2019 | 29-07-2019 |
| No. of Batches | 3 | | |
| Date of Submission | | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr. No.** | **Documents to Be Provided** | **Status** |

| | | |
|---|---|---|
| 1. | Reference of previous approval of applications with stability study data of the firm. | |
| 2. | Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer. | Submitted |
| 3. | Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer | Submitted. |
| 4. | Stability study data of API from API manufacturer | Not Submitted |
| 5. | Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. | Not submitted. |
| 6. | Documents for the procurement of API with approval from DRAP (in case of import). | Submitted. |
| 7. | Protocols followed for conduction of stability study | Submitted |
| 8. | Method used for analysis of FPP | Submitted |
| 9. | Drug-excipients compatibility studies (where applicable) | Submitted |
| 10. | Complete batch manufacturing record of three stability batches. | Submitted |
| 11. | Record of comparative dissolution data (where applicable) | Submitted against reference product ZOFRAN MELT 4mg in all 3 medium |
| 12. | Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. | Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm. |
| 13. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Submitted. |
| 14. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | Not submitted. |

**Remarks of Evaluator:**

| Sr. No. | Observation | Reply by the firm |
|---|---|---|

| | | |
|---|---|---|
| **1** | Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. GMP certificate of finish product manufacturer is also required. | |
| **2** | Stability study data of API from API manufacturer | |
| **3** | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | |
| **4** | Provide the evidence of said formulation as the reference product is available as ondansetron base however you have used Ondansetron As Hcl | |

**Decision of 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.**

The firm has submitted the reply vide online tracking ID No. 8YE-9JW-URZU dated 30-05-225.

| **Reason** | **Reply** |
|---|---|
| Stability study data of API from API manufacturer | 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A is submitted. |
| Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | **submitted** |
| Provide the evidence of said formulation as the reference product is available as ondansetron base however you have used Ondansetron As Hcl | The firm has stated that their product was manufactured from Ondansetron base rather than Ondansteron as HCl. The firm has submitted analytical record which confirms the label claim as:<br>Each tablet contains:<br>Ondansetron…..4mg |
| **The active ingredient in ZOFRAN ODT Orally Disintegrating Tablets is ondansetron base, the racemic form of ondansetron, and a selective blocking agent of the serotonin 5-HT$_3$ receptor type. Chemically it is (±)1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one. It has the following structural formula:** | |
| Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. GMP certificate of finish product manufacturer is also required. | Copy of approval letter for License No. FDA0MFG/SR-1309/2024-2025 dated 01-03-2025 valid till 13-02-2030 is submitted.<br>Copy of GMP certificate No. DSD/SPL.CELL-I/CR-1916/2024-25 valid till 14-04-2026 is submitted.<br>GMP/last inspection report of finished product manufacturer is not submitted. |
| **Decision: Approved.** | |

| | | |
|---|---|---|
| 37. | Name and address of manufacturer / Applicant | M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan |
| | Brand Name +Dosage Form + Strength | Onset 8mg Tablet |
| | Composition | Each Orodispersible Tablet Contains:<br>Ondansetron As Hcl…8mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 60 dated 01-01-2019 Rs.20,000/- dated 01-01-2019 |

| | | |
|---|---|---|
| | Pharmacological Group | ANTIEMETICS AND ANTINAUSEANTS |
| | Type of Form | Form 5. |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | |
| | Approval status of product in Reference Regulator Authorities | Zofran Melt 8mg tablet USFDA Approved |
| | Me-too status | |
| | GMP status | |
| | Remarks of the Evaluator | |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Onset 4mg Tablet | | |
| Manufacturer of API | **Anugraha chemicals (As per COA)** | | |
| API Lot No. | | | |
| Description of Pack (Container closure system) | Alu-Alu foil | | |
| Stability Storage Condition | Real time: 30˚C ± 2˚ C / 65% ± 5% RH<br>Accelerated: 40 °C ± 2 °C / 75% ± 5% | | |
| Time Period | Real time: 09 months<br>Accelerated: 06 months | | |
| Frequency | Accelerated: 0, 1, 2, 3,4, 6 (months)<br>Real Time: 0, 3, 6, 9 (months) | | |
| Batch No. | OND4-TR002 | OND4-TR003 | OND4-TR004 |
| Batch Size | 1000 | 1000 | 1000 |
| Manufacturing Date | 12-2018 | 06-2019 | 06-2019 |
| Date of Initiation | 19-12-2018 | 30-07-2019 | 29-07-2019 |

| | |
|---|---|
| No. of Batches | 3 |
| Date of Submission | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr. No.** | **Documents to Be Provided** | **Status** |
| 1. | Reference of previous approval of applications with stability study data of the firm. | |
| 2. | Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer. | Submitted |
| 3. | Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer | Submitted. |
| 4. | Stability study data of API from API manufacturer | Not submitted. |

| | | |
|---|---|---|
| 5. | Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. | Not submitted. |
| 6. | Documents for the procurement of API with approval from DRAP (in case of import). | Submitted. |
| 7. | Protocols followed for conduction of stability study | Submitted |
| 8. | Method used for analysis of FPP | Submitted |
| 9. | Drug-excipients compatibility studies (where applicable) | Submitted |
| 10. | Complete batch manufacturing record of three stability batches. | Submitted |
| 11. | Record of comparative dissolution data (where applicable) | Submitted against reference product ZOFRAN MELT 4mg in all 3 medium |
| 12. | Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. | Firm has submitted stability data sheets for three batches. Respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. are submitted by the firm. |
| 13. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Submitted. |
| 14. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | Not submitted. |

**Remarks of Evaluator:**

| Sr. No. | Observation | Reply by the firm |
|---|---|---|

| | | |
|---|---|---|
| **1** | Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. GMP certificate of finish product manufacturer is also required. | |
| **2** | Stability study data of API from API manufacturer | |
| **3** | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | |
| **4** | Provide the evidence of said formulation as the reference product is available as ondansetron base however you have used Ondansetron As Hcl | |

Decision of 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

Reply: The firm has submitted the reply vide online tracking ID No. YXP-74Z-VY2L dated 30-05-225.

| Reason | Reply |
|---|---|
| Stability study data of API from API manufacturer | 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-A is submitted. |
| Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | submitted |
| Provide the evidence of said formulation as the reference product is available as ondansetron base however you have used Ondansetron As Hcl | The firm has stated that their product was manufactured from Ondansetron base rather than Ondansteron as HCl. The firm has submitted analytical record which confirms the label claim as:<br>Each tablet contains:<br>Ondansetron…..8mg |
| The active ingredient in ZOFRAN ODT Orally Disintegrating Tablets is ondansetron base, the racemic form of ondansetron, and a selective blocking agent of the serotonin 5-$HT_3$ receptor type. Chemically it is (±)1, 2, 3, 9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one. It has the following structural formula: | |
| Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. GMP certificate of finish product manufacturer is also required. | Copy of approval letter for License No. FDA0MFG/SR-1309/2024-2025 dated 01-03-2025 valid till 13-02-2030 is submitted.<br>Copy of GMP certificate No. DSD/SPL.CELL-I/CR-1916/2024-25 valid till 14-04-2026 is submitted.<br>GMP/last inspection report of finished product manufacturer is not submitted. |
| Decision: Approved. | |

| | | |
|---|---|---|
| 38. | Name and address of manufacturer / Applicant | **M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi** |
| | Brand Name +Dosage Form + Strength | Emgly 10mg Tablet |
| | Composition | Each film coated tablet contains:<br>Empagliflozin……10 mg |
| | Diary No. Date of R& I & fee | From-5 Dy. No. 180 dated 03-02-2017 50,000/- dated 02-02-2017 |

| | |
|---|---|
| Pharmacological Group | Antidiabetic (sodium-glucose co-transporter 2 (SGLT2) inhibitors) |
| Type of Form | Form 5-D |
| Finished product Specifications | Manufacturer's Specification |
| Pack size & Demanded Price | Pack size & MRP as per SRO. |
| Approval status of product in Reference Regulator Authorities | Jardiance tablets (USFDA Approved) |
| Me-too status | Emsyn 10mg tablets of M/s The Searle Company Limited, Karachi. (Reg. No. 093089) |
| GMP status | Submitted, Certificate No. 007/2022-DRAP (K), Dated: 20-01-2022. (Valid for 2 years). |
| Remarks of the Evaluator | |

**STABILITY STUDY DATA**

| | |
|---|---|
| Drug | Emgly 10mg Tablet |
| Manufacturer of API | Chifeng Arker Pharmaceutical Technology Co. Ltd.<br>Address: No. 8 Mysun Street, Hongshan Economic Development Zone, Chifeng, Inner Mongolia, China. |
| API Lot No. | D86-200401 |
| Description of Pack (Container closure system) | 3x10's, Alu-Au Blister |
| Stability Storage Condition | Real time: 30°C ± 2° C / 65% ± 5% RH<br>Accelerated: 40 °C ± 2 °C / 75% ± 5% |
| Time Period | Real time: 06 months Accelerated: 06 months |
| Frequency | Accelerated: 0, 3, 6 (months) |

| | | | |
|---|---|---|---|
| | Real Time: 0, 3, 6, (months) | | |
| Batch No. | PLT-T-137 | PLT-T-138 | PLT-T-139 |
| Batch Size | 2000 Tablets | 2000 Tablets | 2000 Tablets |
| Manufacturing Date | 02-2021 | 02-2021 | 02-2021 |
| Date of Initiation | 03.2021 | 03.2021 | 03.2021 |
| No. of Batches | 03 | | |
| Date of Submission | Dy. No. 31022 dated 01-11-2022. | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents to Be Provided | Status |
|---|---|---|
| 1. | Reference of previous approval of applications with stability study data of the firm. | Not submitted |
| 2. | Certificate of Analysis of API from both API Manufacturer and Finished Product manufacturer. | Firm has submitted Copy of COA of the drug substance (Empagliflozin) from M/s. Chifeng Arker Pharmaceutical Technology Co. Ltd.<br><br>Firm has also submitted COA of the drug substance with batch number D87-200401 and manufacturing date Jan-22. (Manufacturer's **Specification)** |
| 3. | Method used for analysis of API from both API Manufacturer and Finished Product Manufacturer | Analytical procedures for the drug substance from both drug substance manufacturers and Finished Product Manufacturer are provided by the firm. |
| 4. | Stability study data of API from API manufacturer | Not submitted |
| 5. | Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. | Firm has Submitted GMP Certificate Vald till 21-05-2023. Issued by Inner Mangolia Pharmaceutical Industry Association. (Not acceptable to DRAP) |
| 6. | Documents for the procurement of API with approval from DRAP (in case of import). | API Procurement In-voice attached.<br>Invoice No. PSPW-200429-2, Invoice cleared by DRAP Karachi office. Dated, 19-05-2020. |
| 7. | Protocols followed for conduction of stability study. | Submitted. |
| 8. | Method used for analysis of FPP | Submitted. |
| 9. | Drug-excipients compatibility studies (where applicable) | Not submitted |
| 10. | Complete batch manufacturing record of three stability batches. | Not submitted |
| 11. | Record of comparative dissolution data (where applicable) | Not submitted. |
| 12. | Data of 03 batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. | Submitted 3 months stability data (Accelerated and Real time). |

| | | |
|---|---|---|
| 13. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Submitted |
| 14. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | Submitted |

**Remarks of Evaluator:**

| Sr. No. | Observation | Reply by the firm |
|---|---|---|
| **1.** | Reference of previous approval of applications with stability study data of the firm shall be submitted. | |
| **2.** | Stability study data of API from API manufacturer shall be submitted. | |
| **3.** | Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. | |
| **4.** | Drug-excipients compatibility studies (where applicable) shall be submitted. | |
| **5.** | Complete batch manufacturing record of three stability batches shall be submitted.. | |
| **6.** | Record of comparative dissolution data shall be submitted. | |
| **7.** | Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd. | |
| **8.** | Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point) | |
| **9.** | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | |

Decision of 344th meeting: Registration Board deferred the case for submission of reply to the above cited shortcomings.

The firm has submitted the reply vide application ID U5G-NLP-1WVG dated 26-06-2025.

| Observation | Reply by the firm |
|---|---|
| Reference of previous approval of applications with stability study data of the firm shall be submitted. | Sacval (Sacuitril+Valsartan) tablet 344th meeting. |
| Stability study data of API from API manufacturer shall be submitted. | 06 months accelerated and 24 months real time stability data of 03 batches according to one IV-A. |
| Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin shall be submitted. | DML No 20160053 valid is 28-12-2025 is submitted. |
| Drug-excipients compatibility studies (where applicable) shall be submitted. | N.A Same excipient as used by innovator. |
| Complete batch manufacturing record of three stability batches shall be submitted.. | Submitted, |
| Record of comparative dissolution data shall be submitted. | Submitted against Jardiance. |
| Submit valid GMP certificate of Barret Hodgson Pakistan (Pvt) Ltd. | **Not submitted.** |
| Submit real time and accelerated stability data on 6 month time point. (As your firm's dossier only contains till 3 month time point) | Submitted along with audit trail report. |
| Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | Submitted. |
| **Decision: Approved.** | |

**Miscellaneous Cases of Form 5:**

A list of cases submitted by M/s Shrooq Pharmaceuticals on Form 5 which were not considered in any meeting, was presented before the Board in its 344th meeting. The Board directed the firm to submit the original fee challans for differential fee of Rs. 12,000/- within 6 months of publication of minutes of the meeting. The firm could not submit the reply within the time.

Following are the details.

| | | |
|---|---|---|
| 39. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Titol Sachet |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 31-03-2010, Rs 8000/- |
| | Composition | Each Sachet contains:<br>Lactitol as monohydrate.....10gm |
| | Pharmacological Group | Anti-laxative |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Available (Sami Pharma) |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- is submitted.<br>The firm shall submit the applicable fee for revision of formulation. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 40. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Fenticon Cream 2% |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 27-10-2010, Rs. 8000 |
| | Composition | Each gram contains:<br>Fenticonazole Nitrate……..2% (w/w) |
| | Pharmacological Group | . GYNAECOLOGICAL ANTI-INFECTIVES DRUG |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |

| | | |
|---|---|---|
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | Lomexin 2% w/w cream HPRA Ireland approved (PA0812/002/001) |
| | Me-too status | Lomexin cream by pacific pharma |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:** Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. (date of publication of minutes 25-02-2025) | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. | |
| | Evaluation by PEC:<br>Original fee receipt of Rs. 12,000/- No. 0823904 is submitted. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 41. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Fenticon V Cream 2% |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 27-10-2010, Rs 8000/- |
| | Composition | Each gram contains:<br>Fenticonazole Nitrate……..2% (w/w) |
| | Pharmacological Group | . GYNAECOLOGICAL ANTI-INFECTIVES DRUG |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Lomexin V cream by pacific pharma |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:** Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Original fee receipt of Rs. 12,000/- No. 0823902 is submitted. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after** | |

| | | |
|---|---|---|
| | **due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 42. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Daylite-Z ORS Sachet |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 14-09-2010, Rs 8000/- |
| | Composition | Each sachet contains:<br>Sodium Chloride … 3.5gm<br>Potassium Chloride … 1.50gm<br>Sodium Citrate … 2.9gm<br>Dextrose Anhydrous … 20gm |
| | Pharmacological Group | Electrolytes |
| | Type of Form | Form 5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | WHO has removed the old/applied formulation of ORS from EML https://list.essentialmeds.org/?section=417&indication=&year=&age=&sex=<br>**Because of the improved effectiveness of reduced osmolarity ORS solution WHO and UNICEF now recommend that countries use and manufacture, for diarrhoea of all etiologies and in all age groups, the following formulation with a total osmolarity of 245 mOsmol/l, in place of the previously recommended ORS solution with a total osmolarity of 311 mOsm/l. It should be emphasized that the new ORS is considered as a medicine, like the old formulation, and has been included in the WHO model list of Essential Medicines. Therefore, it should be manufactured as a pharmaceutical product.**<br>Sodium Chloride … 2.6gm<br>Potassium Chloride … 1.50gm<br>Sodium Citrate … 2.9gm<br>Dextrose Anhydrous … 13.5gm |
| | Me-too status | Z-ORS Sachet by Xenon Pharmaceuticals |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- without mentioning the name of the product is submitted. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |

| | | |
|---|---|---|
| 43. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Calcipo-B Ointment |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 30-07-2010, Rs 8000/- |
| | Composition | Each gram contains:<br>Calcipotriol (hydrous) … 50mcg<br>Betamethasone as Dipropionate…0.5mg |
| | Pharmacological Group | Vit D analogue/Corticosteroid |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Recibet Ointment by Remington |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Original fee receipt of Rs. 12,000/- 819096 is submitted.<br>The firm shall submit fee for revision of label claim as per reference product. | |
| | Decision: | |
| 44. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Betin tablet 48mg |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 30-07-2010, Rs 8000/- |
| | Composition | Each tablet contains:<br>Betahistine as dihydrchloride……..48mg |
| | Pharmacological Group | |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | Strength of 48mg could not be confirmed |
| | Me-too status | Available (atco) |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 | |

| | | |
|---|---|---|
| | months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- is submitted.<br>The firm shall submit fee for revision of label claim as per reference product. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 45. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Colmin Tablet |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 29-12-2010, Rs 8000/- |
| | Composition | Each tablet contains:<br>Ossein Mineral Complex 830mg<br>Eq. to<br>Calcium … 177.6mg<br>Phosphorus … 82.2mg<br>Residual Mineral Salt … 24.8mg<br>Collagen … 224mg<br>Other Protein … 88.4mg<br>Trace elements |
| | Pharmacological Group | |
| | Type of Form | Form 5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference<br>Regulatory Authorities. | Could not be confirmed |
| | Me-too status | |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025).<br>The formulation is not as per me-too product. | |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- is submitted.<br>The firm shall submit fee for revision of label claim as per reference product. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 46. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |

| | | |
|---|---|---|
| | Brand Name +Dosage Form + Strength | Benz-C Lotion |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 31-03-2010, Rs 8000/- |
| | Composition | Eacch mL contains:<br>Clindamycin Phosphate … 10mg/ml<br>Benzyl peroxide … 50mg/ml |
| | Pharmacological Group | |
| | Type of Form | Form 5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | Available in Gel form in MHRA |
| | Me-too status | Available (Valor Pharma) |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- is submitted. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 47. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Rasa Tablet 0.5mg |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 16-11-2010, Rs 8000/- |
| | Composition | Each film coated tablet contains:<br>Rasagiline as Mesylate…..0.5mg |
| | Pharmacological Group | Anti parkinson |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved as uncoated |
| | Me-too status | Available (searle |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |

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|---|---|---|
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- is submitted.<br>The firm shall submit the applicable fee for revision of formulation (form film coated to uncoated) | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 48. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Rasa Tablet 1mg |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 16-11-2010, Rs 8000/- |
| | Composition | Each film coated tablet contains:<br>Rasagiline as Mesylate…..1mg |
| | Pharmacological Group | Anti parkinson |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved as uncoated |
| | Me-too status | Available (Searle) |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- is submitted.<br>The firm shall submit the applicable fee for revision of formulation (form film coated to uncoated) | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |

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|---|---|---|
| 49. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Mosefen Tablet 0.5mg |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 10-10-2010, Rs 8000/- |
| | Composition | Each film coated tablet contains:<br>Pizotifen as Hydrogen Maleate.....0.5mg |
| | Pharmacological Group | SEDATING ANTIHISTAMINE DRUG |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. | |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) | |
| | Evaluation by PEC:<br><br>Copy of fee receipt of Rs. 12,000/- is submitted. | |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 50. | Name and address of manufacturer | M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore |
| | Brand Name +Dosage Form + Strength | Daylite ORS Sachet |
| | Diary No. Date of R& I & fee | Diary No. Nil. Dated 14-09-2010, Rs 8000/- |
| | Composition | Each sachet contains:<br>Sodium Chloride … 1.3gm<br>Potassium Chloride … 0.75gm<br>Sodium Citrate … 1.45gm<br>Dextrose Anhydrous … 6.75gm |
| | Pharmacological Group | Electrolytes |
| | Type of Form | Form 5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | As per sro |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmd |
| | Me-too status | Could not be confirmed |
| | GMP status | Not submitted |
| | Remarks of the Evaluator. | |

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|---|---|
| | **Decision of 344th held on 21st Dec to 2nd January, 2025 Meeting:**<br>Registration Board deferred the above applications for submission of original receipt for submission of fee of Rs.12000/- within 6 months of publication of minutes of instant meeting on DRAP website. |
| | **Firm's response**: The applicant has submitted the response vide online tracking ID NO. **YYB-LTJ-BV1W** dated 31-12-2025 whereas the reply should have been submitted within 6 months of publication of the minutes of 344th meeting. (date of publication of minutes 25-02-2025) |
| | Evaluation by PEC:<br>Copy of fee receipt of Rs. 12,000/- without mentioning the name of the product is submitted. |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** |

**New Cases for registration of veterinary drugs never considered before**

| | | |
|---|---|---|
| 51. | Name and address of manufacturer / Applicant | Decent Pharma, Plot No. 30, Street No. SS-3, RCCI, Rawat |
| | Brand Name +Dosage Form + Strength | Piprazol Oral Liquid |
| | Composition | Each 100ml contains:<br>Piprazine Citrate ……..... 37 % |
| | Tracking ID / Diary No. Date of R& I & fee | Form 5, Dy No. 19206, Dated 02-08-2023 (**verified from R&I DRAP)**<br>Rs. 30,000/- Dated 02-08-2023<br>**Duplicate dossier submitted vide ID** ZWV-19U-9R8Y dated 04-03-2026 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specification | (USP Specification) |
| | Pack size & Demanded Price | 50ml, 100ml, 450ml, 500ml 1liter 3 liter and 30 Liter & Decontrolled |
| | Me-too status | Piprasol Oral Solution Reg. No. 058981, M/s Biogen Pharma 8 KM Chakbeli Road, Rawat |
| | Target species | poultry (Layer and Breeders) |
| | GMP status | |
| | Remarks of the Evaluator | Submitted for consideration of the Registration Board, in light of decision of 206th meeting of the Authority. |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st** | |

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|---|---|---|
| | **December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 52. | Name and address of manufacturer / Applicant | Decent Pharma, Plot No. 30, Street No. SS-3, RCCI, Rawat |
| | Brand Name +Dosage Form + Strength | Vita-4 Oral liquid |
| | Composition | Each ml contains:<br>Vitamin A…….. 10,000 IU<br>Vitamin D3……..... 2,000 IU<br>Vitamin E ……..…… 4 mg<br>Vitamin K3……..… 2 mg |
| | Tracking ID / Diary No. Date of R& I & fee | Form 5, Dy No. 19207 Dated 02-08-2023, (**verified from R&I DRAP)**<br>Rs. 30,000/- Dated 02-08-2023<br>**Duplicate dossier submitted vide ID** ZWV-19U-9R8Y dated 04-03-2026 |
| | Pharmacological Group | Multivitamins |
| | Type of Form | Form 5 |
| | Finished product Specification | As per Innovator's Specifications. |
| | Pack size & Demanded Price | 100 mL, 500 mL, 1Liter, 2.5 Liter, 5 Liter and 20 Liter & Decontrolled |
| | Me-too status | Symodek Reg. No. 119855, Symans Pharmaceuticals Lahore |
| | Target species | Cattle, calves, sheep and goats |
| | GMP status | |
| | Remarks of the Evaluator | Submitted for consideration of the Registration Board, in light of decision of 206$^{th}$ meeting of the Authority. |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31$^{st}$ December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 53. | Name and address of manufacturer / Applicant | Decent Pharma, Plot No. 30, Street No. SS-3, RCCI, Rawat |
| | Brand Name +Dosage Form + Strength | Gramycin 100mL Injection |
| | Composition | Each 100ml Contains: |

| | | |
|---|---|---|
| | | Gentamicin sulfate……..... 15.90 g<br>equal to Gentamicin base 10.00 g |
| | Tracking ID / Diary No. Date of R& I & fee | Form 5, Dy No. 19208 Dated 02-08-2023, (**verified from R&I DRAP)**<br>Rs. 30,000/- Dated 02-08-2023<br>**Duplicate dossier submitted vide ID** ZWV-19U-9R8Y dated 04-03-2026 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP Specifications |
| | Pack size & Demanded Price | 100ml: Decontrolled |
| | Me-too status | 034594GENTASEL-10 INJECTION., Selmore Pharmaceuticals Lahore |
| | Target species | Cattle, calves, sheep, goats, poultry, Dog and cats. |
| | GMP status | |
| | Remarks of the Evaluator | Submitted for consideration of the Registration Board, in light of decision of 206th meeting of the Authority. |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |
| 54. | Name and address of manufacturer / Applicant | Decent Pharma, Plot No. 30, Street No. SS-3, RCCI, Rawat |
| | Brand Name +Dosage Form + Strength | Flugent 100mL Liquid Injection |
| | Composition | Each ml contains:<br>Gentamicin sulfate..... 10 mg<br>Flumequine …..... 20 mg |
| | Tracking ID / Diary No. Date of R& I & fee | Form 5, Dy No. 19205, Dated 02-08-2023 (**verified from R&I DRAP)**<br>Rs. 30,000/- Dated 02-08-2023<br>**Duplicate dossier submitted vide ID** ZWV-19U-9R8Y dated 04-03-2026 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |

| | | |
|---|---|---|
| | Finished product Specification | As per Innovator's Specifications. |
| | Pack size & Demanded Price | 100ml: Decontrolled |
| | Me-too status | Gentasel- F Reg. No. 071090, Selmore Pharmaceuticals Lahore |
| | Target species | Cattle, calves, sheep, goats and poultry, dogs and cats |
| | GMP status | |
| | Remarks of the Evaluator | Submitted for consideration of the Registration Board, in light of decision of 206th meeting of the Authority. |
| | **Decision: During the meeting representative of PPMA requested the Board to extend the time line for submission of replies of deferred cases of Form 5 which was 31st December, 2024. The Board hold the decisions of those deferred cases which were submitted after due data and asked the PPMA to approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.** | |

| | | |
|---|---|---|
| 55. | Name, address of Applicant / Marketing Authorization Holder | Surge Laboratories (Pvt.) Ltd., 10th Km, Faisalabad road, Bikhi District, Sheikhupura Pakistan |
| | Name, address of Manufacturing site. | Surge Laboratories (Pvt.) Ltd., 10th Km, Faisalabad road, Bikhi District, Sheikhupura Pakistan |
| | Status of the applicant | ☒ Manufacturer<br>☐ Importer<br>☐ Is involved in none of the above (contract giver) |
| | GMP status of the Finished product manufacturer | Firm has submitted copy of GMP certificate dated 05-04-2022 based on inspection conducted on 05-10- 2021 |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter No. F. 1-18/95-Lic (Vol-III) dated 11-01-2022 which specifies Dry powder injectable (cephalosporin) |
| | Status of application | ☐ New Drug Product (NDP)<br>☒ Generic Drug Product (GDP) |
| | Intended use of pharmaceutical product | ☐ Domestic sale<br>☐ Export sale<br>☒ Domestic and Export sales |
| | Dy. No. and date of submission | Dy. No. 25815 dated 13-09-2022 |
| | Details of fee submitted | Rs.30,000/- dated 27-07-2022 |

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| | | (Deposit slip#38543763329) |
| | The proposed proprietary name / brand name | XTRAZID-AV 2g/0.5g Powder for solution for infusion |
| | Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit | Each vial contains:<br>Ceftazidime pentahydrate eq. to Ceftazidime……2g<br>Avibactam sodium eq. to avibactam…0.5g |
| | Pharmaceutical form of applied drug | Intravenous infusion |
| | Pharmacotherapeutic Group of (API) | Ceftazidime belongs to the group of antibiotics called “cephalosporin”<br>Avibactam is “beta-lactamase inhibitor” |
| | Reference to Finished product specifications | Innovators Specs. |
| | Proposed Pack size | 20ml vial of sterile dry for injection + 1 ampoule of 10ml Sterile Water for Injection to make 12ml clear solution in a single pack |
| | Proposed unit price | As per SRO |
| | The status in reference regulatory authorities | Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion MHRA Approved<br>Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion TGA Approved<br>AVYCAZ (ceftazidime/avibactam) 2g/0.5g for injection USFDA Approved |
| | For generic drugs (me-too status) | Zavicefta Injection 2g/0.5g (Powder for Concentrate for Solution for Infusion) by M/s Pfizer Pakistan Ltd (Reg#106848) |
| | Name and address of API manufacturer. | M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China |
| | Module-II (Quality Overall Summary) | Firm has submitted QOS as per WHO QOS-PD template. Summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance and drug product is submitted. |
| | Module III (Drug Substance) | The firm has submitted detail of nomenclature, structure, general properties, solubilities, |

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|---|---|---|
| | | physical form, manufacturers, description of manufacturing |
| | | process and controls, specifications, analytical procedures and its verification, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. |
| | Stability Studies of Drug Substance (Conditions & duration of Stability studies) | Stability study conditions:<br>Real time: 30˚C ± 2˚C / 65% ± 5%RH for 24 months Accelerated: 40˚C ± 2˚C / 75% ± 5%RH for 6 months Batches: (180601, 180602, 180603) |
| | Module-III (Drug Product): | The firm has submitted detail of manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedure and its verification studies, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug product. |
| | Pharmaceutical equivalence and comparative dissolution profile | Pharmaceutical Equivalence have been established against the brand that is Zavicefta 2g/0.5g Powder for solution for infusion IV by M/s Pfizer Limited., by performing quality tests (Description, pH, Sterility test and Assay). |
| | Analytical method validation/verification of product | Firm has submitted method validation studies including linearity, range, accuracy, precision, specificity, LOD, LOQ, system suitability, robustness. |

STABILITY STUDY DATA

| | | | |
|---|---|---|---|
| Manufacturer of API | M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, Inner Mongolia, China | | |
| API Lot No. | 2105001 | | |
| Description of Pack (Container closure system) | 20ml clear glass vial tubular USP Type-I | | |
| Stability Storage Condition | Real time: 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| Time Period | Real time: 6 months Accelerated: 6 months | | |
| Frequency | Accelerated: 0, 3, 6 (Months)<br>Real Time: 0, 3, 6 (Months) | | |
| Batch No. | CFA-2.5-001 | CFA-2.5-002 | CFA-2.5-003 |
| Batch Size | 15 vials | 15 vials | 15 vials |

| | | | |
|---|---|---|---|
| Manufacturing Date | 17-8-2021 | 24-9-2021 | 24-9-2021 |
| Date of Initiation | 10-2022 | 10-2022 | 10-2022 |
| No. of Batches | 03 | | |

DOCUMENTS / DATA TO BE PROVIDED ALONG WITH STABILITY STUDY DATA

| | | |
|---|---|---|
| 1. | Reference of previous approval of applications with stability study data of the firm (if any) | N/A |
| 2. | Approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. | Firm has submitted copy of GMP certificate in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, China issued by |
| | | China Food and Drug Administration valid upto 21- 02-2022.<br><br>Firm has also submitted copy of DML (certificate No#Nei20160028) in in the name of M/s Chifeng Addisun Pharmaceutical Co., Ltd., 3 Minsheng street, Economic development zone of Hongshan District , Chifeng, China valid upto 27-12-2025. |
| 3. | Documents for the procurement of API with approval from DRAP (in case of import). | Firm has submitted copy of invoice dated 17-06-2021 for import of 300gm of Avibactam and Ceftazidim sterile (Batch#2105001) in name of M/s Surge Laboratories (Pvt) Ltd attested by AD (I&E) DRAP Lahore dated 09-07-2021.<br><br>Firm has also submitted copy of form 6 dated 09-07- 2021 for import of 300gm of Avibactam and Ceftazidim sterile powder (1:4) in name of M/s Surge Laboratories (Pvt) Ltd attested by AD (I&E) DRAP Lahore dated 09-07-2021. |
| 4. | Data of stability batches will be supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. | Firm has submitted data of stability batches supported by attested respective documents like chromatograms, Raw data sheets, COA, summary data sheets etc. |
| 5. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing | Not submitted |
| 6. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | Record of Manual data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) |

Remarks of Evaluator [XI]: Letters of deficiency sent on 19th May 2023 and reminder on 25th August 2023 but no reply received

| Section | Observations |
|---|---|
| 1.5.10 | • Clearly mention the dosage form of applied drug |

| | |
|---|---|
| 1.6.5 | • Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required |
| 2.3.R.1 | • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life<br>• Justification shall be submitted for the dispensed quantity of drug substance against the label claim with reference to the potency of drug substance determined during drug substance analysis by M/s Surge Laboratories.<br>• Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance are different than that recommended by innovator product |
| 3.2.S.4 | • Justification is required for using different chromatographic conditions i.e. mobile phase composition (buffer: acetonitrile; 50;50), injection volume (20ul), isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance<br>• Justification is required for using different chromatographic conditions i.e. mobile phase composition, injection volume (20ul), flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance<br>• Justification is required for not performing the test for reconstitutions, content uniformity, pyridine content, particulate matter, bacterial endotoxin and sterility in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer |
| 3.2.P.1 | • Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug. |
| 3.2.P.2 | • Justification is required since pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, identification, pyridine content, uniformity of dosage unit, particulate matter, water content, and bacterial endotoxins |
| 3.2.P.5 | • Justification is required for not including the test for pyridine content and water content in finished product specification by drug product manufacturer as recommended by innovator product review document<br>• The limits of pH test for drug substance by drug product manufacturer was 5.5-7.5 while limits of pH test for drug product by drug product manufacturer was 5-7.5, clarify<br>• Justification is required for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document |
| 3.2.P.8 | • Justification is required for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document |

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| | • Clarification is required as you have mentioned the manufacturing date of trial batches CFA-2.5-002 and CFA-2.5-003 as august instead of October in in-use stability study |

Previous Decision (M-331-DRB): Registration Board deferred the case for submission of reply to the above cited shortcomings

Response of firm:

| Section | Deferment Reason | Response of Firm |
|---|---|---|
| 1.5.10 | • Clearly mention the dosage form of applied drug | • Corrected dosage form according to innovator<br>literature as Intravenous injection in section 1.5.10. |
| 1.6.5 | • Valid GMP certificate of drug substance manufacturer issued by relevant regulatory authority of country of origin is required | • The firm submitted that after the amendment of the Drug Administration Law (DAL) of the People's Republic of China, the requirement for GMP has been abolished, and China no longer issues GMP certificates. The declaration by the National Medical Drugs Administration is submitted<br>• Firm has also submitted copy DML# 20160028 of M/s Chifeng Addisun Pharmaceutical Co., Ltd., No. 3 Minsheng street, Economic development zone of Hongshan District ,<br>Chifeng, Inner Mongolia, China valid upto 27- 12-2025 |
| 2.3.R.1 | • Justify the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life | • The firm submitted that Ceftazidime 2.0gm + Avibactam 0.5gm sterile ready-to-fill pre-mixed powder material provided by manufacturer to be filled in aseptic conditions and no formulation and manufacturing procedure (instead of aseptic filling) is involved, on the basis of this risk assessment we can rely on the stability studies (attached) provided by the manufacturer according to ICH Zone IVA conditions.<br>• On the basis of above declaration, we have designed trials quantity as minimum as possible to do the necessary testing/studies. However, we commit to provide complete testing of Finished product till shelf life for commercial batches.<br>• Three batches each of 15 vials were prepared to conduct testing upto 06 months for stability |
| | | studies on the above mentioned rationale with necessary test studies.<br>• Justification letter and Undertaking is submitted |

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| | • Justification shall be submitted for the dispensed quantity of drug substance against the label claim with reference to the potency of drug substance determined during drug substance analysis by M/s Surge Laboratories. | • The firm submitted that as per manufacturer COA of drug substance % potency of Ceftazidime as pentahydrate is 64.80% and Avibactum as sodium is 16.80% while on testing by Drug product manufacturer results obtained for Ceftazidime pentahydrate is 60.99% and Avibactum as sodium is 15.75% on as is basis. So the dispensed quantity of drug substance taken is 49.185gm/batch by considering 60.99% assay.<br>• <u>Calculation of proposed weight on the basis of Ceftazidime potency:</u><br>Assay of Ceftazidime (On as is basis) = 60.99%<br>Fill weight = label claim x 100/ Assay % (on as such basis)<br>=2000x100/60.99 = 3279mg/vial<br>• <u>Calculation of proposed weight on the basis of Avibactum potency</u><br>Assay of Avibactum on as is basis = 15.75%<br>Fill weight = label claim x 100/ Assay % (on as such basis)<br>=500 x 100/15.75 = 3174mg/vial<br>• Fill weight of Ceftazidime + Avibactum injection has been selected 3279mg/vial to calculate the batch size which is maximum of both and have both API > 100%.<br>• Justification letter is submitted |
| | • Justification shall be submitted as the content of sodium bicarbonate in premixed drug substance are different than that recommended by<br>innovator product | • Content of Sodium bi carbonate in premixed drug substance are not different as recommended by innovator product. Justification letter for the same is submitted. |

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| 3.2.S.4 | • Justification is required for using different chromatographic conditions i.e. mobile phase composition (buffer: acetonitrile; 50;50), injection volume (20ul), isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance<br>• Justification is required for using different chromatographic conditions i.e. mobile phase composition, injection volume<br>(20ul), flow rate than that recommended by drug substance | • The firm submitted that we have done analytical method validation on our In-House method as per ICH Q2(R1) guidelines use in API testing. Since the API is non–compendia so our In-House validated method is also applicable for testing of API<br>• Changes are made due to better elution of both API's.<br>• Justification letter is submitted |
| | manufacturer for assay of ceftazidime drug substance | |
| | • Justification is required for not performing the test for reconstitutions, content uniformity, pyridine content, particulate matter, bacterial endotoxin and sterility in batch analysis of drug substance by drug product manufacturer as recommended by drug substance manufacturer | • The firm submitted that test for particulate matter, bacterial endotoxin and sterility were performed on API but not reported in chemical test results. In-House COA as separate reports were generated by microbiology department which are submitted.<br>• However, since this material was sterile ready to fill material and no addition of excipients or formulation has been carried at our site, so tests for content uniformity and pyridine content were performed on finished product testing. At API testing stage these tests were taken from API manufacturer COA.<br>• Revise API COA is submitted. |
| 3.2.P.1 | • Provide information including type of diluent, its composition, quantity or volume, specifications and regulatory status in Pakistan for the diluent which is to be provided along with the applied drug. | • The powder for Injection Ceftazidime 2gm+Avibactam 0.5gm is required to be reconstituted with 10ml of Water For Injection prior to mix with intravenous infusion.<br>• Type of Diluent Used for Reconstitution: Water For Injection 10ml Filled in 10ml glass ampoule USP Type-I.<br>• Composition:<br>Each 10ml ampoule contains 10ml of Sterilized Water For Injection [BP Specs.]<br>• Regulatory Status in Pakistan: |

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| | | This diluent (Water for Injection 10ml) having Drug Registration Number:026762 which will be provided with the applied drug product for registration. |
| 3.2.P.2 | • Justification is required since pharmaceutical equivalence study does not include complete testing of the drug product and the innovator product including the tests recommended by innovator product review document (description on reconstitution, reconstitution time, identification, pyridine content, uniformity of dosage unit,<br>particulate matter, water content, and bacterial endotoxins | • The firm submitted that we have again conducted pharmaceutical equivalence studies including complete testing of drug product manufactured by us and the innovator product.<br>• Updated Pharmaceutical Equivalence studies with complete testing is submitted |
| 3.2.P.5 | • Justification is required for not including the test for pyridine content and water content in finished product specification by drug product manufacturer as recommended by innovator product<br>review document | • The firm submitted that we have previously revised Finished Product Specifications mentioning all test as per innovator product review document including test for pyridine content and water content.<br>• Updated Finished Product Specifications are submitted. |
| | • The limits of pH test for drug<br>substance by drug product manufacturer was 5.5-7.5 while<br>limits of pH test for drug product by | • The firm submitted that the limits of pH for drug<br>substance by API manufacturer was 5.5 – 7.5, while we have mentioned pH range 5.0 – 7.5 in<br>submitted product specifications. It was a |

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| | drug substance manufacturer was 5-7.5, clarify | typographical error while compiling product specifications. The pH range 5.5 – 7.5 is the actual and all of our pH results provided in the submitted documents are in the range of 5.5 - 7.5. We have made necessary corrections in the specifications and related documents.<br><br>• pH Data of All Trial Batches of Ceftazidime 2gm + Avibactam 0.5gm Injection and Reference Product is given below:<br><br>Batch Results<br><br>Innovator Batch 6.46<br><br>Trial Batch CFA-2.5-001 6.45<br><br>Trial Batch CFA-2.5-002 6.60<br><br>Trial Batch CFA-2.5-003 6.51<br><br>Trial Batch CFA-2.5-004 6.72<br><br>• Above data shows that pH of the trial samples<br><br>and innovator sample is comparable and well within the range (5.5 – 7.5). |
| | • Justification is required for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product<br><br>manufacturer as recommended by innovator product review document | • The firm submitted that we have manufactured another trial batch, Batch No: CFA-2.5-004 and complete testing was performed on said batch.<br><br>• COA of said batch and justification letter is submitted. |
| 3.2.P.8 | • Justification is required for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document<br><br>• Clarification is required as you have mentioned the manufacturing date of trial batches CFA-2.5-002 and CFA- | • Same justification letter as above.<br><br>• The firm submitted that manufacturing date of trial batches CFA-2.5-002 and CFA-2.5-003 was September 2021. Date mention on the report of In-Use stability studies as August is a typo- error. Corrected document /report is submitted<br><br>– |

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| | 2.5-003 as august instead of October<br><br>in in-use stability study | |

Decision of 333rd meeting of Registration Board:

Deferred for submission of following:

- Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021.
- Justification of the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time stability study till claimed shelf life
- Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance
- Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance
- Justification for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial

endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document.

- Justification for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document

**Response of the Firm:**

| Sr.no. | Shortcomings | Response of the Firm |
|---|---|---|
| **1.** | Fee of Rs. 7,500/- for correction/pre-approval change/ in product specifications, as per notification No.F.7-11/2012-B&A/DRAP dated 13-07-2021. | Firm submitted the fee of Rs. **9400 in the head of pre-registration variation.** |
| **2.** | Justification of the batch size of trial batches against the number of units required for complete testing of drug product during stability study including real time | Firm replied that three new batches were manufactured having batch size of 250 vials sufficient enough to perform complete stability studies till shelf life of product. |

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| | stability study till claimed shelf life | |
| **3.** | Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, isocratic method than that recommended by drug substance manufacturer for assay of avibactam drug substance | The chromatographic conditions and Method of Analysis used in analytical studies for AvibactAm drug substance and Ceftazidime drug substance by drug product manufacturer is same as provided by Drug substance manufacturer.<br><br>Monograph of Drug Substance Manufacturer and Drug Product Manufacturer and comparison of chromatographic condition are submitted. |
| **4.** | Justification for using different chromatographic conditions i.e. mobile phase composition, injection volume, flow rate than that recommended by drug substance manufacturer for assay of ceftazidime drug substance | |
| **5.** | Justification for not performing the test for description on reconstitution, reconstitutions time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document. | Firm replied that Complete testing covering the test for description on reconstitution, reconstitution time, uniformity of dosage units, pyridine content, water content, particulate matter, bacterial endotoxin and sterility in batch analysis by drug product manufacturer as recommended by innovator product review document has been performed.<br><br>However, firm has submitted only the stability sheets without any supporting documents and BMR. |
| **6.** | Justification for not performing the test for description on reconstitution, reconstitutions time, pyridine content, water content, particulate matter in stability study by drug product manufacturer as recommended by innovator product review document | Complete testing covering the test for description on reconstitution, reconstitution time, pyridine content, water content, and particulate matter in stability study by drug product manufacturer as recommended by innovator product review document has been performed. |

Decision of 353rd meeting of Registration Board:

Registration Board deferred the product for submission of the BMR of new developed stability batches, Raw data sheets, Chromatograms and the procurement documents of API.

**Firm in its reply submitted the BMR of newly developed stability batches, Raw data sheets, Chromatograms and the procurement documents of API.**

**Decision: Approved.**

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| 56. | Name, address of Applicant / Importer | M/s. Revive Health Care, Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan. |
| | Details of Drug Sale License of importer | License No: 05-352-0065-031159D<br>Address: Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore. Pakistan.<br>Address of Go down: NA<br>Validity: 21.05.2027<br>Status: License to sell drugs as distributor |
| | Name and address of marketing authorization holder (abroad) | M/s. Jenphar Bangladesh Ltd.<br>Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh<br>Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh |
| | Name, address of manufacturer(s) | M/s. Jenphar Bangladesh Ltd.<br>Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh<br>Office address: SKS-Tower,Level-8,7-VIP Road, Mohakhali Dhaka-1206, Bangladesh |
| | Name of exporting country | Bangladesh |
| | Detail of certificates attached (CoPP, Free sale certificate, GMP certificate) | CoPP: Original legalized COPP (Certificate# DA/6-134/09/10160 issued on 21-05-2023 by Government of the people's republic of Bangladesh, Ministry of Health & Family welfare, Directorate General of Drug Administration, Oushad Bhaban, Mohkhali Dhaka-1212, and Bangladesh.<br>GMP: Firm has submitted Legalized GMP certificate (Certificate No. DGDA/6-134/09/195) issued by Directorate General of Drug Administration, Dhaka, Bangladesh and valid upto 30-09-2023. |
| | Details of letter of authorization / sole agency agreement | Firm has submitted copy of letter of authorization certificate from M/s. Jenphar Bangladesh Limited. The letter specifies that the manufacturer appoints M/s Revive Health Care. to register their products in Pakistan. |
| | Status of the applicant | ☐ Manufacturer<br>☒ Importer<br>☐ Is involved in none of the above (contract giver) |
| | Status of application | ☒ New Drug Product (NDP) |

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| | | ☐ Generic Drug Product (GDP) |
| | Intended use of pharmaceutical product | ☒ Domestic sale<br>☐ Export sale<br>☐ Domestic and Export sales |
| | For imported products, specify one the these | ☒ Finished Pharmaceutical product import<br>☐ Bulk import and local repackaging<br>☐ Bulk import and local repackaging for export purpose only |
| | Dy. No. and date of submission | Dy. No.24504 , Date: 06-10-2023 |
| | Details of fee submitted | PKR 75,000/- 19/09/2023 |
| | The proposed proprietary name / brand name | Tasso Tablet 80mg |
| | Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit | Each Film coated tablet contains:<br>Osimertinib (as mesylate)…..80mg |
| | Pharmaceutical form of applied drug | Tablet |
| | Pharmacotherapeutic Group of (API) | Antineoplastic agents, protein kinase inhibitors (L01EB04) |
| | Reference to Finished product specifications | In house |
| | Proposed Pack size | As per SRO |
| | Proposed unit price | As per current pricing policy of DRAP |
| | The status in reference regulatory authorities | Tagrisso 80mg Tablet (USFDA Approved) |
| | For generic drugs (me-too status) | NA |
| | Module-II (Quality Overall Summary) | Firm has submitted QOS as per WHO QOS-PD template. Firm has summarized information related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. |

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| | Name, address of drug substance manufacturer | ShengDa Pharmaceutical Co., Limited. |
| | Module-III Drug Substance: | Firm has submitted detailed drug substance data for both sources related to nomenclature, structure, general properties, solubilities, physical form, manufacturers, description of manufacturing process and controls, impurities, specifications, analytical procedures and its validation, batch analysis and justification of specification, reference standard, container closure system and stability studies of drug substance. |
| | Stability Studies of Drug Substance<br>(Conditions & duration of Stability studies) | Firm has submitted long term stability study data of 3 batches of drug substance at 25°C ± 2°C / 60 ± 5% RH for 3 months. The accelerated stability data is conducted at 40°C ± 2°C / 75 ± 5% RH for 3 months |
| | Module-III Drug Product: | Firm has submitted data of drug product including its description, composition, pharmaceutical development, manufacture, manufacturing process and process control, process validation protocols, control of excipients, control of drug product, specifications, analytical procedures, validation of analytical procedures, batch analysis, justification of specifications, reference standard or materials, container closure system and stability. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative analysis Studies against the reference product Tagrisso 80mg Tablet (M/s. AstraZeneca) has been submitted. |
| | Analytical method validation/verification of product | Firm has submitted analytical method validation studies for the applied product. |
| | Container closure system of the drug product | HDPE bottle |
| | Stability study data of drug product, shelf life and storage conditions | Firm has submitted stability study data of 3 batches.<br>Accelerated stability studies have been conducted at 40°C±2°C and 75%±5% RH for 6 months.<br>Real time stability studies conducted at 30°C±2°C and 65% ± 5% for 24 months |

Evaluation by PEC:

Therapeutic indications TAGRISSO as monotherapy is indicated for:

- the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.

• the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations.

• the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

| S.no. | Section | Observations/Deficiencies/ Short-comings |
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| 1. | 1.3.4 | Submit product specific letter of authorization from the Product License Holder, since the submitted authorization letter was not specified the product. |
| 2. | 1.3.5 | 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. |
| 3. | 3.2.S.2.1 | Provide the complete manufacturing address of drug substance manufacturer, since you have only specified the title of drug substance manufacturer. |
| 4. | 3.2.S.4.1-3.2.S.4.2 | Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer. |
| 5. | 3.2.S.4.3 | Provide analytical method validation report performed by drug product manufacturer. |
| 6. | 3.2.S.4.4 | Provide batch analysis report of drug substance by the drug product manufacturer. |
| 7. | 3.2.S.5 | Provide certificate of analysis of reference standard /working standard used for testing of the product. |
| 8. | 3.2.S.7 | Submit stability data of drug substance performed both at accelerated and long term conditions till the claimed re-test period, since you have only submitted the data of 2 time points i.e. 1st and 3rd month. |
| 9. | 3.2.P.2.6 | Innovator product claimed that tablets are formulated to be dispersible, when dosing of whole tablets is not possible, tablets may be administered as an aqueous dispersion. Reference to the innovator claim, did the applied formulation also dispersed in the similar manner as of innovator product. Further, did you performed the study for Use of Tablet Dispersion and impact of dispersion preparation on physiochemical properties of the final dosage form were assessed while formulation development. |
| 10. | Conclusion of CDP report stated that test/applied formulation is the product of M/s. Beacon Pharmaceuticals, (Faridpur,sreepur,gazipur) Bangladesh, validation protocol claims that the Tasso tablet i.e. the applied product is of M/s. Julphar Bangladesh Ltd.(Gazipur,Sreepur) while the product license holder is M/s. Jenphar Bangladesh Ltd. (Vill-Faridpur, PS-Sreepur Dis-Gazipur).Clarification is required regarding the disparity observed related to the manufacturer of drug product in different section of CTD dossier, further, submitted the complete address of drug product manufacturer, since all three mentioned manufacturer have same address. | |
| 11. | 3.2.P.5.1 | Justify the dissolution acceptance limit i.e. NLT 80% (Q) within 45 minutes adopted for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes. |

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| 12. | 3.2.P.5.4 | Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard. |
| 13. | 2.3.R.1.1 | Provide copy of Batch Manufacturing Record (BMR) of all the batches of drug product for which stability studies data is provided in Module 3 section 3.2. P.8. |

Decision of 333rd meeting of Registration Board:

Deferred for submission of reply to above cited shortcomings.

Response of the Firm:

| S.no. | Observations/Deficiencies/ Short-comings | Response of the Firm |
|---|---|---|
| 1. | Submit product specific letter of authorization from the Product License Holder, since the submitted authorization letter was not specified the product. | Firm submitted the product specific Letter of authorization from the product License Holder. |
| 2. | 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 submitted a letter mentioning that they have separate oncology manufacturing facility without any GMP certificate or inspection report. |
| 3. | Provide the complete manufacturing address of drug substance manufacturer, since you have only specified the title of drug substance manufacturer. | Firm submitted the complete address of API manufacturer "M/s. Shengda Pharmaceuticals Co. Ltd., Block H, Zhigu Industrial Park, Yintian Road, Xixiang, Baoan, Shenzhen China". |
| 4. | Submit the specification and detailed analytical procedure of drug substance by drug product manufacturer. | Submitted |
| 5. | Provide analytical method validation report performed by drug product manufacturer. | Submitted |
| 6. | Provide batch analysis report of drug substance by the drug product manufacturer. | Submitted |
| 7. | Provide certificate of analysis of reference standard /working standard used for testing of the product. | Submitted |
| 8. | Submit stability data of drug substance performed both at accelerated and long term conditions till the claimed re-test period, since you have only submitted the data of 2 time points i.e. 1st and 3rd month. | Firm submitted the stability data of drug substance till the re-test period of 24 months. |
| 9. | Innovator product claimed that tablets are formulated to be dispersible, when dosing | Firm submitted SmPC of the applied product in which the tablet aqueous dispersion preparation |

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| | of whole tablets is not possible, tablets may be administered as an aqueous dispersion. Reference to the innovator claim, did the applied formulation also dispersed in the similar manner as of innovator product. Further, did you performed the study for Use of Tablet Dispersion and impact of dispersion preparation on physiochemical properties of the final dosage form were assessed while formulation development. | has been given. Further submit the tablet dispersion comparative study of applied product. |
| 10. | Conclusion of CDP report stated that test/applied formulation is the product of M/s. Beacon Pharmaceuticals, (Faridpur,sreepur,gazipur) Bangladesh, validation protocol claims that the Tasso tablet i.e. the applied product is of M/s. Julphar Bangladesh Ltd.(Gazipur,Sreepur) while the product license holder is M/s. Jenphar Bangladesh Ltd. (Vill-Faridpur, PS-Sreepur Dis-Gazipur).Clarification is required regarding the disparity observed related to the manufacturer of drug product in different section of CTD dossier, further, submitted the complete address of drug product manufacturer, since all three mentioned manufacturer have same address.<br><br>Firm replied that Manufacturer of the product is M/s. Jenphar Bangladesh Limited (Vill-Faridpur, PS-Sreepur Dis- Gazipur) a changed name from M/s. Julphar Bangladesh Ltd. With same address. Further applicant replied that Manufacturer has performed CDP of the applied product with innovator as well as local Me-Too available products in Bangladesh, if the conclusion of CDP report of other company is mistakenly attached then please ignore it. | |
| 11. | Justify the dissolution acceptance limit i.e. NLT 80% (Q) within 45 minutes adopted for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes. | Firm replied that in submitted CDP the dissolution profile showed the dissolution results greater than 93% of all three medias after 30 minutes which meets the acceptance criteria NLT 80%(Q), where manufacturer of the product decided the time of dissolution 45minutes where results are greater than 100%.<br><br>However, according to general chapter of USP <1092> "*During product development, the collection of complete dissolution profile data is recommended from biobatches and stability batches at specified intervals, such as 10, 15, 20, 30, 40, 50, and 60 min or 15, 20, 30, 45, and 60 min, because these data are used to establish the dissolution acceptance criterion/criteria. From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%. However, this time point should not be less than 15 min".* |
| 12. | Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard. | Firm submitted change of company name letter from Julphar to Jenphar in the reply of this query. |
| Decision of 336th meeting:<br>Deferred for submission/clarification of following: | | |

- Justify for adopting the dissolution acceptance limit NLT 80% (Q) within 45 minutes for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes, when the dissolution profile showed the dissolution results greater than 85% of all three medias within 30 minutes. Since USP general chapter <1092> recommends that "*From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%".*
- Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.

Response of the Firm:

- Justify for adopting the dissolution acceptance limit NLT 80% (Q) within 45 minutes for the applied product comparing the acceptance limit of innovator product i.e. NLT (Q) within 30minutes, when the dissolution profile showed the dissolution results greater than 85% of all three medias within 30 minutes. Since USP general chapter <1092> recommends that "*From the dissolution profile data, a Q value of 80% should be set at the first time point where the average dissolution is at least 85%".*

As per provided CDP the dissolution profile (limit NLT 80% (Q) within 30 minutes) complies the results, so Manufacturer of the product (Jenphar Bangladesh, Ltd) has adopted the dissolution limit NLT 80% (Q) within 30 minutes as per specification limit of Innovator's drug product.Updated Specifications, Method of Analysis and COA of the applied product is provided for you reference.

- Submitted analytical method validation report is of Osimertinib 80mg Tablet of M/s. Julphar Bangladesh Ltd. while the applied product is Tasso 80 mg Tablet of M/s. Jenphar Bangladesh Ltd., clarification is required in this regard.

Since at the stage of analytical method development and validation, the AMV of the product was performed by M/s. Julphar Bangladesh Ltd. with the product "Osimertinib 80mg Tablet. The product was applied for registration with Brand name "Tasso 80 mg Tablet by M/s. Julphar Bangladesh Ltd and later the product was placed on free sales and commercialization. After that stage & Registration of the Product Tasso 80 mg Tablet: the company name was changed from "M/s. Julphar Bangladesh Ltd." to "M/s Jenphar Bangladesh Ltd." So, Tasso 80 mg Tablet is registered brand of M/s. Jenphar Bangladesh Ltd.
(Company change name justification Vetter was provided earlier)

**Decision of 343rd meeting of Registration Board:** Deferred for confirmation of availability of separate oncology manufacturing facility at the manufacturing site of M/s. Jenphar Bangladesh Ltd. Plant address: Vill-Faridpur, PS-Sreepur Dis- Gazipur Bangladesh.

**Response of the Firm:**

Firm informed that the Oncology facility of the Manufacturer, Jenphar Bangladesh was inspected by DRAP, under virtual inspection program on Dated 10.11 2025 and same section product (Juparib Tablets 150mg) was approved, and registration Letter was issued on Dated: 24.11.2025 under Registration Number 128885.

**Decision: Approved subject to current import policy.**

# Drug Regulatory Authority of Pakistan

## (Pharmaceutical Evaluation & Registration Division)

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## Registration Board 360 Meeting Minutes:

| Sr. No | Title | Description |
|---|---|---|
| 1 | Case Category | New Section (Abdul Mughees) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GZS-QM9-LPV1, 2026-02-20) |
| | Detail of Fee Submitted | 38700,<br>2026-01-29, |
| | The proposed proprietary name / brand name | **Dasani 100mg Tablet** |
| | Label Claim | Each film coated tablet contains:<br>Dasatinib.....100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,20's-As per SRO,30's-As per SRO,60's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | Dasatinib 100mg Tablet |
| | Pharmacotherapeutic Group of (API) | Multikinase inhibitor (Anti cancer) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Accelerated Stability Study {0, 3, 6 months (completed)}, Long term / Real time stability study{0,3, 6) months (completed)} |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence and CDP has been provided, |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | The firm has withdrawn the instant application vide general request Tracking ID NE2-66J-LMNP. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as applciation withdrawn by the applicant | |
| 2 | Case Category | New Section (Abdul Mughees) |

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| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RYY-JE6-AG17, 2026-04-15) |
| | Detail of Fee Submitted | 38700,<br>2026-04-08, |
| | The proposed proprietary name / brand name | **Pomalid** |
| | Label Claim | Each capsule contains: Pomalidomide.....4mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100's-As per SRO,21's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C in a cool and dry place. Protect from heat & light. |
| | For generic drugs (me-too Status) | Product name: Pomyda 4.0mg Capsule Registration No: 128915 Company Name: Revive Health Care |
| | Pharmacotherapeutic Group of (API) | Immunomodulatory agent (IMiD) and a third-generation thalidomide analogue. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Provided Accelerated Stability Study {0, 3 months}, Long term / Real time stability study{0, 3 months } |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence and Comparative Dissolution Profile Provided |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | Product Name: POMALYST Manufacturer: Manufactured for; Celgene Corporation Summit, NJ 07901 Reference Regulatory Authority: FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | Provided |
| | **Evaluation Remarks** | |
| | The firm has withdrawn the instant application vide general request Tracking ID NE2-66J-LMNP. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as applciation withdrawn by the applicant | |
| 3 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000900)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B5P-LA9-ZWNQ, 2024-07-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-05, |
| | The proposed proprietary name / brand name | **Empathan 10mg Tablet** |
| | Label Claim | Each film coated tablet contains: Empagliflozin.....10mg |

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| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14's, 28's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Empozin 10mg Tablet by M/s Macter International |
| | Pharmacotherapeutic Group of (API) | A10BK03; Sodium-glucose co-transporter 2 (SGLT2) inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of 3 batches (1500 tablets each) at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Jardiance |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches (20190101 , 20190102, 20190102) at long term and accelerated conditions |
| | The status in reference regulatory authorities | Jardiance Tablet 10mg by M/s Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA. |
| | GMP status of the firm | GMP report dated 03.04.2023 with satisfactory GMP |
| | Evidence of approval of manufacturing facility | DML dated 05.03.2019; Renewal |
| | **Evaluation Remarks** | |
| | 1. 21 CFR complaince status 2. Justification of difference in manufacturing approach viz-a-viz innovator as per DRAP guidelines 3. Stability chromatogram EMP TabSTBT003A/CDissS6 Date Acquired: 3/16/2024 12:54:10 PMPKT (page 567 of module 3) is not visible in the submitted audit trail. Please procide evidence audit trail, 21 CFR complaint certificate. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected on the following grounds:-<br><br>1. The firm has not submitted evidence for 21 CFR compliance.<br><br>2. Stability chromatogram EMP TabSTBT003A/CDissS6 Date Acquired: 3/16/2024 12:54:10 PMPKT (page 567 of module 3) is not found in the submitted audit trail. | |
| 4 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000900)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GHZ-4TA-M74E, 2024-08-21) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-05, |
| | The proposed proprietary name / brand name | **Empathan 25mg Tablet** |
| | Label Claim | Each film coated tablet contains:<br>Empagliflozin.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 28's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C |

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| | For generic drugs (me-too Status) | Empozin 25mg Tablet by M/s Macter International |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | Jardiance Tablet 25mg by M/s Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA. |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | evidence for 21 CFR compliance. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as the firm has not submitted evidence for 21 CFR complaince | |
| 5 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HTH-ZHP-J4VA, 2024-08-20) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-11, |
| | The proposed proprietary name / brand name | **Linaglo 10mg/5mg Tablets** |
| | Label Claim | Each film coated tablet containsEmpagliflozin....10mgLinagliptin..... 5mgInnovators Specs. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14s Tablets -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package. |
| | For generic drugs (me-too Status) | Glyxambi 10mg and 5mg Tablet |
| | Pharmacotherapeutic Group of (API) | Antidiabetic: SGLT2 inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical Co Ltd ,Fuxin Long Rui Pharmaceutical Co. Ltd |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 for Linagliptin DIL for empagliflozin |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |

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|---|---|---|
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Food and Drug Regulatory Authority USA |
| | GMP status of the firm | GMP dated 21 October 2022 |
| | Evidence of approval of manufacturing facility | DML dated 19.09.2021 |
| | **Evaluation Remarks** | |
| | The procurement documents have been submitted in therelevant section for your kind review.It is further clarified that the trial batches of Linaglo weremanufactured using Empagliflozin imported for commercialbatches (Batch No L-CP042220601). In this regard, the relevantsupporting procurement documents have been attached for yourreference.This is further submitted that prior to the implementation of theonline Import/Export System, import consignments wereroutinely cleared on the basis of the approved Drug ImportLicense (DIL) and Commercial Invoice under the prevailingmanual process.During September-October 2022, the manual Import/ExportSystem was transitioned to the online portal (ie.dra.gov.pk).Following this transition, we applied for and obtained the DrugImport License (DIL) through the online system upon the arrivalof the shipment and submitted the same to the Customsauthorities.At that time, Customs authorities did not require a ClearanceCertificate for the release of imported consignments and wereclearing shipments on the basis of the approved DIL.Consequently, no Clearance Certificate was applied for. Werespectfully submit that this omission was neither deliberate norintended to circumvent any regulatory requirement, butoccurred due to the transition from the manual system to thenewly implemented online process and the prevailing clearancepractices adopted by the Customs authorities at that time. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of Invoice, goods declaration and airway bills. | |
| 6 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VW7-EZY-YAYN, 2024-07-31) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-22, |
| | The proposed proprietary name / brand name | **WENSITA XR 100/1000mg TABLET** |
| | Label Claim | Each Extended Release Tablet Contains: Metformin Hydrochloride (USP) as Extended-Release Core Tablet .....1000mg Sitagliptin as Phosphate Monohydrate (USP) as Immediate Release Coated Layer.....100mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | SITAGLU-MET XR TABLET 100/1000mg TABLET by HILTON PHARMA |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearnace for Metformin; Local procurement of Sitagliptin from Sakh Pharma |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA approved |
| | GMP status of the firm | GMP certificate dated 21.07.2022 |
| | Evidence of approval of manufacturing facility | DML No. 000790 dated 03.02.2019; renewal of DML acknowledgement dated 28.12.2023 |
| | **Evaluation Remarks** | |
| | Manufacturing method employed was different from the manufacturing method of the innovator. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for following innovator's method of manufacturing | |
| 7 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PEE-J6S-3ASY, 2024-07-31) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-22, |
| | The proposed proprietary name / brand name | **WENSITA XR 50/1000mg TABLET** |
| | Label Claim | Each Film Coated Extended Release Tablet Contains: Metformin Hydrochloride (USP) as Extended-Release Core Tablet .....1000mg Sitagliptinas Phosphate Monohydrate (USP) as Immediate Release Coated Layer...50mg (Product complies Innovator’s Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | SITAGLU-MET XR TABLET 50/1000mg TABLET by HILTON PHARMA |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearnace for Metformin; Local procurement of Sitagliptin from Sakh Pharma |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA approved |
| | GMP status of the firm | GMP certificate dated 21.07.2022 |
| | Evidence of approval of manufacturing facility | DML No. 000790 dated 03.02.2019; renewal of DML acknowledgement dated 28.12.2023 |
| | **Evaluation Remarks** | |
| | Manufacturing method employed was different from the innovator. | |

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| | **Decision** | |
| | **Deferred**<br><br>Deferred for following innovator's method of manufacturing | |
| 8 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)** |
| | Application Form Dy. No / Tracking ID & date of submission | (67L-S2E-T22E, 2024-10-21) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-09-01, 2024-10-21 |
| | The proposed proprietary name / brand name | **WENSITA XR 50/500mg TABLET** |
| | Label Claim | Each Film Coated Extended Release Tablet Contains: Metformin Hydrochloride (USP) as Extended-Release Core Tablet .....500mg Sitagliptinas Phosphate Monohydrate (USP) as Immediate Release Coated Layer.....50mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | SITAGLU-MET XR TABLET 50/500mg TABLET by Hilton Pharma |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearnace for Metformin; Local procurement of Sitagliptin from Sakh Pharma |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA approved |
| | GMP status of the firm | GMP certificate dated 21.07.2022 |
| | Evidence of approval of manufacturing facility | DML No. 000790 dated 03.02.2019; renewal of DML acknowledgement dated 28.12.2023 |
| | **Evaluation Remarks** | |
| | Manufacturing method employed is different from the innovator. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for following innovator's method of manufacturing | |
| 9 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q1A-BR9-S3BZ, 2024-10-29) |

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| | Detail of Fee Submitted | 75000.0,<br>2023-10-25, |
| | The proposed proprietary name / brand name | **EMPEG-ML 10mg + 5mg + 1000mg XR TABLET** |
| | Label Claim | Each Film Coated Extended Release Tablet contains: Empagliflozin.....10MG Linagliptin.....5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)storage below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API on loan from Weatherfolds. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Latest GMP required |
| | Evidence of approval of manufacturing facility | DML No 000882 dated 11.04.2018; Renewal submitted on 28.03.2023 |
| | **Evaluation Remarks** | |
| | Manufacturing method employed was different from innovator. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for following innovator's method of manufacturing | |
| 10 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EDD-36V-BYMY, 2024-10-29) |
| | Detail of Fee Submitted | 75000.0,<br>2023-10-25, |
| | The proposed proprietary name / brand name | **EMPEG-ML 12.5mg + 2.5mg + 1000mg XR TABLET** |
| | Label Claim | Each Film Coated Extended Release Tablet contains: Empagliflozin.....12.5MG Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |

| | | |
|---|---|---|
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)storage below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Weatherfolds. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Latest GMP required |
| | Evidence of approval of manufacturing facility | DML No 000882 dated 11.04.2018; Renewal submitted on 28.03.2023 |
| | **Evaluation Remarks** | |
| | Manufacutring method employed is different from innovator. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for following innovator's method of manufacturing | |
| 11 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GNA-RBW-VWS2, 2024-10-29) |
| | Detail of Fee Submitted | 75000.0,<br>2023-10-25, |
| | The proposed proprietary name / brand name | **EMPEG-ML 25mg + 5mg + 1000mg XR TABLET** |
| | Label Claim | Each Film Coated Extended Release Tablet contains: Empagliflozin.....25MG Linagliptin.....5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator’s Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)storage below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Weatherfolds. |

| | | |
|---|---|---|
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Latest GMP required |
| | Evidence of approval of manufacturing facility | DML No 000882 dated 11.04.2018; Renewal submitted on 28.03.2023 |
| | **Evaluation Remarks** | |
| | Manufacturing method employed is different from the innovator. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for following innovator's method of manufacturing | |
| 12 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JSM-BRT-VA6W, 2024-10-29) |
| | Detail of Fee Submitted | 75000.0,<br>2023-10-25, |
| | The proposed proprietary name / brand name | **EMPEG-ML 5mg + 2.5mg + 1000mg XR TABLET** |
| | Label Claim | Each Film Coated Extended Release Tablet contains: Empagliflozin.....5MG Linagliptin.....2.5MG (As immediate release core) Metformin Hydrochloride*.....1000MG (As extended release core) (Product Complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)storage below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API on loan from Weatherfolds. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Latest GMP required |
| | Evidence of approval of manufacturing facility | DML No 000882 dated 11.04.2018; Renewal submitted on 28.03.2023 |
| | **Evaluation Remarks** | |
| | Manufacturing method employed was different from the innovator. | |
| | **Decision** | |

| | | |
|---|---|---|
| | **Deferred**<br><br>Deferred for following innovator's method of manufacturing | |
| 13 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HVG-5PB-Y8RE, 2024-08-21) |
| | Detail of Fee Submitted | 30000.0,<br>2024-01-15, |
| | The proposed proprietary name / brand name | **Empa 10mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains:Empagliflozin ..... 10 mg(Manufacturer’s Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 14's-As per SRO,20's-As per SRO,28's-As per SRO,7’s-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Do not store above 30°C. |
| | For generic drugs (me-too Status) | Diampa Getz |
| | Pharmacotherapeutic Group of (API) | Antidiabateic; SGLT 2 inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zhejiang Huahai Pharmaceutical Co., Ltd. (Chuannan Site) |
| | Detail of stability batches of drug product | Three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate No. K-1209024285463 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | UKMHRA (Jardiance 10mg Tablet) |
| | GMP status of the firm | GMP certificate 26.09.2025 |
| | Evidence of approval of manufacturing facility | DML no 000616 dated 12.4.2022; Evidence for renewal required |
| | **Evaluation Remarks** | |
| | Correction in the name of Dissolution Apparatus in the testing method and fee for revision of specification. | |
| | **Decision** | |
| | **Approved**<br><br>Subject to revision of specifications and submission of applicable fee | |
| 14 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UEN-HG8-LQT1, 2024-08-21) |
| | Detail of Fee Submitted | 30000.0,<br>2024-01-15, |
| | The proposed proprietary name / brand name | **Empa 25mg Tablet** |

| | | |
|---|---|---|
| | Label Claim | Each Film Coated Tablet Contains:Empagliflozin ..... 25 mg(Manufacturer's Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 14's-As per SRO,20's-As per SRO,28's-As per SRO,7's-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Do not store above 30°C. |
| | For generic drugs (me-too Status) | Diampa Getz |
| | Pharmacotherapeutic Group of (API) | Antidiabateic; SGLT 2 inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zhejiang Huahai Pharmaceutical Co., Ltd. (Chuannan Site) |
| | Detail of stability batches of drug product | Three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate No. K-1209024285463 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | UKMHRA (Jardiance 25mg Tablet) |
| | GMP status of the firm | GMP certificate 26.09.2025 |
| | Evidence of approval of manufacturing facility | DML no 000616 dated 12.4.2022; Evidence for renewal required |
| | **Evaluation Remarks** | |
| | Change of name of dissolution apparatus in testing method and fee for revision of specifications | |
| | **Decision** | |
| | **Approved**<br><br>Subject to revision of testing method and submission of fee for revision of specifications | |
| 15 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GR8-HVV-QVMU, 2024-08-27) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-29, |
| | The proposed proprietary name / brand name | **EMPA-MET 12.5mg/1000mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains:Empagliflozin ..... 12.5mg Metformin HCL 1000 mg(Manufacturer's Specifications) |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 14's-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Do not store above 30°C. |
| | For generic drugs (me-too Status) | Xenglu-met (093068) |
| | Pharmacotherapeutic Group of (API) | Antidiabateic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Ipca Laboratories Limited,ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. |
| | Detail of stability batches of drug product | Three batches at long-term and accelerated conditions |

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| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | US FDA & UKMHRA (Segluroet 12.5/1000mg Tablet) |
| | GMP status of the firm | DML no 000616 dated 12.4.2022; Evidence for renewal required |
| | Evidence of approval of manufacturing facility | DML no 000616 dated 12.4.2022; Evidence for renewal required |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 16 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Linta Pharmaceuticals Private Limited** Plot No. 3, Street No. S-5, National Industrial Zone, Rawat. Islamabad. **(000810)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VSB-AHJ-8V7G, 2024-08-28) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-23, |
| | The proposed proprietary name / brand name | **Glifzon 25mg** |
| | Label Claim | Each film coated tablet contains Empagliflozin 25mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)room temperature |
| | For generic drugs (me-too Status) | Diampa 25mg tablet Getz |
| | Pharmacotherapeutic Group of (API) | Antidiabetic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Anhui Youcare Kaiyue Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Seraph Pharma |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed against Diampa 25 mg tablet Batch # 079FB6 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Jardianc 25 mg tablet Country where sold / registered; Germany Manufactured by: Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173 55216 Ingelheim am Rhein Germany |
| | GMP status of the firm | GMP certificate dated 13.03.2024 |
| | Evidence of approval of manufacturing facility | DML No 000810 dated 02.04.2020 |
| | **Evaluation Remarks** | |

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| | API loan intimation | |
| | **Decision** | |
| | **Approved**<br><br>Subject to verification of API loan | |
| 17 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8NX-VM9-H5RA, 2024-08-28) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-20, |
| | The proposed proprietary name / brand name | **EMPAC-M 12.5mg/500mg** |
| | Label Claim | Each film coated tablet contains:<br>Empagliflozin.....12.5mg Metformin HCl.....500mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2 x 7 's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 °C |
| | For generic drugs (me-too Status) | Diampa-M 12.5mg/500mg Tablet(Getz Pharma) |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Aarti Drugs limited ,Fuxin Long Rui Pharmaceutical. Co.,Ltd. |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificates provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed against Xenglu Met 12.5/500mg tablets B# 150299 manufactured by Hilton Pharma, Karachi |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Synjardy 12.5mg/500mg Tablet (Boehringer Ingelheim Germany) |
| | GMP status of the firm | GMP required |
| | Evidence of approval of manufacturing facility | DML no 000643 dated 24.12.2023 |
| | **Evaluation Remarks** | |
| | GMP required | |
| | **Decision** | |
| | **Approved**<br><br>Subject to submission of latest GMP certificate/ report of the applicant | |
| 18 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)** |
| | Application Form Dy. No / Tracking ID & date of submission | (195-AHX-J16R, 2024-08-29) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-29, |

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| | The proposed proprietary name / brand name | **EMPA-MET 12.5mg/500mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains:Empagliflozin MS*..... 12.5 mg Metformin HCL B.P ..... 500 mg(Manufacturer's Specifications) |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 14's-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Do not store above 30°C. |
| | For generic drugs (me-too Status) | Xenglu-met |
| | Pharmacotherapeutic Group of (API) | Antidiabateic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Ipca Laboratories Limited,ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. |
| | Detail of stability batches of drug product | Three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA & UKMHRA |
| | GMP status of the firm | DML no 000616 dated 12.4.2022; Evidence for renewal required |
| | Evidence of approval of manufacturing facility | DML no 000616 dated 12.4.2022; Evidence for renewal required |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 19 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Pinnacle Biotech (Pvt.) Ltd.** FD-49-A8, FD-50-A8, FD-51-A8, Korangi Creek Industrial Park, Karachi. **(000939)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9G8-5DJ-JJDY, 2024-09-25) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-27, 2024-09-11 |
| | The proposed proprietary name / brand name | **Linaglo 25mg/5mg Tablets** |
| | Label Claim | Each film coated tablet containsEmpagliflozin....25mgLinagliptin..... 5mgInnovators Specs |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14s Tablets -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Shelf life only applies under appropriate conditions of storage specified on package. |
| | For generic drugs (me-too Status) | Glyxambi 25mg and 5mg Tablet |
| | Pharmacotherapeutic Group of (API) | Antidiabetic: SGLT2 inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical Co. Ltd |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |

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| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 for Linagliptin DIL for empagliflozin |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Food and Drug Regulatory Authority USA |
| | GMP status of the firm | GMP dated 21 October 2022 |
| | Evidence of approval of manufacturing facility | DML dated 19.09.2021 |
| | **Evaluation Remarks** | |
| | The procurement documents have been submitted in the relevant section for your kind review.nIt is further clarified that the trial batches of Linaglo weremanufactured using Empagliflozin imported for commercial batches (Batch No L-CP042220601). In this regard, the relevant supporting procurement documents have been attached for your reference. This is further submitted that prior to the implementation of the online Import/Export System, import consignments were routinely cleared on the basis of the approved Drug ImportLicense (DIL) and Commercial Invoice under the prevailing manual process.During September-October 2022, the manual Import/Export System was transitioned to the online portal (ie.dra.gov.pk). Following this transition, we applied for and obtained the Drug Import License (DIL) through the online system upon the arrival of the shipment and submitted the same to the Customs authorities. At that time, Customs authorities did not require a Clearance Certificate for the release of imported consignments and were clearing shipments on the basis of the approved DIL. Consequently, no Clearance Certificate was applied for. We respectfully submit that this omission was neither deliberate nor intended to circumvent any regulatory requirement, but occurred due to the transition from the manual system to the newly implemented online process and the prevailing clearance practices adopted by the Customs authorities at that time. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for invoice, Goods Declaration and airway bill. | |
| 20 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HTV-MEJ-8M3A, 2024-10-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-18, |
| | The proposed proprietary name / brand name | **Triglu-XR 10/5/1000mg Tablet** |
| | Label Claim | Each Film-coated extended-release Tablet Contains: Empagliflozin.....10mg Linagliptin.....5mg (as immediate release coating) Metformin HCl.....1000mg (as extended-release core) (As per Innovator's specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store below 30°C in Cool & Dry Place. |
| | For generic drugs (me-too Status) | Emplimet XR 10/5/1000mg Tablet |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |

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| | Name & address of API manufacturer | AARTI DRUGS LIMITED,BAKUL PHARMA PRIVATE LIMITED,ZHEJIANG HUAYI PHARMACEUTICAL CO., LTD. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Horizin Healthcare, Lahore. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed against Trijardy XR 10/5/1000 mg by Boheringer Ingelheim Batch / Lot # 3285684 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Registered drug by US FDA as TRIJARDY (Empagliflozin/Linagliptin/Metformin HCL 10/5/1000mg Tablets),for ORAL Use. |
| | GMP status of the firm | GMP certificate dated 25.05.2021 |
| | Evidence of approval of manufacturing facility | DML No 000427 dated 01.04.2016 with evidence of renewal dated 18.03.2021 |
| | **Evaluation Remarks** | |
| | API on loan fromHorizin Healthcare, Lahore. | |
| | **Decision** | |
| | **Approved**<br><br>Subject to verification of API loan | |
| 21 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9SV-9VA-JNXT, 2024-10-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-18, |
| | The proposed proprietary name / brand name | **Triglu-XR 12.5/2.5/1000mg Tablet** |
| | Label Claim | Each Film-coated extended-release Tablet Contains: Empagliflozin.....12.5mg Linagliptin.....2.5mg (as immediate release coating) Metformin HCl.....1000mg (as extended release coating) (As per Innovator's specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30°C in Cool & Dry Place. |
| | For generic drugs (me-too Status) | Emplimet XR 12.5/2.5/1000mg Tablet |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | AARTI DRUGS LIMITED,BAKUL PHARMA PRIVATE LIMITED,ZHEJIANG HUAYI PHARMACEUTICAL CO., LTD. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Horizin Healthcare, Lahore. |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed against Trijardy XR 12.5/2.5/1000 mg by Boheringer Ingelheim Batch / Lot # 3285681 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Registered drug by US FDA as TRIJARDY (Empagliflozin/Linagliptin/Metformin HCL 12.5/2.5/1000mg Tablets),for ORAL Use. |
| | GMP status of the firm | GMP certificate dated 25.05.2021 |
| | Evidence of approval of manufacturing facility | DML No 000427 dated 01.04.2016 with evidence of renewal dated 18.03.2021 |
| | **Evaluation Remarks** | |
| | API on loan from Horizon Healthcare, Lahore. | |
| | **Decision** | |
| | **Approved**<br><br>Subject to verification of API loan | |
| 22 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2TB-ZAY-8Q24, 2024-10-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-18, |
| | The proposed proprietary name / brand name | **Triglu-XR 25/5/1000mg tablet** |
| | Label Claim | Each Film-coated extended-release Tablet Contains: Empagliflozin.....25mg Linagliptin.....5mg (As immediate release coating) Metformin HCl.....1000mg (as extended-release core) (As per Innovator's specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30°C in Cool & Dry Place. |
| | For generic drugs (me-too Status) | Emplimet XR 25/5/1000mg Tablet |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | AARTI DRUGS LIMITED,BAKUL PHARMA PRIVATE LIMITED,ZHEJIANG HUAYI PHARMACEUTICAL CO., LTD. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API on loan from Horizon Healthcare, Lahore. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed against Trijardy XR 25/5/1000 mg by Boheringer Ingelheim Batch / Lot # 3287302 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Registered drug by US FDA as TRIJARDY (Empagliflozin/Linagliptin/Metformin HCL 25/5/1000mg Tablets),for ORAL Use. |
| | GMP status of the firm | GMP certificate dated 25.05.2021 |

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| | Evidence of approval of manufacturing facility | DML No 000427 dated 01.04.2016 with evidence of renewal dated 18.03.2021 |
| | **Evaluation Remarks** | |
| | API on loan from Horizon Healthcare, Lahore. | |
| | **Decision** | |
| | **Approved**<br><br>Subject to verification of API loan | |
| 23 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1U5-JXL-Q1X1, 2024-10-09) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-20, |
| | The proposed proprietary name / brand name | **Empac - M 12.5mg+1000mg Tablet** |
| | Label Claim | Each film coated Tablet contains:<br>Empagliflozin.....12.5mg<br>Metformin.....1000mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2 x 7 's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 °C |
| | For generic drugs (me-too Status) | Diampa-M 12.5mg/1000mg Tablet(Getz Pharma) |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Aarti Drugs Limited ,Fuxin Long Rui Pharmaceutical. Co.,Ltd. |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificates provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Synjardy 12.5mg/1000mg Tablet (Boehringer Ingelheim Germany) |
| | GMP status of the firm | GMP required |
| | Evidence of approval of manufacturing facility | DML no 000643 dated 24.12.2023 |
| | **Evaluation Remarks** | |
| | GMP required | |
| | **Decision** | |
| | **Approved**<br><br>Subject to provision of latest GMP certificate/ report of the applicant | |
| 24 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (2ZG-BP1-2V86, 2024-10-10) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-09, |
| | The proposed proprietary name / brand name | **OMERGO 25mg TABLET** |
| | Label Claim | Each Film Coated Tablet contains:<br>Omarigliptin.....25mg (Product Complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | Omaril Tablet by Genix Pharma |
| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at lonf-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API on loan from Weather Folds Pharmaceuticals, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at lonf-term and accelerated conditions |
| | The status in reference regulatory authorities | PMDA approved |
| | GMP status of the firm | DML No 000790; renewal acknowledgement dated 28.12.2023 |
| | Evidence of approval of manufacturing facility | DML No 000790; renewal acknowledgement dated 28.12.2023 |
| | **Evaluation Remarks** | |
| | GMP required | |
| | **Decision** | |
| | **Approved**<br><br>Subject to provision of latest GMP certificate/ report of the applicant | |
| 25 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L5X-LN6-6JU5, 2024-10-10) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-09, |
| | The proposed proprietary name / brand name | **OMERGO 12.5mg TABLET** |
| | Label Claim | Each Film Coated Tablet contains:<br>Omarigliptin.....12.5mg (Product Complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | Omaril Tablet by Genix Pharma |

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| | Pharmacotherapeutic Group of (API) | Antidiabetics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at lonf-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Weather Folds Pharmaceuticals, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at lonf-term and accelerated conditions |
| | The status in reference regulatory authorities | PMDA approved |
| | GMP status of the firm | DML No 000790; renewal acknowledgement dated 28.12.2023 |
| | Evidence of approval of manufacturing facility | DML No 000790; renewal acknowledgement dated 28.12.2023 |
| | **Evaluation Remarks** | |
| | GMP required | |
| | **Decision** | |
| | **Approved**<br><br>Subject to provision of latest GMP certificate/ report of the applicant | |
| 26 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QLZ-B77-97G3, 2024-10-21) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-30, |
| | The proposed proprietary name / brand name | **Empine M 5/500mg Tablets** |
| | Label Claim | Each film coated tablet contains:<br>Empagliflozin/Metformin HCl .....5/500mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)below 30 º C |
| | For generic drugs (me-too Status) | Diampa-M 5/500mg tablet, Getz Pharma, Pakistan |
| | Pharmacotherapeutic Group of (API) | Antidiabetic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | AARTI DRUGS LIMITED Mahendra Industrial Estate Plot No. – 109 –D Road No.29, Sion (East), Mumbai – 400 022. INDIA.,Anhui Youcare Kaiyue Pharmaceutical Co., Ltd. Industrial Avenue area A, Economic Development Zone, Taihe County, Anhui Province, China |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Seraph Pharmaceuticals. |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Empagliflozin/Metformin HCl 5/500mg filmcoated tablets,USFDA Approved |
| | GMP status of the firm | DML NO. 000955 dated 28.4.2022 |
| | Evidence of approval of manufacturing facility | DML NO. 000955 dated 28.4.2022 |
| | **Evaluation Remarks** | |
| | API on loan from Seraph Pharmaceuticals Latest GMP report | |
| | **Decision** | |
| | **Approved**<br><br>Subject to provision of latest GMP of the applicant and verification of API loan | |
| 27 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZVX-768-WTD2, 2024-10-21) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-30, |
| | The proposed proprietary name / brand name | **Empine M 12.5/500mg Tablets** |
| | Label Claim | Each film coated tablet contains:<br>Empagliflozin/Metformin HCl .....12.5/500mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)below 30 º C |
| | For generic drugs (me-too Status) | Diampa-M 12.5/500mg tablet, Getz Pharma, Pakistan |
| | Pharmacotherapeutic Group of (API) | Antidiabetic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | AARTI DRUGS LIMITED Mahendra Industrial Estate Plot No. – 109 –D Road No.29, Sion (East), Mumbai – 400 022. INDIA.,Anhui Youcare Kaiyue Pharmaceutical Co., Ltd. Industrial Avenue area A, Economic Development Zone, Taihe County, Anhui Province, China |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API on loan from Seraph Pharmaceuticals. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Empagliflozin/Metformin HCl 12.5/500mg film-coated tablets,USFDA Approved. |
| | GMP status of the firm | GMP report dated 18.11.2025 |
| | Evidence of approval of manufacturing facility | DML NO. 000955 dated 28.4.2022 |
| | **Evaluation Remarks** | |
| | API on loan from Seraph Pharmaceuticals. | |

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| | **Decision** | |
| | **Approved**<br><br>Subject to verificaiton of API loan | |
| 28 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WH3-7E9-3UD1, 2024-10-21) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-30, |
| | The proposed proprietary name / brand name | **Empine M 12.5/1000mg Tablets** |
| | Label Claim | Each film coated tablet contains:<br>Empagliflozin/Metformin HCl .....12.5/1000mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)below 30 º C |
| | For generic drugs (me-too Status) | Diampa-M 12.5/1000mg tablet, Getz Pharma, Pakistan |
| | Pharmacotherapeutic Group of (API) | Antidiabetic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | AARTI DRUGS LIMITED Mahendra Industrial Estate Plot No. – 109 –D Road No.29, Sion (East), Mumbai – 400 022. INDIA.,Anhui Youcare Kaiyue Pharmaceutical Co., Ltd. Industrial Avenue area A, Economic Development Zone, Taihe County, Anhui Province, China |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API on loan from Seraph Pharmaceuticals. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Empagliflozin/Metformin HCl 12.5/1000mg film-coated tablets,USFDA Approved. |
| | GMP status of the firm | DML NO. 000955 dated 28.4.2022 |
| | Evidence of approval of manufacturing facility | DML NO. 000955 dated 28.4.2022 |
| | **Evaluation Remarks** | |
| | API on loan from Seraph Pharmaceuticals. | |
| | **Decision** | |
| | **Approved**<br><br>Subject to verificaiton of API loan | |
| 29 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Pharmedic Laboratories (Pvt.) Ltd Lahore** 16-Km Multan Road, Lahore **(000228)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7Q9-Z58-6GGY, 2024-10-30) |

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| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-05-20, 2024-10-14 |
| | The proposed proprietary name / brand name | **Artu-S Tablet** |
| | Label Claim | Each film coated tablet contains: 6.48mg ertugliflozin (as ertugliflozin L-Pyroglutamic acid) equivalent to 5mg Ertugliflozin 128.5mg of Sitagliptin phosphate (equivalent to 100mg of Sitagliptin) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | A blister pack of 1 -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 30 C, store in the original package in order to protect from moisture. |
| | For generic drugs (me-too Status) | Trevia R2 |
| | Pharmacotherapeutic Group of (API) | Anti-diabetic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zhejiang Hongyuan Pharmaceutical Co., Ltd.,Zhejiang Tianyu Pharmaceutical Co; Ltd |
| | Detail of stability batches of drug product | Three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Steglujan tablets Merck & Co., Inc. USA https://www.accessdata.fda.gov/drugsatfda_docs/l |
| | GMP status of the firm | GMP certificate dated 05.07.2025 |
| | Evidence of approval of manufacturing facility | DML 000228 |
| | **Evaluation Remarks** | |
| | Submitted | |
| | **Decision** | |
| | **Approved** | |
| 30 | Case Category | Routine (Abdul Mughees) |
| | Name, address of Applicant. | **Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YLV-8L8-ZBPD, 2024-12-20) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-07-11, 2024-11-27 |
| | The proposed proprietary name / brand name | **Tenergy Tablet 20mg** |
| | Label Claim | Each film coated tablet contains: Teneligliptin (as hydrobromide hydrate)..... 20mg (Innovator’s Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,7's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30 °C |

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| | For generic drugs (me-too Status) | Tenliptin Tablet 20mg, Manufactured by: Indus Pharma (Pvt) Ltd. |
| | Pharmacotherapeutic Group of (API) | ATC A10BH08; Dipeptidyl peptidase 4 (DPP-4) inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Source of Drug Substance: Glenmark Life Sciences Limited. Address: Plot No. 141-143/160-165/170-172, Chandramouli Sahakari Audhogik Vasahat Maryadit, Pune-Hyderabad Highway, Mohol, Dist. Solapur, 413213, Maharashtra, India. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate E-592080430 dated 14.06.2023 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | TENELIA Tablet 20mg, Registered in Pharmaceuticals and Medical Devices Agency (PMDA) |
| | GMP status of the firm | DML renewal report dated 22.02.2024 |
| | Evidence of approval of manufacturing facility | DML No. 000498 dated 22.06.2022 |
| | **Evaluation Remarks** | |
| | The application fulfills codal formalities and is submitted for consideration of the Board. | |
| | **Decision** | |
| | **Approved** | |
| 31 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan **(000061)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8HS-2UM-EDYW, 2025-02-13) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-16, |
| | The proposed proprietary name / brand name | **Empaflo-LT 10mg/5mg Tablet** |
| | Label Claim | Each film-coated tablet contains:<br>Empagliflozin.....10mg<br>Linagliptin.....5 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14’s-As per SRO,28's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Xenglu-Lin 10 mg/5mg Tablets (Hilton Pharma) |
| | Pharmacotherapeutic Group of (API) | Anti-Diabetic; SGLT 2 Inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical Co., Ltd Holder address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000,Ruyuan HEC Pharm Co,. Ltd., Xiaba |

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|---|---|---|
| | | Development Zone, Shaoguan City, Guangdong Province |
| | Detail of stability batches of drug product | Data of three batches on long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Empagliflozin: Clearance certificate No. E-2380354308341 Linagliptin: Clearance Certificate No. E-5420854305839 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches on long-term and accelerated conditions |
| | The status in reference regulatory authorities | Glyxambi 10 mg/5 mg film-coated tablets (USFDA) |
| | GMP status of the firm | GMP dated 03.10.2023 |
| | Evidence of approval of manufacturing facility | Renewal of DML No. 000061 dated 19.06.2023 having Tablet Section (General) |
| | **Evaluation Remarks** | |
| | Under exports facilitation. | |
| | **Decision** | |
| | **Approved** | |
| 32 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan **(000061)** |
| | Application Form Dy. No / Tracking ID & date of submission | (X1M-YW4-WJZT, 2025-02-13) |
| | Detail of Fee Submitted | 37000.0, 2024-10-16, |
| | The proposed proprietary name / brand name | **Empaflo-LT 25mg/5mg Tablet** |
| | Label Claim | Each film-coated tablet contains: Empagliflozin ..... 25 mg Linagliptin ..... 5 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14'S-As per SRO,28'S-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Xenglu-Lin 25 mg/5mg Tablets (Hilton Pharma) |
| | Pharmacotherapeutic Group of (API) | Anti-Diabetic; SGLT 2 Inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical Co., Ltd Holder address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000, China,Ruyuan HEC Pharm Co,. Ltd.,Xiaba Development Zone, Shaoguan City, Guangdong Province |
| | Detail of stability batches of drug product | Data of three batches on long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Empagliflozin: Clearance certificate No. E-2380354308341 Linagliptin: Clearance Certificate No. E-5420854305839 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches on long-term and accelerated conditions |

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| | The status in reference regulatory authorities | Glyxambi 25 mg/5 mg film-coated tablets (USFDA) |
| | GMP status of the firm | GMP dated 03.10.2023 |
| | Evidence of approval of manufacturing facility | Renewal of DML No. 000061 dated 19.06.2023 having Tablet Section (General) |
| | **Evaluation Remarks** | |
| | Under exports facilitation. | |
| | **Decision** | |
| | **Approved** | |
| 33 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan **(000061)** |
| | Application Form Dy. No / Tracking ID & date of submission | (P5Q-NHV-HXRQ, 2025-03-04) |
| | Detail of Fee Submitted | 75000.0,<br>2024-04-09, |
| | The proposed proprietary name / brand name | **Mommy Mix-it Powder** |
| | Label Claim | Each 1 gm sachet contains Vitamin A as Vitamin A palmitate 400 mcg RAE Vitamin E 50% as Alpha-tocopheryl acetate 5 mg Vitamin D3 as Cholecalciferol 200 I.U. 5 mcg Vitamin B1 as Thiamine mononitrate 0.5 mg Vitamin B2 as Riboflavin sodium phosphate 0.5 mg Vitamin B3 as nicotinamide 6 mg Vitamin B6 as Pyridoxine HCl 0.5 mg Vitamin B12 as Cyanocobalamin 0.9 mcg Vitamin B9 as Folic acid 90 mcg Vitamin C as Sodium ascorbate 30 mg Iron as Ferrous fumarate microencapsulated 10 mg Zinc as Zinc sulfat |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | Each unit carton con-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Do not store above 30 °C. |
| | For generic drugs (me-too Status) | Not applicable |
| | Pharmacotherapeutic Group of (API) | Multivitamins and Minerals |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Heilongjiang NHU Biotechnology Co Ltd No 2 Haotian Road Economic and Technological Development Zone Suihua Heilongjiang China,Dr. Paul Lohmann GmbH & Co KGAA Hauptstrasse 2 D 31860 Emmerthal Germany,Fermenta Biotech Limited Fermenta biotech limited Z109 B&C SEZ II Dahej Taluka Vagara Dist Bharuch 392130 Gujarat India,Hubei Guangji Pharmaceutical Co Ltd The New and High Industrial Park Wuxue City Hubei Province China,Jiangxi Tianxin Pharmaceutical Co Ltd Leanjiang Industrial Zone Leping Jiangxi China 333300 China,Ningxia Kingvit Pharmaceutical Co Ltd The New Chemical Materials Park Zone B of Ningdong Chemical and Energy Industrial Base Ningxia China,Sigma Aldrich Riedstrabe 2 89555 Steinheim am Albuch Germany,Western |

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| | | Drugs Limited F 271 A Mewar Industrial Area Madri Udaipur 313003 Rajasthan India,Xinchang NHU Vitamins Company Ltd High-tech industry zone Meizhu Xinchang county Zhejiang province P.R. China,Xinchang NHU Vitamins Company Ltd High-tech industry zone Meizhu Xinchang county Zhejiang province PR China |
| | Detail of stability batches of drug product | Data of three batches on long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Multiple Micronutrient Powder manufactured by RENATA Bangladesh, approved by GAIN and UN Batch No X0923552 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches on long-term and accelerated conditions |
| | The status in reference regulatory authorities | Vitamin and Mineral Powder by Renata Limited (Bangladesh) |
| | GMP status of the firm | GMP dated 03.10.2023 |
| | Evidence of approval of manufacturing facility | Renewal of DML No. 000061 dated 19.06.2023 having Tablet Section (General) |
| | **Evaluation Remarks** | |
| | Firm was unable to provide RRA reference and replied instead. As per WHO recommendations, Micronutrient Powder (MNP) is classified as an essential medicine in the National Essential Medicines List (NEML) of October 2018 Page 62 ( https://www.dra.gov.pk/wp-content/uploads/2022/07/NEML ... R-2018.pdf ). This aligns with the Government of Pakistan's commitment to ensuring equity and quality in the delivery of essential preventive and curative care services to all citizens, in accordance with the National Health Vision 2016-2025. The World Health Organization (WHO) has classified MNP as essential medicines, formulated in accordance with UNICEF-approved specifications. Remington Pharmaceutical Industries has developed a formulation that adheres to the UNICEF product specification sheet guidelines of 2017, targeting children aged 6 to 59 months. This formulation was subsequently recommended by WHO in the National Essential Medicines List (NEML) of 2018. The updated UNICEF Product Specification Sheet for Multiple Micronutrient Powder (MNP) 2021 (https://www.unicef.org/supply/media/16661/file/S158020 ... cation.pdf ) maintains the same formulation as the 2017 specifications and is recommended by WHO in the National Essential Medicines List (NEML) 2018 The safety and efficacy of Micronutrient powder (MNP) confirmed by clinical data submitted to Reference Regulatory Authority (WHO), including findings from relevant clinical trial. Innovator's RMP | |
| | **Decision** | |
| | **Approved** | |
| 34 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan **(000061)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XR8-AS9-BX3R, 2025-05-12) |
| | Detail of Fee Submitted | 37000.0,<br>2025-03-20, |
| | The proposed proprietary name / brand name | **Ertuglip 5mg/100mg Tablet** |
| | Label Claim | Each film-coated tablet contains: 6.48mg Ertugliflozin L-Pyroglutamic Acid equivalent to Ertugliflozin.....5mg 128.5mg Sitagliptin |

| | | |
|---|---|---|
| | | Phosphate Monohydrate equivalent to Sitagliptin.....100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10'S-As per SRO,14'S-As per SRO,20'S-As per SRO,28'S-As per SRO,30'S-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | TreviaR2 Tablet (Getz Pharma) |
| | Pharmacotherapeutic Group of (API) | Antidiabetic: SGLT 2 inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical CO.,Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000 |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Ertugliflozin: Clearance certificate No. E-6393400645874 Sitagliptin: CLearance certificate: E-5567500644713 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | USFDA |
| | GMP status of the firm | GMP certificate dated 03.10.2023 |
| | Evidence of approval of manufacturing facility | Renewal of DML No. 000061 dated 19.06.2023 with Tablet General section |
| | **Evaluation Remarks** | |
| | Fee for revision of specifications | |
| | **Decision** | |
| | **Approved**<br><br>The Registraiton Board approved the grant of registration subject to submission of fee for revision of specificaitons. | |
| 35 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan **(000061)** |
| | Application Form Dy. No / Tracking ID & date of submission | (H4U-X47-8DR3, 2025-05-15) |
| | Detail of Fee Submitted | 37000.0,<br>2025-03-20, |
| | The proposed proprietary name / brand name | **Ertuglip 15mg/100mg Tablet** |
| | Label Claim | Each film-coated tablet contains: 19.43mg Ertugliflozin L-Pyroglutamic acid equivalent to Ertugliflozin.....15mg 128.5mg Sitagliptin phosphate monohydrate equivalent to Sitagliptin.....100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10'S-As per SRO,14'S-As per SRO,20'S -As per SRO,28'S -As per SRO,30'S-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | TreviaR2 15mg/100mg (Getz Pharma) |
| | Pharmacotherapeutic Group of (API) | |

| | | |
|---|---|---|
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical CO.,Ltd Address: Fluoride Industrial Park, Fumeng County (Yi Ma Tu), Fuxin City, Liaoning Province -123000 |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | USFDA |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Fee for revision of specifications | |
| | **Decision** | |
| | **Approved**<br><br>Subject to subimission of fee for revision of specifications | |
| 36 | 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 | (7VB-QYD-DGST, 2026-03-10) |
| | Detail of Fee Submitted | 313500,<br>2026-02-21, |
| | The proposed proprietary name / brand name | **Ponaxen 45mg Tablet** |
| | Label Claim | Each film coated tablet contains... Ponatinib Hydrochloride 48.080mg eq. to Ponatinib 45mg. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 30's (1x30)-As per SRO |
| | Shelf Life (Unit) | 24 MonthStore below 30°C. |
| | For generic drugs (me-too Status) | Ponatinix 45mg Tablets (Himmel Pharmaceuticals) |
| | Pharmacotherapeutic Group of (API) | Kaifeng Pharmaceutical(Group)Company Limited (China). |
| | Name, address of Manufacturing site: | Everest Pharmaceuticals Limited.-Plot No: B-45, 46 & 33, BSCIC I/A, Kanchpur, Narayanganj, -Bangladesh |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached in Relavant section of Module 3. |
| | Name, address of Marketing Authorization Holder: | Everest Pharmaceuticals Limited., Rahman's Regnum Centre (11th Floor) 191/1, Tejgaon C/A, Dhaka-1208, 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) | Attached in Relavant section of Module 3. |
| | The status in reference regulatory authorities | Iclusig 45mg Film-coated Tablets (Netherlands) |

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| | **Evaluation Remarks** | |
| | The CDP has been revised as the previous studies showed higher dissolution of API in higher pH despite the fact that API is soluble in lower pH. Legalized LOA and CoPP | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to:<br><br>1. Provision of legalized letter of Authorization<br><br>2. Provision of legalized CoPP<br><br>3. Import policy for inspection | |
| 37 | 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 | (PHN-GSS-2H63, 2026-03-10) |
| | Detail of Fee Submitted | 313500,<br>2026-02-21, |
| | The proposed proprietary name / brand name | **Ponaxen 15 mg tablet** |
| | Label Claim | Each 15 mg film-coated tablet contains 15 mg ponatinib (as ponatinib hydrochloride). |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x30's-As per SRO |
| | Shelf Life (Unit) | 24 MonthDo not store above 30°C. |
| | For generic drugs (me-too Status) | Ponatinix 15mg tablet |
| | Pharmacotherapeutic Group of (API) | Tyrosine Kinase Inhibitor (Anti- neoplastic) |
| | 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 | Attached in relevant section of Module 3 |
| | Name, address of Marketing Authorization Holder: | Everest pharmaceuticals limited, Rahman's Regnum Center (11 th Floor) 191/1 Tejgaon C/A, Dhaka-1208, Bangladesh, Bangladesh |
| | Details of Certificates (CoPP/FSC/cGMP): | Valid |
| | Details of Authorization Letter : | Not applicable for finished product importer |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in relevant section of Module 3 |
| | The status in reference regulatory authorities | Iclusig 15 mg film-coated tablets |
| | **Evaluation Remarks** | |
| | The CDP has been revised as the previous studies showed higher dissolution of API in higher pH despite the fact that API is soluble in lower pH. Legalized LOA and CoPP | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to:<br><br>1. Provision of legalized letter of Authorization<br><br>2. Provision of legalized CoPP | |

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| | 3. Import policy for inspection | |
| 38 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Martin Dow Limited** Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan **(000267)** |
| | Application Form Dy. No / Tracking ID & date of submission | (21S-E8M-LQRS, 2026-05-14) |
| | Detail of Fee Submitted | 97200,<br>2026-05-07, |
| | The proposed proprietary name / brand name | **Enfentra Inhalation Suspension 3mg/2.5ml** |
| | Label Claim | Each ampoule contains: Ensifentrine 3mg in 2.5ml aq. suspension |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x 5's -As per SRO |
| | Shelf Life (Unit) | 24 MonthStore below 30 °C |
| | For generic drugs (me-too Status) | Not Applicable |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase inhibitors |
| | Name, address of Manufacturing site: | M/s Hudson Pharma (Pvt) Ltd-D-93, North West Industrial Zone, Port Qasim Authority, Karachi- |
| | Name & address of API manufacturer | Not Applicable |
| | Detail of stability batches of drug product | Zone IV stability data of 3 batches attached |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Documents for procurement of Ensifentrine provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharma equivalence against Innovator Ohtuvayre Inhalation Suspension submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Zone IV stability data of 3 batches attached |
| | The status in reference regulatory authorities | Ohtuvayre Inhalation Suspension of US FDA |
| | GMP status of the firm | Valid till 02-10-2028 |
| | Evidence of approval of manufacturing facility | Plastic Respules section |
| | **Evaluation Remarks** | |
| | Under export facilitation 1. Justification for not including delivered dose uniformity and aerodynamic droplet size distribution which is essential for inhalation suspensions as per guidelines that innovator followed Reply of the firm: Because our formulation physically mirrors the innovator, its atomization mechanics will inherently generate a parallel droplet size distribution. However, to fully satisfy recommended requirements, Hudson Pharma hereby formally commits to submitting the complete ADSD and Delivered Dose Uniformity data as a mandatory addendum before commercialization of the product. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for:<br><br>1. performing delivered dose uniformity and aerodynamic droplet size distribution tests,<br><br>2. revision of specifications along with requiste fee | |
| 39 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Highnoon Laboratories Ltd** 17.5 KM, Multan Road, **(000155)** |
| | Application Form Dy. No / Tracking ID & date of submission | (61J-PML-Z3M9, 2026-05-20) |

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| | Detail of Fee Submitted | 38700,<br>2026-04-13, |
| | The proposed proprietary name / brand name | **Vylinta MXR 5/1000mg Tablets** |
| | Label Claim | Each film coated tablet contains;<br>Linagliptin.....5mg Metformin HCl (extended release).....1000mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x10's-As per SRO,10 x2's-As per SRO,2 x7's-As per SRO,3x10's-As per SRO,7x4's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 30°C |
| | For generic drugs (me-too Status) | Linagen-M XR Tablets 5mg/1000mg (127008) Ferozsons Laboratories Limited |
| | Pharmacotherapeutic Group of (API) | Anti-Diabetics ATC Code: A10BD11 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Not Applicable |
| | Detail of stability batches of drug product | RDP0076-04, RDP0076-05, RDP0076-06. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | RO-77F227, RO-559E72 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Study was conducted for Comparative Dissolution Profile of Linagliptin /Metformin HCl 5/1000mg Tablet and Jentadueto XR 5/1000mg. Dissolution profile for both found to be satisfactory. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Zone IV A |
| | The status in reference regulatory authorities | JENTADUETO® XR USFDA |
| | GMP status of the firm | Validity 07-01-2029 |
| | Evidence of approval of manufacturing facility | Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (YiMaTu), Fuxin City, Liaoning Province, China (for Linagliptin), Ipca Laboratories Limited H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India (for Metformin HCl) |
| | **Evaluation Remarks** | |
| | Under export facilitation | |
| | **Decision** | |
| | **Approved** | |
| 40 | Case Category | Export Facilitation (Abdul Mughees) |
| | Name, address of Applicant. | **Highnoon Laboratories Ltd** 17.5 KM, Multan Road, **(000155)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6UZ-68E-3MBW, 2026-05-20) |
| | Detail of Fee Submitted | 38700,<br>2026-04-13, |
| | The proposed proprietary name / brand name | **Vylinta MXR 2.5/1000mg Tablets** |
| | Label Claim | Each film coated tablet contains:<br>Linagliptin.....2.5mg Metformin HCl(extended release).....1000mg |
| | Reference to Finished product specifications | As per Innovators Specification |

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| | Proposed Pack Size | 1 x10's-As per SRO,2 x10's-As per SRO,2 x7's-As per SRO,3x10's-As per SRO,7x4's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 30°C |
| | For generic drugs (me-too Status) | Linagen-M XR Tablets 2.5mg/1000mg (127007) Ferozsons Laboratories Limited |
| | Pharmacotherapeutic Group of (API) | Anti-Diabetics ATC Code: A10BD11 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Not Applicable |
| | Detail of stability batches of drug product | Data of three batches RDP0076-01, RDP0076-02, RDP0076-03 at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | RO-77F227, RO-559E72 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Study was conducted for Comparative Dissolution Profile of Linagliptin /Metformin HCl 2.5/1000mg Tablet and Jentadueto XR 2.5/1000mg. Dissolution profile for both found to be satisfactory. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | JENTADUETO® XR USFDA |
| | GMP status of the firm | Validity 07-01-2029 |
| | Evidence of approval of manufacturing facility | Fuxin Long Rui Pharmaceutical CO., Ltd Address: Fluoride Industrial Park, Fumeng County (YiMaTu), Fuxin City, Liaoning Province, China (for Linagliptin), Ipca Laboratories Limited H-4, M.I.D.C., Waluj Aurangabad (Maharashtra) Pin: 431136, India (for Metformin HCl) |
| | **Evaluation Remarks** | |
| | Under export facilitation | |
| | **Decision** | |
| | **Approved** | |
| 41 | Case Category | New Molecule/Formulation (Abdul Mughees) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GE4-VRT-PY4V, 2025-10-07) |
| | Detail of Fee Submitted | 75000.0, 2025-05-30, |
| | The proposed proprietary name / brand name | **Darox Tablets** |
| | Label Claim | Each Film Coated Tablet Contains: Daridorexant HCl equivalent to Daridorexant.....25mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 30's Tablets-As per SRO |
| | Shelf Life (Unit) | 2 Yearstore below 30C at cool & dry place |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Daridorexant is a dual orexin receptor antagonist (DORA) |
| | Name, address of Manufacturing site: | Self Manufacturing |

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| | Name & address of API manufacturer | Shandong Loncom Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | DRTL-001, DRTL-002, DRTL-003 Each of 1500 Tablets |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Attached with invoice number DIL-C-A09912 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed with QUVIVIQ Tablets 25mg |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Accelerated and Real time stability studies conducted on Zone IV a stability conditions |
| | The status in reference regulatory authorities | UK (MHRA) |
| | GMP status of the firm | Valid w.e.f 14-04-2025 |
| | Evidence of approval of manufacturing facility | DML#000427 w.e.f 01-04-21 |
| | **Evaluation Remarks** | |
| | Innovator's RMP | |
| | **Decision** | |
| | **Approved**<br><br>Subject to submission of innovato's RMP | |
| 42 | Case Category | New Molecule/Formulation (Abdul Mughees) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6MH-46W-Q6SJ, 2025-09-30) |
| | Detail of Fee Submitted | 75000.0,<br>2025-05-30, |
| | The proposed proprietary name / brand name | **Darox Tablets 50mg** |
| | Label Claim | Each film coated tablet contains Daridorexant HCl eq. to: Daridorexant 50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 30's Tablets-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30C at cool & dry place |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Daridorexant is a dual orexin receptor antagonist (DORA) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Shandong Loncom Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | DRTH-001 DRTH-002 DRTH-003 Each of 1500 Tablets |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Attached with Invoice No DIL-C-A09912 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pperformed with QUVIVIQ 50mg Tablets |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Accelerated and Real time stability studies conducted on Zone IV a stability conditions |
| | The status in reference regulatory authorities | UK (MHRA) |
| | GMP status of the firm | Valid w.e.f 14-04-2025 |
| | Evidence of approval of manufacturing facility | DML#000427 w.e.f 01-04-21 |
| | **Evaluation Remarks** | |
| | Innovator's RMP | |

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| | **Decision** | |
| | **Approved**<br><br>Subject to submission of innovato's RMP | |
| 43 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7NL-LRZ-G2RR, 2024-05-08) |
| | Detail of Fee Submitted | 30000.0,<br>2024-04-04, |
| | The proposed proprietary name / brand name | **RIVAS 3mg Capsule** |
| | Label Claim | Each capsule contains: Rivastigmine hydrogen tartrate eq. to Rivastigmine.....3mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 7s, 14s, 28s, 30s, 6-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degree |
| | For generic drugs (me-too Status) | Exelon 3mg capsule, Novartis |
| | Pharmacotherapeutic Group of (API) | N06DA03 ANTI-DEMENTIA DRUGS, Anticholinesterases |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Shodhana Laboratories Limited |
| | Detail of stability batches of drug product | 2 batches, 10,000 capsules each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate of 1kg drug substance is submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Exelon 3mg Capsule B. No. B8916E M/s Novartis Istambul |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | EMA Aproved - Rivastigmine Sandoz 3 mg hard capsules Sandoz GmbH, Austria |
| | GMP status of the firm | copy of GMP certificate issued on basis of inspection dated 22.05.2023 is submitted |
| | Evidence of approval of manufacturing facility | Renewal letter dated 27.04.2020 is submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 44 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WEQ-5TT-WJQ3, 2024-05-23) |
| | Detail of Fee Submitted | 30000.0,<br>2024-04-04, |
| | The proposed proprietary name / brand name | **RIVAS 6mg Capsule** |
| | Label Claim | Each capsule contains Rivastigmine hydrogen tartrate eq. to Rivastigmine.....6mg |
| | Reference to Finished product specifications | British Pharmacopeia |

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| | Proposed Pack Size | 7s, 14s, 28s, 30s, 6-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degree |
| | For generic drugs (me-too Status) | Exelon 6mg capsule, Novartis |
| | Pharmacotherapeutic Group of (API) | N06DA03 ANTI-DEMENTIA DRUGS, Anticholinesterases |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Shodhana Laboratories Limited |
| | Detail of stability batches of drug product | 2 batches, 10,000 capsules each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate of 1kg drug substance is submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Exelon 6mg Capsule B. No. BCHR2 M/s Novartis Istambul |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | EMA Aproved - Rivastigmine Sandoz 6 mg hard capsules Sandoz GmbH, Austria |
| | GMP status of the firm | copy of GMP certificate issued on basis of inspection dated 22.05.2023 is submitted |
| | Evidence of approval of manufacturing facility | Renewal letter dated 27.04.2020 is submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 45 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (D75-J4B-TZZB, 2024-06-03) |
| | Detail of Fee Submitted | 30000.0, 2024-05-06, |
| | The proposed proprietary name / brand name | **Rivas Oral Solution 2mg / ml** |
| | Label Claim | Each ml contains: Rivastigmine Hydrogen Tartrate equivalent to Rivastigmine .....2mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | Amber glass bottle o-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | N06DA03 Anticholinesterases |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Shodhana Laboratories Limited |
| | Detail of stability batches of drug product | 3 batches, 100 bottles of 120ml each, |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate of 1kg drug substance is submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Riveme Oral Solution 2mg/ml B. No. 009L351 Mfg Genix Pharma |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVb conditions, upto 60 months |
| | The status in reference regulatory authorities | MHRA Approved (Rivastigmine 2 mg/ml oral solution by Kent Pharma UK Limited, United |

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| | | Kingdom) |
| | GMP status of the firm | GMP certificate issued on basis of inspection dated 22.05.2023 is submitted. |
| | Evidence of approval of manufacturing facility | Renewal letter dated 27.04.2020 is submitted, Liquid syrup General section is mentioned. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 46 | Case Category | New Section (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZWG-9UV-R7ZS, 2026-03-12) |
| | Detail of Fee Submitted | 38700,<br>2026-02-17, |
| | The proposed proprietary name / brand name | **Esticef 1g Injection IV** |
| | Label Claim | Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....1000mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Aventriax 1g IV Injection (Sanofi-Aventis Pakistan Limited ) |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Sinopharm Weiqida Pharmaceutical Co. Ltd |
| | Detail of stability batches of drug product | 3 batches, 750 vials each. upto 6th month time point data is submitted. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Taken loan from M/s Aulton pharma. Clearance letter and loan letter are submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Oxidil 1g Inj. B. No. 296N081 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa, upto 36 months. |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section approval letter dated 07.06.2021 is submitted. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 47 | Case Category | New Section (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (MSP-LBD-HJ61, 2026-03-05) |
| | Detail of Fee Submitted | 38700,<br>2026-02-17, |
| | The proposed proprietary name / brand name | **Esticef 250mg Injection IV** |
| | Label Claim | Each vial contains: Ceftriaxone Sodium Eq. to Ceftriaxone.....250mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Aventriax 250mg IV Injection (Sanofi-Aventis Pakistan Limited ) |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Qilu Antibiotics Pharmaceutical Co., Ltd., No.849 DongJia Town, Licheng District, Jinan City, Shandong Province, China. |
| | Detail of stability batches of drug product | 3 batches, 750 vials each. upto 6th month time point data is submitted. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Taken loan from M/s Aulton pharma. Clearance letter and loan letter are submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Oxidil 250mg IV in j. B. No. LYM035 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa, upto 36 months. |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section approval letter dated 07.06.2021 is submitted. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 48 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ESY-M7S-EGNW, 2026-03-05) |
| | Detail of Fee Submitted | 38700,<br>2026-02-17, |
| | The proposed proprietary name / brand name | **Esticef 500mg Injection IV** |
| | Label Claim | Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....500mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Aventriax 500mg IV Injection (Sanofi-Aventis Pakistan Limited ) |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |

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|---|---|---|
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Qilu Antibiotics Pharmaceutical Co. Ltd, |
| | Detail of stability batches of drug product | 3 batches, 750 vials each. upto 6th month time point data is submitted. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Taken loan from M/s Aulton pharma. Clearance letter and loan letter are submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Oxidil 500mg Inj B. No. 295N021 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa, upto 36 months. |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section approval letter dated 07.06.2021 is submitted. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 49 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PVR-HNH-P842, 2026-03-05) |
| | Detail of Fee Submitted | 38700,<br>2026-02-17, |
| | The proposed proprietary name / brand name | **Tradex 1g Injection IM** |
| | Label Claim | Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....1000mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Aventriax 1g Injection (Sanofi-Aventis Pakistan Limited ) |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Qilu Antibiotics Pharmaceutical Co., Ltd., No.849 DongJia Town, Licheng District, Jinan City, Shandong Province, China. |
| | Detail of stability batches of drug product | 3 batches, 750 vials each. upto 6th month time point data is submitted. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Taken loan from M/s Aulton pharma. Clearance letter and loan letter are submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | ROCEPHIN 1G INJECTION IM B. No. B0961 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa, upto 36 months. |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | New License |

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| | Evidence of approval of manufacturing facility | Section approval letter dated 07.06.2021 is submitted. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 50 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EVM-B46-ALB7, 2026-03-05) |
| | Detail of Fee Submitted | 38700,<br>2026-02-17, |
| | The proposed proprietary name / brand name | **Tradex 500mg Injection IM** |
| | Label Claim | Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....500mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Aventriax 500mg Injection (Sanofi-Aventis Pakistan Limited ) |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Qilu Antibiotics Pharmaceutical Co., Ltd., No.849 DongJia Town, Licheng District, Jinan City, Shandong Province, China. |
| | Detail of stability batches of drug product | 3 batches, 750 vials each. upto 6th month time point data is submitted. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Taken loan from M/s Aulton pharma. Clearance letter and loan letter are submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | OXIDIL 500MG INJECTION IM B. No. LYM011 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa, upto 36 months. |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section approval letter dated 07.06.2021 is submitted. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 51 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4W4-DU5-122G, 2026-03-05) |

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| | Detail of Fee Submitted | 38700,<br>2026-02-17, |
| | The proposed proprietary name / brand name | **Tradex 250mg Injection IM** |
| | Label Claim | Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....250mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Aventriax 250mg Injection (Sanofi-Aventis Pakistan Limited ) |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Qilu Antibiotics Pharmaceutical Co., Ltd., No.849 DongJia Town, Licheng District, Jinan City, Shandong Province, China. |
| | Detail of stability batches of drug product | 3 batches, 750 vials each. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Taken loan from M/s Aulton, Clearance certificate and loan intimation letter is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | OXIDIL 250MG INJECTION IM LYM022 Sami Pharmaceuticals |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section approval letter dated 08.06.2021 is submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 52 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Himont Pharmaceuticals (Pvt.) Ltd.** 17-km Ferozpur Road, Lahore **(000231)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z9G-ZWN-4G4U, 2024-11-11) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-21, |
| | The proposed proprietary name / brand name | **Apicard 5mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Apixaban .....5mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 14-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 25°C or below at Dry place |
| | For generic drugs (me-too Status) | Available |
| | Pharmacotherapeutic Group of (API) | Direct factor Xa inhibitors B01AF02 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Glenmark LifeSciences |
| | Detail of stability batches of drug product | 3 batches, 2500 tablets each |
| | Documents for the procurement of API with approval from DRAP | AD attested invoice of drug substance is submitted |

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| | (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Apixaget 5mg Tablet B. No. 058FD5 M/s Getz |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Available |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 53 | Case Category | Contract Manufacturing (Adil Saeed) |
| | Name, address of Applicant. | **M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XVL-T4U-N4VS, 2024-11-12) |
| | Detail of Fee Submitted | 93000.0,<br>2024-10-03, |
| | The proposed proprietary name / brand name | **Befylin 600mg Tablet** |
| | Label Claim | Each film coated tablet contains Bamifylline hydrochloride..... 600 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's, 10's, 14's, 20'-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C. Protect from heat, light and moisture |
| | For generic drugs (me-too Status) | Bamizine 600 mg Tablet by Lucky Core Industries Limited (ICI Pakistan Limited) Formerly Cirin Pharmaceuticals Pvt. Ltd |
| | Pharmacotherapeutic Group of (API) | R03DA08 OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES |
| | Name, address of Manufacturing site: | Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi - |
| | Name & address of API manufacturer | Bakul Pharma Pvt. Ltd. |
| | Detail of stability batches of drug product | 3 batches, 1500 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6 is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Briofil 600mg Film coated Tablet B. No. 852164 Mfg M/s Teofarma Italy |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | -- |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Me-too of applied product is available but RRA approval of the applied product could not be verified. Firm was asked to submit valid RRA reference and firm has submitted following response; | |

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| | Bamifylline Tablets 400 mg were previously approved and marketed in Italy under authorization granted by the AIFA. The product has a history of clinical use in respiratory disorders. The product was subsequently voluntarily withdrawn from the Italian market due to commercial considerations and declining clinical demand, and not due to any concerns related to safety, efficacy, or quality. Currently, no valid approval from a reference regulatory authority (SRA) exists; therefore, this application is submitted as a full dossier for independent evaluation by DRAP. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred till policy decision on products having me-too reference but no valid RRA. | |
| 54 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B9Q-BD6-ZT5J, 2024-10-16) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-09, |
| | The proposed proprietary name / brand name | **Bamifyl 600mg tablet** |
| | Label Claim | Each film coated tablet contains Bamifylline hydrochloride..... 600 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's, 10's, 14's, 20'-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C. Protect from heat, light and moisture |
| | For generic drugs (me-too Status) | Bamizine 600 mg Tablet by Lucky Core Industries Limited (ICI Pakistan Limited) Formerly Cirin Pharmaceuticals Pvt. Ltd |
| | Pharmacotherapeutic Group of (API) | R03DA08 OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Bakul Pharma Pvt. Ltd. |
| | Detail of stability batches of drug product | 3 batches, 1500 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6 is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Briofil 600mg Film coated Tablet B. No. 852164 Mfg M/s Teofarma Italy |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Not verifible |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Me-too of applied product is available but RRA approval of the applied product could not be verified. Firm was asked to submit valid RRA reference and firm has submitted following response; | |
| | Bamifylline Tablets 400 mg were previously approved and marketed in Italy under authorization granted by the AIFA. The product has a history of clinical use in respiratory disorders. The product was subsequently voluntarily withdrawn from the Italian market due to commercial considerations and declining clinical demand, and not due to any concerns related to safety, efficacy, or quality. Currently, no valid approval from a reference regulatory authority (SRA) exists; therefore, this application is submitted as a full dossier for independent evaluation by DRAP. | |

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| | **Decision** | |
| | **Deferred**<br><br>Deferred till policy decision on products having me-too reference but no valid RRA reference. | |
| 55 | Case Category | Contract Manufacturing (Adil Saeed) |
| | Name, address of Applicant. | **Cherwel Pharmaceutical** Plot #20,Phase #04, Hattar Industrial Estate Hattar Haripur **(000606)** |
| | Application Form Dy. No / Tracking ID & date of submission | (V4L-SUP-XJ3V, 2024-10-31) |
| | Detail of Fee Submitted | 75000.0, 18000.0<br>2024-09-06, 2024-10-04 |
| | The proposed proprietary name / brand name | **RISE-D 5mg/ml** |
| | Label Claim | Each 1 ml ampoule contains:<br>Cholecalciferol.....5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's & 5's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Indrop-D Injection Manufacturer/Registration holder: NEUTRO PHARMA (PVT) LTD. Registration number: 023170 |
| | Pharmacotherapeutic Group of (API) | Vitamin D |
| | Name, address of Manufacturing site: | Swiss Pharmaceuticals Pvt. Ltd.-A/159, S.I.T.E. II , Super Highway, Karachi – Pakistan- |
| | The status in reference regulatory authorities | Vitamin d3 bon Manufacturer: STERKEM PHARMA Marketing Authorisation Number: N/A Approved by: France |
| | Detail of previous approval | Approved in PRVC case. |
| | **Evaluation Remarks** | |
| | Data already approved in a PRVC case of change of manufacturing site. | |
| | **Decision** | |
| | **Approved** | |
| 56 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Bloom Pharmaceuticals (Pvt) Ltd.** Plot No. 30, Phase I & II, Industrial Estate, Hattar **(000374)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PBJ-ZR2-UM44, 2024-03-28) |
| | Detail of Fee Submitted | 30000.0,<br>2024-03-13, |
| | The proposed proprietary name / brand name | **Isonine 20mg Capsule** |
| | Label Claim | Each hard gelatin capsule contains:<br>Isotretinoin.....20mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10's-As per SRO,3x10's-As per SRO,5's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature, in a cool and dry place. Protect from heat and light. |
| | For generic drugs (me-too Status) | Roaccutane Capsules 20mg of Roche Pakistan Ltd. |
| | Pharmacotherapeutic Group of (API) | D10BA01 Retinoids for treatment of acne |
| | Name, address of Manufacturing site: | Self Manufacturing |

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| | Name & address of API manufacturer | Chongqing Huapont Shengchem Pharmaceutical Co. Ltd No. 666 Rongjun Road, Nanjin Avenue Hechuan District, Chongqing P. R. China |
| | Detail of stability batches of drug product | 3 batches. 16000 capsules each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | AD attested invoice mentioning 1kg drug substance is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Serbica 20mg Capsule Batch No. 1H432 Mfg: M/s Seraph |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Absorica™ 20mg Capsules, USFDA Approved, M Ranbaxy Laboratories Inc. |
| | GMP status of the firm | Copy of GMP certificate based on inspection dated21.06.2022 is submitted |
| | Evidence of approval of manufacturing facility | Copy of renewal letter dated 15.11.2021 is submitted wherein Capsule (General) section is mentioned |
| | **Evaluation Remarks** | |
| | The firm has applied for BP specifications and has tested their product as per BP specifications. In BP monograph is of softgel capsule, whereas applied product is a hardgel capsule. Firm was asked to justify it firm has stated that same monograph can be used for testing of both softgel and hard gel capsule. | |
| | Pharmaceutical equivalence is established against similar product of Seraph pharmaceuticals. | |
| | **Decision** | |
| | **Deferred**<br><br>Board deferred the case for revision of specifications as per innovator and submission of testing data of trial batches as per revised method, along with requisite fee for preregistration variation. | |
| 57 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Benson Pharmaceuticals** Plot No.03, Main Road, National Industrial Zone, RCCI, Rawat, Rawalpindi **(000447)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NQB-R76-RNVQ, 2026-01-28) |
| | Detail of Fee Submitted | 38700,<br>2025-12-30, |
| | The proposed proprietary name / brand name | **Bengra 50mg Tablet** |
| | Label Claim | Each film coated tablet contains Sildenafil Citrate eq. to Sildenafil.....50 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 4,6, 10, 20, 30, 100-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Below 30 degree centigrade |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase type-5 (PDE-5) inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches, 5000 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | drug import license is submitted. |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Viagra 50mg Tablet B. No. 19686524AH |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | FDA |
| | GMP status of the firm | GMP certificate is submitted |
| | Evidence of approval of manufacturing facility | Section approval letter is submitted |
| | **Evaluation Remarks** | |
| | The application has been processed on priority in compliance to the decision of DRAP authority regarding ED drugs. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 58 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Benson Pharmaceuticals** Plot No.03, Main Road, National Industrial Zone, RCCI, Rawat, Rawalpindi **(000447)** |
| | Application Form Dy. No / Tracking ID & date of submission | (D52-WMD-ULYD, 2026-01-28) |
| | Detail of Fee Submitted | 38700,<br>2025-12-30, |
| | The proposed proprietary name / brand name | **Bengra 100mg** |
| | Label Claim | Each film coated tablet contains Sildenafil Citrate eq. to Sildenafil....100 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 4,6, 10, 20, 30, 100-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Below 30 degree centigrade |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase type-5 (PDE-5) inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches, 5000 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Drug import license is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Viagra 100mg tablet B. No. 01R0226A |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | submitted |
| | The status in reference regulatory authorities | FDA |
| | GMP status of the firm | GMP certificate issued on basis of inspection dated 16.11.2022 is submitted |
| | Evidence of approval of manufacturing facility | Renewal letter dated 29.02.2024 is submitted. |
| | **Evaluation Remarks** | |
| | The application has been processed on priority in compliance to the decision of DRAP authorityregarding ED drugs. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 59 | Case Category | New License (Adil Saeed) |

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| | Name, address of Applicant. | **AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YVW-22U-VQRH, 2025-04-17) |
| | Detail of Fee Submitted | 37000.0, 2025-04-07, |
| | The proposed proprietary name / brand name | **Dulo-20 20mg Capsule** |
| | Label Claim | Each Capsule Contains: - Duloxetine hydrochloride Enteric Coated Pellets Eq. to Duloxetine .....20mg Capsule. |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C in a cool and dry place. |
| | For generic drugs (me-too Status) | Lyta 20mg Capsule by Getz Pharma (Pvt.) Ltd Karachi |
| | Pharmacotherapeutic Group of (API) | N06AX21 Anti-depressant |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan |
| | Detail of stability batches of drug product | 3 batches of 700 Capsule each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API purchased from Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP performed against Lyta 20mg Capsule by Getz Pharma (Pvt.) Ltd Karachi B. No. 077C36 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per Zone IVa conditions |
| | The status in reference regulatory authorities | MHRA Approved. |
| | GMP status of the firm | New DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued dated 17-02-2023. |
| | Evidence of approval of manufacturing facility | New DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued dated 17-02-2023. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 60 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W59-PD1-1ZU2, 2025-04-17) |
| | Detail of Fee Submitted | 37000.0, 2025-04-07, |
| | The proposed proprietary name / brand name | **Dulo-30 30mg Capsule** |
| | Label Claim | Each Capsule Contains: - Duloxetine Hydrochloride Enteric Coated Pellets Eq. to Duloxetine .....30mg. |
| | Reference to Finished product specifications | United States Pharmacopeia |

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| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C in a cool and dry place. |
| | For generic drugs (me-too Status) | Lyta 30mg Capsule BY Getz Pharma (Pvt.) Ltd Karachi |
| | Pharmacotherapeutic Group of (API) | N06AX21 Anti-depressant |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan |
| | Detail of stability batches of drug product | 3 batches of 700 Capsule each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API purchased from Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakista |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP performed against Lyta 30mg Capsule by Getz Pharma (Pvt.) Ltd Karachi B. No. 184G34 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per Zone IV conditions |
| | The status in reference regulatory authorities | MHRA Approved. |
| | GMP status of the firm | New DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued dated 17-02-2023. |
| | Evidence of approval of manufacturing facility | New DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued dated 17-02-2023. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 61 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U2N-YAX-GEJ8, 2025-04-17) |
| | Detail of Fee Submitted | 37000.0, 2025-04-07, |
| | The proposed proprietary name / brand name | **Dulo-60 60mg Capsule** |
| | Label Claim | Each Capsule Contains: - Duloxetine Hydrochloride Enteric Coated Pellets Eq. to Duloxetine .....60mg. |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C in a cool and dry place. |
| | For generic drugs (me-too Status) | Lyta 60mg Capsule by Getz Pharma (Pvt.) Ltd Karachi |
| | Pharmacotherapeutic Group of (API) | N06AX21 Anti-depressant |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan |
| | Detail of stability batches of drug product | 3 batches of 700 Capsule each |

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| | Documents for the procurement of API with approval from DRAP (in case of Import) | API purchased from Vision Pharmaceuticals Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakista |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP performed against Lyta 60mg Capsule by Getz Pharma (Pvt.) Ltd Karachi B. No. 039035 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per Zone IV conditions |
| | The status in reference regulatory authorities | MHRA Approved. |
| | GMP status of the firm | New DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued dated 17-02-2023. |
| | Evidence of approval of manufacturing facility | New DML including section of "Capsule (General)" vide letter no. F.1-9/2016-Lic issued dated 17-02-2023. |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 62 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Martin Dow Limited** Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan **(000267)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5YX-4P3-D84N, 2026-03-09) |
| | Detail of Fee Submitted | 38700,<br>2025-12-17, |
| | The proposed proprietary name / brand name | **Sildirekt Tablet 50mg** |
| | Label Claim | Each film-coated tablet contains: Sildenafil Citrate equivalent to Sildenafil..... 50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1 x 2's-As per SRO,1 x 4's-As per SRO,2 x 4's - As per SRO,2 x 5's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | I-Pill Tablets - Mfg. By Genix Pharma Pvt. Ltd. |
| | Pharmacotherapeutic Group of (API) | Drug used in erectile dysfunction |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | 3 batches 3000 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form-6 specifying the import of 'Sildenafil Citrate from Century Pharmaceuticals' is provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE & CDP performed against "I-Pill Tablet" by Genix Pharma Pvt. Ltd" |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of 3 batches on Zone IV-A provided |
| | The status in reference regulatory authorities | Viagra Tablets by VIATRIS (USFDA Approved) |
| | GMP status of the firm | GMP (Valid till 02-08-2027) |
| | Evidence of approval of manufacturing facility | Section Approval dated 15-Sep-2021 mentions the availability of Tablet (General) Section |
| | **Evaluation Remarks** | |

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| | Priority as per decision of authority for drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 63 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Martin Dow Limited** Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan **(000267)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R9Z-RQ1-643D, 2026-03-09) |
| | Detail of Fee Submitted | 38700,<br>2025-12-17, |
| | The proposed proprietary name / brand name | **Sildirekt Tablet 25mg** |
| | Label Claim | Each film-coated tablet contains: Sildenafil Citrate equivalent to Sildenafil..... 25mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1 x 2's-As per SRO,1 x 4's-As per SRO,2 x 4's-As per SRO,2 x 5's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | I-Pill Tablets - Mfg. By Genix Pharma Pvt. Ltd. |
| | Pharmacotherapeutic Group of (API) | Drugs used in erectile dysfunction |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Stability data of 3 batches on Zone IV provided |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form-6 specifying the import of 'Sildenafil Citrate from Century Pharmaceuticals' is provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE & CDP performed against "I-Pill Tablet" by Genix Pharma Pvt. Ltd" |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of 3 batches on Zone IV-A provided |
| | The status in reference regulatory authorities | Viagra Tablets by VIATRIS (USFDA Approved) |
| | GMP status of the firm | GMP (Valid till 02-08-2027) |
| | Evidence of approval of manufacturing facility | Section Approval dated 15-Sep-2021 mentions the availability of Tablet (General) Section |
| | **Evaluation Remarks** | |
| | Priority as per decision of authority for drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 64 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)** |
| | Application Form Dy. No / Tracking ID & date of submission | (G5R-57X-28ZM, 2024-11-04) |
| | Detail of Fee Submitted | 75000.0,<br>2024-10-09, |
| | The proposed proprietary name / brand name | **Feritol** |

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| | Label Claim | Each Capsule contains Ferric maltol eq. to Iron.....30mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's, 10's, 14's, 20'-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 20°C to 25 °C; excursions permitted to 15°C to 30°C |
| | For generic drugs (me-too Status) | Not Applicable |
| | Pharmacotherapeutic Group of (API) | Iron Preparation |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Global Calcium Private Limited |
| | Detail of stability batches of drug product | 3 batches. 1500 capsules each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Accrufer Ferric Maltol 30mg Capsule B. No. 512473 M/s Sheild TX |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | USFDA Approved.<br>Accrufer 30 mg (Ferric Maltol) Capsule by Shield TX |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 65 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N3E-5Y8-8LYD, 2026-02-20) |
| | Detail of Fee Submitted | 38700,<br>2026-02-17, |
| | The proposed proprietary name / brand name | **Selmoxi 400mg Tablets** |
| | Label Claim | Each film coated tablet contains: Moxifloxacin as Hydrochloride.....400mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1x5's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Moksi 400mg Tablet (M/s Abbott Pharmaceuticals) |
| | Pharmacotherapeutic Group of (API) | Quinolone antibacterial, fluoroquinolones |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | PHARMAGEN LIMITED, Kot Nabi Bukshwala, 34 Km Ferozepur Road, Lahore. |
| | Detail of stability batches of drug product | 3 batches, 1000 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Local purchased from M/s PharmaGen |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Moksi 400mg tabs Mfg Abbott |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section approval letter attached at 1.3.5 |
| | **Evaluation Remarks** | |
| | Application fullfills codal formalities. Recommended for consideration of the board. | |
| | **Decision** | |
| | **Approved** | |
| 66 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Rite Bio Sciences (Pvt) Ltd.** Plot No. 9-A, Street No. N-5, RCCI Rawat **(000871)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RGB-EBS-34NR, 2026-03-09) |
| | Detail of Fee Submitted | 38700,<br>2026-02-26, |
| | The proposed proprietary name / brand name | **SATIS 25mg TABLETS** |
| | Label Claim | Each Film coated Tablet contains: SILDENAFIL CITRATE equivalent to SILDENAFIL ..... 25mg (USP Specs) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's,20's,30's,40's& 100's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | Product Name:: Ripple 25mg Tablet Registration No: 127629 Company Name: Solaris Life Sciences Private Limited, Company Address: Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase type 5 (PDE5) inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Century Pharmaceuticals Limited, 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India |
| | Detail of stability batches of drug product | 3 batches, 1500 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Silagro 25mg Tablet B. no. SHH001 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Priority as per decision of Authority for drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |

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| 67 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JDD-G54-7DNU, 2026-03-09) |
| | Detail of Fee Submitted | 38700,<br>2026-02-13, |
| | The proposed proprietary name / brand name | **Silnafix 100mg Tablets** |
| | Label Claim | Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil .....100mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Hilagra 100mg tablet Reg.#128040 Hilton Pharma (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase type 5 (PDE5) inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Century Pharmaceuticals Limited, 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India Telephone number +91 2676 220912, +91 2676 223220 Fax number +91 265 2226023 |
| | Detail of stability batches of drug product | 3 batches, 1200 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Hilagra 100mg tabs of Hilton Pharma B. No. 160095 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Sildenafil Accord 100 mg film-coated tablets by Accord Healthcare Ireland Ltd. Approved by HPRA |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Priority as per decision of Authority for drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 68 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J23-8LU-PJL7, 2026-03-09) |
| | Detail of Fee Submitted | 38700,<br>2026-02-13, |
| | The proposed proprietary name / brand name | **Silnafix 50mg Tablets** |
| | Label Claim | Each film coated tablet contains: Sildenafil citrate equivalent to Sildenafil .....50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |

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| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Ripple 50mg tablet Reg.#127630 Solaris Life Sciences (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase type 5 (PDE5) inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Century Pharmaceuticals Limited, 103-106, GIDC, Halol Dist. Panchmahals- 389 350, India Telephone number +91 2676 220912, +91 2676 223220 Fax number +91 265 2226023 |
| | Detail of stability batches of drug product | 3 batches, 1200 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Ripple 50mg Tablet M/s Solaris Life Sciences. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Comply |
| | The status in reference regulatory authorities | Sildenafil Accord 50 mg film-coated tablets by Accord Healthcare Ireland Ltd. Approved by HPRA |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Comply |
| | **Evaluation Remarks** | |
| | Priority as per decision of Authority for drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 69 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Himont Pharmaceuticals (Pvt.) Ltd.** 17-km Ferozpur Road, Lahore **(000231)** |
| | Application Form Dy. No / Tracking ID & date of submission | (A35-V41-LW8E, 2024-12-20) |
| | Detail of Fee Submitted | 37000.0, 2024-09-12, |
| | The proposed proprietary name / brand name | **Apicard Tablet 2.5mg** |
| | Label Claim | Each Film Coated Tablet Contains: Apixaban ..... 2.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at Room Temperature |
| | For generic drugs (me-too Status) | Apixaget 2.5mg |
| | Pharmacotherapeutic Group of (API) | B01AF02 Direct factor Xa inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | NA |
| | Detail of stability batches of drug product | 3 batches, 2500 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | AD attested invoice is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Apixaget 2.5mg Tablet B. No. 050FD4 Mfg M/s Getz |

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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MHRA |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 70 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HRM-8MY-HW28, 2024-05-27) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-15, |
| | The proposed proprietary name / brand name | **VOXETO 10MG TABLET** |
| | Label Claim | Each film coated tablet contains: Vortioxetine hydrobromide eq. to vortioxetine.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | Brintellix Tablet 10 Mg Registration Number 087081 |
| | Pharmacotherapeutic Group of (API) | Other antidepressants |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Proton Pharma Limited Solutions Ltd 1 Fine Chemical Zone Chongqing Chem IND Park Changshou Chongqing |
| | Detail of stability batches of drug product | 3 batches, 1500 tablets |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Taken loan from M/s Weatherfolds. Clearance certificate and loan letter is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Brintellix 10mg Tablet Mfg H.Lundbeck Denmark B. No. 2733585 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MHRA approved |
| | GMP status of the firm | Copy of GMP certificate is submitted. |
| | Evidence of approval of manufacturing facility | Renewal letter issued in 2016 is submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 71 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha **(000874)** |
| | Application Form Dy. No / Tracking ID & date of submission | (25Z-EBT-RTRN, 2024-10-10) |

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| | Detail of Fee Submitted | 37000.0,<br>2024-09-10, |
| | The proposed proprietary name / brand name | **setralet 100mg** |
| | Label Claim | Each film coated tablet contains: Sertraline hydrochloride eq. to Sertraline .....100mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 20,s 30,s 50,s 100,s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30 °C |
| | For generic drugs (me-too Status) | Biosert 100mg tablet by Ms bio lab |
| | Pharmacotherapeutic Group of (API) | N06AB06 Selective serotonin reuptake inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | indian source |
| | Detail of stability batches of drug product | 3 batches, 2500 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Zoloft 100mg Tablet |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | https://www.medicines.org.uk/emc/product |
| | GMP status of the firm | GMP certificate is submitted. |
| | Evidence of approval of manufacturing facility | Section approval letter dated 26 03 2018 is submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 72 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E4S-2HL-REYG, 2026-03-05) |
| | Detail of Fee Submitted | 38700,<br>2025-11-12, |
| | The proposed proprietary name / brand name | **Letrowen 2.5mg Tablets** |
| | Label Claim | Each film coated tablet contains: Letrozole .....2.5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1x10's; 3x10's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Lezra-Excel 2.5mg Tablets ( M/s Excel Healthcare (Pvt) Ltd ) |
| | Pharmacotherapeutic Group of (API) | aromatase inhibitor, Antineoplastic and immunomodulating agents L02BG04 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | WanYang Hengshui Pharmaceutical Co., Ltd |
| | Detail of stability batches of drug product | 3 batches, 1000 tablets each |
| | Documents for the procurement of API with approval from DRAP | Clearance certificate is submitted |

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| | (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Lezra-Excel 2.5mg tabs |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Subnitted |
| | The status in reference regulatory authorities | MHRA & FDA Approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section approval is submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 73 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WJG-L8V-QDLU, 2025-09-17) |
| | Detail of Fee Submitted | 37000.0, 1700<br>2025-06-19, 2025-09-10 |
| | The proposed proprietary name / brand name | **Clinda-P 2% Vaginal cream** |
| | Label Claim | Each gram Contains: Clindamycin phosphate eq. to Clindamycin .....20mg (USP specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C in a cool and dry place. |
| | For generic drugs (me-too Status) | CLYCIN-V BY SHAIGAN PHARMACEUTICALS (PVT.)LTD |
| | Pharmacotherapeutic Group of (API) | Antibiotic (Lincosamide) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | ZHEJIANG HISOAR CHUANNAN–PHARMACEUTICAL CO;(LTD) No.100 Waisha Branch Road, Jiaojiang District, Taizhou City, Zhejiang Province, P.R. China. |
| | Detail of stability batches of drug product | 50 PACKS FOR EACH BATCH. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | taken loan from M/s Neutro pharma. AD attested invoice and loan letter is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence and comparative dissolution profile is against CLYCIN-V BY SHAIGAN PHARMACEUTICALS (PVT.)LTD |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability studies are according to zone IV A. |
| | The status in reference regulatory authorities | USFDA approved |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |

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| 74 | Case Category | New License (Adil Saeed) |
| | Name, address of Applicant. | **AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T9Q-95D-HDU6, 2025-07-14) |
| | Detail of Fee Submitted | 37000.0,<br>2025-06-19, |
| | The proposed proprietary name / brand name | **CLINDA-P 1% TOPICAL GEL** |
| | Label Claim | Each gram contains: Clindamycin phosphate Equivalent to clindamycin....10 mg (USP specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | as per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C and dry place. |
| | For generic drugs (me-too Status) | CLINAGEL by GlaxoSmithKline Pakistan Limited |
| | Pharmacotherapeutic Group of (API) | D10AF01 Antiinfectives for treatment of acne |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | ZHEJIANG HISOAR CHUANNAN PHARMACEUTICAL CO;(LTD) No. 100 Waisha Branch Road, Jiaojiang District, Taizhou City, Zhejiang Province, P.R. China. |
| | Detail of stability batches of drug product | 50 Packs for each batch, 3 batches total |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | AD attested invoice is submitted, taken loan from M/s Neutro Pharma |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence and Comparative Dissolution is taken place Against CLINAGEL by GlaxoSmithKline Pakistan Limited B. No. XK2M |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability submitted of zone iv A. upto 36 months |
| | The status in reference regulatory authorities | FDA Approved. |
| | GMP status of the firm | New DML |
| | Evidence of approval of manufacturing facility | Semi solid general section approved vide letter dated 17.02.2023 |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 75 | Case Category | Any Other (Adil Saeed) |
| | Name, address of Applicant. | **Glitz Pharma** Plot No. 265, Industrial Triangle, Kahuta Road, Islamabad, Pakistan. **(000571)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y67-64V-RDYX, 2026-02-06) |
| | Detail of Fee Submitted | 38700,<br>2026-01-30, |
| | The proposed proprietary name / brand name | **Silitz 100mg Tablet** |
| | Label Claim | Each film-coated tablet contains: Sildenafil Citrate eq. to Sildenafil.....100mg |
| | Reference to Finished product specifications | United States Pharmacopeia |

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| | Proposed Pack Size | 1's-As per SRO,10's-As per SRO,2's-As per SRO,24's-As per SRO,4's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Controlled Room Temperature |
| | For generic drugs (me-too Status) | Attached (Hilagra 100mg Tablet by Hilton Pharma) |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase Type 5 (PDE5) Inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 2 batches, 5000 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate is submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Hilagra 100mg Tablet of M/s Hilton Pharma |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MHRA Reference Attached |
| | GMP status of the firm | Valid GMP certificate is submitted |
| | Evidence of approval of manufacturing facility | Section approval letter is submitted |
| | **Evaluation Remarks** | |
| | Priority as per decision of authority for applications of drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 76 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EJS-1Q1-QRZJ, 2024-10-30) |
| | Detail of Fee Submitted | 75000.0, 18000.0<br>2024-07-05, 2024-09-12 |
| | The proposed proprietary name / brand name | **Iromont 500mg/10ml Injection** |
| | Label Claim | Each 10ml Vial Contains: Ferric Carboxymaltose Equivalent to Iron....500mg (Innovators Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10ml x 1s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30 degree centigrade |
| | For generic drugs (me-too Status) | Feservoir 500mg/10ml Injection (Martin Dow) |
| | Pharmacotherapeutic Group of (API) | Iron preparation. |
| | Name, address of Manufacturing site: | GT Pharma (Pvt) Ltd.-Plot # 713-Sunder Industrial Estate, Lahore.- |
| | Name & address of API manufacturer | Nanjing Hencer Pharmaceutical Co. Ltd. (Address: No. 18 Jichang Road, Lishui Economic & Technological Development Zone, Nanjing City, Jiangsu Province, China.) |
| | Detail of stability batches of drug product | 3 batches, 100 vials each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate is submitted. Taken loan from M/s Cunningham |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Feservoir 500mg/10ml inj B. No. L22028 M/s Martin Dow |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MHRA |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 77 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y5B-UMT-HVPA, 2024-07-23) |
| | Detail of Fee Submitted | 30000.0,<br>2023-02-22, |
| | The proposed proprietary name / brand name | **Diosone 500mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains: Micronized purified flavonoid fraction ..... 500 mg Corresponding to:<br>Diosmin..... 450 mg<br>Hesperidin..... 50 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°c |
| | For generic drugs (me-too Status) | DISPEDROL Tablet by MEEZAB INT HYDERABAD |
| | Pharmacotherapeutic Group of (API) | VASCULOPROTECTANTS / CAPILLARY-ACTING DRUGS / BIOFLAVONOIDS, ATC code: C05CA53: cardiovascular system. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Hunan Yuantong Pharmaceutical Co., Ltd No. 747, Kangwan Road, Liuyang Economic Development Zone, Changsha City, Hunan Province, P. R. China |
| | Detail of stability batches of drug product | 3 batches, 1200 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Drug Import license is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Daflon 500mg Tablets B. No. 51199 Servier Pharmaceutical Lahore |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | http://agence-prd.ansm.sante.fr/php/ecodex/extrait.php?specid=60064527 |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |

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| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Approved** | |
| 78 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PGJ-W92-R8G5, 2024-06-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-03-04, |
| | The proposed proprietary name / brand name | **Neuvanco 1gm Powder for solution for Injection** |
| | Label Claim | Each vial contains Vancomycin Hydrochloride eq. Vancomycin.....1000 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 01-As per SRO |
| | Shelf Life (Unit) | 18 Month(s)Store between 15 - 30°C in a dry place, protect from light |
| | For generic drugs (me-too Status) | Vancomycin HCl Injection by Abbot |
| | Pharmacotherapeutic Group of (API) | J01XA01 Glycopeptide antibacterials |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd. Address: No. 8 Nangang Road, Jiangyin Industrial Concentration Zone, Fuqing, Fuzhou City, Fujian Province, P. R. China |
| | Detail of stability batches of drug product | 3 batches, 300 vials each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | AD attested invoice is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Vinjec 1000mg Injection B. No. VN230022 Mfg M/s Bosch Pharma Pvt. Ltd. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 5C upto 36 months |
| | The status in reference regulatory authorities | Vancocin CP by Aspen Pharmacare |
| | GMP status of the firm | Copy of GMP certificate issued on basis of inspection dated 14.04.2022 is submitted |
| | Evidence of approval of manufacturing facility | Section approval letter dated 29.01.2019 is submitted, |
| | **Evaluation Remarks** | |

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| Application fulfils codal formalities. |
| Application was deferred in 353rd meeting of Registration board with following decision; |
| The board deferred the case for further deliberation regarding manufacturing of vancomycin in general powder injectable section. The firm shall be asked to provide evidence of practices of RRA countries regarding this product i.e. whether vancomycin injection is manufactured in general injectable section or otherwise. |
| The firm was asked for clarification and have submitted following response; |
| "In Reference Regulatory Authority (RRA) countries—including the USA (FDA), European Union (EMA), UK (MHRA), and Canada (Health Canada)—Vancomycin Injection is typically manufactured in general injectable sections. Unlike highly sensitizing agents like penicillins or cephalosporins, Vancomycin is not subject to mandatory facility segregation.Regulatory Classification: RRAs like the US FDA (21 CFR 211.42) and EMA only mandate dedicated facilities |

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| | for specific classes (e.g., certain beta-lactams, cytotoxics, and radiopharmaceuticals). Vancomycin, a glycopeptide, falls under "General Products".DRAP already register vancomycin hcl Injection in general dry pwoder injection section." | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 79 | Case Category | New Section (Adil Saeed) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2J8-LWP-PWJ7, 2026-02-10) |
| | Detail of Fee Submitted | 75000,<br>2025-08-07, |
| | The proposed proprietary name / brand name | **Lovaz 1g Soft Gelatin Capsule** |
| | Label Claim | Each Capsule Contains: omega-3-acid ethyl ester liquid concentrate 1 gram eq. to 900mg omega-3-acid ethyl esters. Eicosatetraenoic acid (EPA) ethyl ester: 465 mg and Docosahexaenoic acid (DHA) ethyl ester: 375 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 120's-As per SRO,30's-As per SRO,60's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | NIL |
| | Pharmacotherapeutic Group of (API) | C10AX06 Antilipemic or lipid-regulating agents |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | KinOmega Biopharm Inc. & No. 161, South Yinghuashan Road Shifang, Deyang City Sichuan, China 618400 |
| | Detail of stability batches of drug product | 3 batches, 900 capsules each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6 is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Lovaza 1g softgel capsule B. No. B-LB1084 Mfg Waylis Therapeutics USA |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Zone IVa, upto 36 months. |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Copy of GMP certificate issued on basis of inspection report dated 03.01.2023 is submitted. |
| | Evidence of approval of manufacturing facility | Softgel section approved vide letter dated 18.05.2021. Renewal letter dated 03.03.2023 also mentions it. |
| | **Evaluation Remarks** | |
| | Application was deferred in 357th meeting of Registration board with following decision; "Deferred for submission of comparative dissolution profile (CDP)." | |
| | Firm has submitted CDP of their product against Lovaza Capsules 1g, Batch No. B-LB1084 Waylias Therapeutics USA. | |
| | Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |

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| | **Deferred**<br><br>Deferred for submission of RMP. | |
| 80 | Case Category | Routine (Adil Saeed) |
| | Name, address of Applicant. | **Health Hub Pakistan** House# 397, South Service Road Sector I-14/4 Islamabad Pakistan **(whole sale/8c-2T2Mu8p4)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6QU-ZN4-JNG7, 2026-02-03) |
| | Detail of Fee Submitted | 300000.0,<br>2025-06-11, |
| | The proposed proprietary name / brand name | **Imiro 350 100ml** |
| | Label Claim | Each 100ml contains; Iohexol 75.5gm eq. to Iodine .....35gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100 ml-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)25°C |
| | For generic drugs (me-too Status) | Omnipaque |
| | Pharmacotherapeutic Group of (API) | V08AB02 Contrast Media |
| | Name, address of Manufacturing site: | Popular Pharmaceuticals PLC.-164, Tongi Industrial Area, Gazipur 1711 -Bangladesh |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | OMNIPAQUE 350 Injection, GE Healthcare Ireland Limited, Cork, Ireland |
| | Name, address of Marketing Authorization Holder: | Health Hub Pakistan, House# 397, South Service Road I-14/4 Islamabad Pakistan, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | COPP and GMP certificate are susbmitted. |
| | Details of Authorization Letter : | NA |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted. |
| | The status in reference regulatory authorities | MYANMAR |
| | **Evaluation Remarks** | |
| | The firm has submitted long term stability data upto 12 months' time point. Application fulfills codal formalities. Recommended for consideration of board. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of complete stability data up to claimed shelf life of finished drug product. | |
| 81 | Case Category | Short Availability Drugs (Adil Saeed) |
| | Name, address of Applicant. | **Health Hub Pakistan** House# 397, South Service Road Sector I-14/4 Islamabad Pakistan **(whole sale/8c-2T2Mu8p4)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5NS-3H1-YQQP, 2025-09-30) |
| | Detail of Fee Submitted | 300000.0,<br>2025-05-21, |
| | The proposed proprietary name / brand name | **Imiro 350** |
| | Label Claim | iohaxol 350 mg/5ml USP |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50 ML-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)25°C |

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|---|---|---|
| | For generic drugs (me-too Status) | Omnipaque |
| | Pharmacotherapeutic Group of (API) | Contrast Media |
| | Name, address of Manufacturing site: | Popular Pharmaceuticals PLC.-164, Tongi Industrial Area, Gazipur 1711 -Bangladesh |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | OMNIPAQUE 350 mg/ml injection 500ml Mfg GE Healthcare Ireland Limited, Cork, Ireland |
| | Name, address of Marketing Authorization Holder: | HEALTH HUB PAKISTAN, House# 397, South Service Road I-14/4 Islamabad Pakistan, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | Valid |
| | Details of Authorization Letter : | NA |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MYANMAR |
| | **Evaluation Remarks** | |

| Observation | Response |
|---|---|
| Although applicant have submitted Module 1 2 &3 but has filled and signed Form 5A instead ofForm 5F. As per current Rules, firm cannot applyon Form 5A for registration of imported druguntil any relaxation is granted by the Authority.In this case there is no relaxation and applicanthas applied on an incorrect form. | Firm has again submitted full fee for registrationalong with signed Form 5F. |
| 3.2.P.2.2 pharmaceutical equivalence is not submitted. An explanation is attached in dossier wherein its mentioned that they have used same formulation as innovator product except HCl for pH adjustment and both products are same, indicating firm has not performed pharmaceutical equivalence | Firm has submitted new product development data dated 02.04.2026. In new data pharmaceutical equivalence is performed against OMNIPAQUE 500 ml |
| 3.2.P.8 Claimed shelf life is 24 months, stability data only up to 18 months is submitted. | Stability data of 3 batches upto 24th month timepoint is submitted |
| Application was deferred in 354th meeting with following decision; Deferred for submission ofrequisite information. | |
| Application fulfills codal formalities. Recommended for consideration of board. | |

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| | **Decision** | |
| | **Approved**<br><br>As per policy for inspection abroad. | |
| 82 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EVB-G83-53HN, 2024-10-18) |
| | Detail of Fee Submitted | 30000.0, 30000.0<br>2024-08-27, 2024-08-27 |
| | The proposed proprietary name / brand name | **Thiocol 4mg Capsule** |

| | | |
|---|---|---|
| | Label Claim | Each Capsule Contains: Thiocolchicoside ..... 4mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2 x 10's -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C , protect from light |
| | For generic drugs (me-too Status) | Muscoril 4mg Capsule |
| | Pharmacotherapeutic Group of (API) | g-aminobutyric acid A (GABA-A) receptors agonist |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Sarv BioLabs Pvt. Limited |
| | Detail of stability batches of drug product | 3 batches having batch size of 1000 capsule each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted copy of clearance certificate dated 26-01-2023 specifying 0.200kg Thiocolchicoside. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Muscoril 4mg capsule by M/s Sanofi-Aventis Pakistan |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per zone IV |
| | The status in reference regulatory authorities | EMA, MHRA, Italian Medicines Agency (AIFA) |
| | GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 28-02-2024. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 17-09-2021 specifying Capsule (General) Section. |
| | **Evaluation Remarks** | |

| Shortcomings | Firm's Response |
|---|---|
| Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer valid upto 09-09-2027. |
| Pictorial evidence of innovator's product/comparator's product including details of name of MAH, batch number, manufacturing date and expiry date against which PE & CDP studies has been submitted is required | Pictorial evidence of innovator's product/comparator's product is submitted |
| Submit the CDP studies of applied product conducted in three physiological media (pH 1.2, pH 4.5, and pH 6.8), including individual and mean dissolution data and standard deviations comparing test and reference products. | CDP studies of applied product in pH 1.2, pH 4.5, and pH 6.8, including individual and mean dissolution data with standard deviations for test and reference products is submitted |

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| | **Decision** | |
| | **Approved** | |
| 83 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DVY-5U7-YL5E, 2024-08-09) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-29, |
| | The proposed proprietary name / brand name | **Thiowel 4mg Capsules** |
| | Label Claim | Each Capsule Contains;<br>Thiocolchicoside.....4mg (Innovator Spec's) |

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|---|---|
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | As per SRO-As per SRO |
| Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| For generic drugs (me-too Status) | Thicocid 4mg capsules, Manufacturer: Albert Pharma (Pvt.) Limited |
| Pharmacotherapeutic Group of (API) | Centrally Acting Myorelaxant |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Alkaliods Private Ltd. |
| Detail of stability batches of drug product | 3 batches having batch size of 1500 capsule each |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted a request letter for borrowing of API (indicating Thiocolchicoside 0.05kg) and loan agreement between M/s Solaris life sciences and M/s Seraph pharmaceuticals for API loan. Firm has also submitted copy of intimation letter submitted in DRAP. Firm has submitted copy of clearance certificate dated 06-09-2023 specifying 02kg Thiocolchicoside in name of M/s Seraph Pharmaceuticals |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Thiocid 4mg capsule by M/s Sanofi Aventis limited |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| The status in reference regulatory authorities | Miorel 4mg capsule, Laboratories(ANSM France Approved) |
| GMP status of the firm | New DML issued dated 17-01-2024 |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Capsule Section-I (General). |

**Evaluation Remarks**

The European Medicines Agency's Committee on Human Medicinal Products (CHMP) hasrecommended that the authorised uses for thiocolchicoside-containing medicines for use by mouthor injection should be restricted across the European Union (EU). These medicines are nowrecommended only as an add-on treatment for painful muscle contractures (permanent tightening ofthe muscle tissue) resulting from spinal conditions in adults and adolescents 16 years of age or older.In addition, the dose of thiocolchicoside by mouth or injection should be restricted. The review ofthiocolchicoside was triggered by the Italian medicines regulatory agency, AIFA, following newexperimental evidence which suggested that thiocolchicoside was broken down in the body into ametabolite called M2 or SL59.0955 that could damage dividing cells, resulting in aneuploidy (anabnormal number or arrangement of chromosomes). As a result AIFA asked the CHMP to examinethe safety profile of this medicine and consider what regulatory action might be appropriate. TheCHMP reviewed the evidence, including the opinions of experts in the field of medicines safety, andconcluded that aneuploidy could occur with M2 at levels not much greater than those seen afterrecommended doses of thiocolchicoside taken by mouth. Aneuploidy is a risk factor for harm to thedeveloping fetus, reduced fertility in men and in theory could increase the risk of developing cancer.The CHMP therefore recommended measures to ensure thiocolchicoside-containing medicines areused as safely as possible. These include restricting the maximum dose and number of days oftreatment when given by mouth or injection. Use is also contra-indicated in pregnancy and lactationor in women of childbearing potential not using contraception, as well as in children or for chronic(long-term) conditions.

| Shortcomings | Firm's Response |
|---|---|
| Copies of drug substance specifications and analytical procedure duly signed by drug substance manufacturer on their letterhead are required | Not submitted |

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| | Clarification is required, as the batch number of API mentioned in COA provided by drug product manufacturer differs from the batch number provided in COA by API manufacturer. | The Batch Number of API Witten in analytical report was incorrect, the revised analytical report with corrected batch number is submitted |
| | Submit complete details of the innovator/comparator product used in PE and CDP studies, including batch number, manufacturing date, expiry date, and marketing authorization holder. Further, clarify the discrepancy in the stated MAH, which is mentioned as Sanofi Aventis Limited at one place and Albert Pharmaceutical at another. | Revised CDP studies including batch number, manufacturing date, expiry date, and manufacturer details are enclosed in Revised module-III. The reference product used in CDP was Muscoril manufactured by Sanofi Aventis limited as mentioned in attached chromatograms, thiocid manufactured by Albert pharma was purchased alternated brand for physical description and not used in CDP |
| | The firm submitted chromatograms bearing the name of a specific analyst. During the evaluation of dossiers submitted by other applicants, it was observed that identical chromatographic data, including the same analyst's name, had also been submitted in those applications. Accordingly, the firm was asked to provide the list of technical staff working in the R&D and Quality Control departments, along with copies of their appointment letters, from January 2024 to date, in order to verify the authenticity of the submitted data. It is pertinent to mention that the other applicants who had submitted the same data subsequently withdrew their applications, which were accordingly rejected. M/s Solaris, however, did not withdraw its application and submitted the requested list of technical staff. Upon review, it was observed that the name of the analyst appearing on the submitted chromatograms is not included in the list of technical personnel provided by the firm. In view of the above discrepancy and concerns regarding the authenticity and ownership of the submitted analytical data, the case is placed before the Registration Board for consideration. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for verification of employment of analyst details present in the chromatograms submitted with the dossier | |
| 84 | Case Category | Contract Manufacturing (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **UniMark Pharmaceuticals Pvt. Ltd.** Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat **(000557)** |
| | Application Form Dy. No / Tracking ID & date of submission | (V5M-E2D-GQ83, 2024-08-09) |
| | Detail of Fee Submitted | 75000.0,<br>2024-05-29, |
| | The proposed proprietary name / brand name | **Irosar 100mg/5ml Injection** |
| | Label Claim | Each 5ml ampoule contains:Iron (III) hydroxide sucrose equivalent to elemental iron..... 100mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 5ml X 5s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)15° to 25°C |
| | For generic drugs (me-too Status) | G-Fer Injection of Global Pharma |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/S Seraph Pharmaceuticals-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan- |
| | The status in reference regulatory authorities | Venofer Injection MHRA approved |
| | Detail of previous approval | Seros-IV 100mg/5ml Injection; 119th PRVC meeting |
| | **Evaluation Remarks** | |
| | The application fulfils codal formalities and is submitted for consideration of Registration Board. | |

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| | **Decision** | |
| | **Approved** | |
| 85 | Case Category | New Section (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Skywin Pharmaceuticals Pvt. Ltd** Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road **(000971)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MDW-8U4-UTAS, 2025-07-24) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-07, |
| | The proposed proprietary name / brand name | **Sky-Ject 50mg+5mg/ml solution for Injection** |
| | Label Claim | Each ml contains Norethisterone Enanthate .....50mg Estradiol Valerate.....5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x 1ml-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature below 30 |
| | For generic drugs (me-too Status) | Norifam Injection 50mg+5mg/ml Solution for I.M. of M/s Zafa Pharmaceutical Laboratories |
| | Pharmacotherapeutic Group of (API) | Norethisterone Enanthate : Progestogens<br>Estradiol: Estrogen |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zhejiang Xianju Junye Pharmaceutical Co., Ltd. Address: No.1 Lingxiu Road, Modern Industrial Centralization Zone, Xianju, Taizhou, |
| | Detail of stability batches of drug product | 3 batches having batch size of 1500 ampoules each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted loan letter from Hansel Pharmaceuticals for procurement of Norethisterone Enanthate, MOU between the firm, form 5 and copy of attested invoice. Firm has submitted loan letter from Wnsfield Pharmaceuticals for procurement of Estradiol Valerate, MOU between the firm, loan intimation letter submitted in DRAP and copy of clearance certificate dated 20-12-2022 specifying 01kg Estradiol Valerate in the name of Wnsfeild Pharmaceuticals |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Norefam Injection |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| | The status in reference regulatory authorities | Estradiol valerate/Norethisterone enantate Solution for injection 5mg/50mg/mL, WHO Approved. |
| | GMP status of the firm | New section |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of grant of additional section dated 26-01-2024 specifying Liquid Injection Ampoule (Hormone) Steroidal. |
| | **Evaluation Remarks** | |

| Shortcomings | Firm's response |
|---|---|
| Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant | Firm has submitted copy of DML of API manufacturer issued by Zhejiang Drug |

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| | regulatory authority of country of origin is required | Administration China valid upto 21-04-2029 |
| | Clarify why Module II has been submitted on the letterhead of Wimits Pharma. | Module II from skywin pharmaceuticals has been submitted |
| | Details of innovator/comparator product including name of marketing authorization holder, batch No#, manufacturing date and expiry date shall be submitted | Firm has submitted details of comparator product. Brand Name: Norifam Injection 50mg+5mg/ml Solution for I.M. Manufacturer Name/Registration holder: M/s Zafa Pharmaceutical Laboratories (Private) Limited, Pakistan. Address: L-4/1, A & B Block-21 Federal B Industrial Area, Karachi Batch No: 387 Mfg Date: 01-23 Exp. Date: 01-28 |
| | Compliance Record of HPLC Software 21CFR & Audit Trail Reports on Product Testing is required | Submitted |
| | | |
| | **Decision** | |
| | **Rejected**<br><br>The Registration Board rejected the application due to the firm's failure to satisfactorily clarify the submission of Module II on the letterhead of another firm. | |
| 86 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **GT Pharma Pvt. Ltd** 713- Sundar Industrial Estate, Sundar Raiwind Road, **(000829)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HGQ-UQG-3366, 2024-06-13) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-23, |
| | The proposed proprietary name / brand name | **G-Azithro Single Dose 1g Packet** |
| | Label Claim | Each Packet Contains: Azithromycin dihydrate eq. to Azithromycin 1g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO,10's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Controlled Room |
| | For generic drugs (me-too Status) | Qu-Zith 1g Sachet by M/s Quaper pvt Ltd |
| | Pharmacotherapeutic Group of (API) | Macrolide |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Citi Pharma |
| | Detail of stability batches of drug product | 3 batches having batch size of 500 sachet each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted that API was obtained from citi pharma for trial, testing and assessment purpose free of cost and received through TCS and submitted purchase order |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against Qu-Zith sachet 1000mg |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A |
| | The status in reference regulatory authorities | ZITHROMAX 1gm/packet for suspension USFDA Approved |
| | GMP status of the firm | The firm has submitted panel inspection report dated 17-11-2023 for issuance of a cGMP certificate, concluding that the facility is operating at a satisfactory level of GMP compliance. |

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| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of renewal of DML dated 10-03-2022 specifying Sachet (General) section. |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
|---|---|
| Submit evidence of RRA of applied product as the submitted evidence has been discontinued | We would like to formally bring to your kind attention the following technical and regulatory justifications to support the approval of our dossier despite the recent update from the US FDA: 1. Non-Safety Related Discontinuation by US FDA: The reference product for Azithromycin 1g oral powder/sachet was originally approved by the US FDA based on established safety and efficacy profiles. Its subsequent transition to the "Discontinued" list by the FDA is strictly due to commercial or marketing decisions by the innovator/sponsor, and not due to any reasons relating to safety, quality, or therapeutic efficacy. No safety alerts recalls have been issued against this strength. 2. Compliance with Official Pharmacopeial Monographs: The active pharmaceutical ingredient (API), Azithromycin Dihydrate, remains a fully recognized and official entity in global standards, including the current United States Pharmacopeia (USP) and British Pharmacopoeia (BP). Our finished product strictly complies with these validated pharmacopeial testing methods, ensuring top-tier Quality Control (QC) and Quality Assurance (QA) compliance. 3. Therapeutic Value and Patient Compliance: The 1g sachet formulation provides a critical single-dose therapeutic regimen for specific indications (such as uncomplicated chlamydial urethritis and cervicitis) which is also recommended by WHO. This high-strength sachet significantly enhances patient compliance compared to multiple split-dose tablets, making it a vital tool for healthcare providers in Pakistan. 4. Commitment to Post-Market Surveillance: GT Pharma Pvt. Ltd guarantees strict adherence to local regulatory guidelines. We commit to executing rigorous post-market surveillance and pharmacovigilance protocols to continuously monitor the product's safety and efficacy profile once registered. |
| Clarification is required since you have claimed for USP specifications for drug substance but the selected chromatographic conditions for assay test are different than USP monograph | The firm submitted that in the Standard Analytical Procedure (SAP) for Azithromycin Dihydrate, the Chromatographic condition was incorrect due to Typo error. We would like to clarify that this was a documentation error only. Material was tested as per Pharmacopeial chromatographic condition, which has been consistently used during method verification (which can be verified through Protocol and Report attach in Module 3) and routine analysis. The SAP has now been Revised to reflect the accurate chromatographic condition. |
| Submit a reference or regulatory guideline supporting the non-requirement of CDP (Comparative Dissolution Profile) studies for Azithromycin for Oral Suspension. | Firm has submitted CDP of applied product against Qu-Zith 1g sachet |

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| | Submit details of comparator's product including name of manufacturer, batch number, manufacturing date and expiry date against which CDP studies has been performed | Firm has submitted details of comparator's product. Comparator Product Name; QU-Zith Sachet 1g Manufacturer Name; Quaper (Pvt.) Ltd. Batch Number; AX2432; Manufacturing Date; 09-2024; Expiry Date; 09-2026 |
| | Clarify why innovator's specifications have been claimed when a BP/USP monograph for Azithromycin for Oral Suspension is available. | This is to clarify that the dossier for G-azithro sachet 1g(Azithromycin) was initially prepared and submitted by following the Me-Too product specifications (QU-ZITH Sachet), as the said product is available in the local market with innovator specification(Issued by Drap) and was used as a reference at the time of dossier submission. That's why we applied our product with innovator specification. Although we are testing as our product G-azithro sachet almost as per USP(Assay). But in order to align our product quality standards with internationally recognized pharmacopoeial, we have now shifted the analytical specifications and test methods from the innovator specifications to the USP monograph. (SAP attached) The change has been implemented to ensure: Compliance with official pharmacopeial standards Enhanced regulatory acceptability Consistency in quality, safety, and efficacy of the finished product It is hereby confirmed that this change in specifications does not affect the formulation, manufacturing process, or intended use of the product as we have performed test on 3 Trial batches at On-going stability Study (23 Month). Results are showing our product is stable and meet specifications as USP. All quality attributes of the G-Azithro sachet continue to comply with the approved requirements. Firm has submitted Rs. 9400/- for revision of specifications on deposit slip#54155869 |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Registration Board in its 275th meeting. | |
| 87 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AYR-TLU-PS9J, 2024-08-28) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-25, |
| | The proposed proprietary name / brand name | **I-SUC Tablet** |
| | Label Claim | Each Chewable Tablet Contains Iron (III) Hydroxide Polymaltose Complex Equivalent to Elemental Iron 100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 3 x 10's -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C , protect from light |
| | For generic drugs (me-too Status) | Ferosoft 100mg Tablet |
| | Pharmacotherapeutic Group of (API) | |

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| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Chemiworld Private Limited |
| Detail of stability batches of drug product | 3 batches having batch size of 2100 tablets each |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted copy of clearance certificate dated 26-01-2023 specifying 0.200kg Thiocolchicoside. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against Ferosoft tablets 100mg by M/s Hilton Pharma |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per zone IV |
| The status in reference regulatory authorities | TGA, MHRA |
| GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 28-02-2024. |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 17-09-2021 specifying Tablet (General) Section. |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
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| Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer based on inspection dated 29-11-2016. Firm has also submitted copy of request letter dated 14-01-2020 for issuance of cGMP. Firm has submitted copy of DML issue/renewal dated 19-07-2017. Firm has also submitted copy of letter of constitution of panel dated 07-08-2025 issued by Licensing Division. |
| CDP studies of applied product against the innovator's/comparator's product in three physiological media is required | The applied product is a chewable tablet. As per USP guidance, there is no general requirement for all chewable tablets to undergo dissolution testing. Dissolution testing is required only when specified in the applicable individual USP monograph. Since no such monograph requirement exists for the applied product, Comparative Dissolution Profile (CDP) studies in three physiological media were not performed. Furthermore, to demonstrate comparability with the comparator product, a Pharmaceutical Equivalence Study has been conducted, and the relevant report is submitted. |
| Justify the use of Sodium Cyclamate, a banned excipient, in the proposed formulation and provide supporting scientific and regulatory evidence for its inclusion. | Sodium Cyclamate (E952) has been included in the proposed formulation as a sweetening agent to improve the palatability of the chewable tablet and to ensure patient acceptability. Its use is based on the composition of the innovator product, Ferofix 100 mg Chewable Tablets, which also contains Sodium Cyclamate (E952) as an excipient. A copy of the innovator's SmPC/composition is attached for your review as Annexure-1. Innovator Product link https://share.google/LUXC6hNAHx2OsIogj<br>Furthermore, Sodium Cyclamate (E952) is not a globally banned excipient. It is an approved food additive and pharmaceutical excipient in many countries, including the European Union and Canada. Its safety has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which has established an Acceptable Daily Intake (ADI), confirming its safe use within the recommended limits. The quantity of Sodium Cyclamate (E952) used in the proposed formulation is within the acceptable safety limits and is intended solely to enhance the taste and patient compliance of the chewable tablet. |

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| | Clarify the real time stability conditions of 30 ± 2 ºC, RH 55 ± 5 % mentioned in stability summary sheets | The stability condition of 30 ± 2°C / RH 55 ± 5% mentioned in the real-time stability summary sheets was due to a typographical error. This has now been corrected. The updated real-time stability summary sheets, reflecting the correct stability conditions, are attached herewith for your review and is attached |
| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the application for revision of formulation by replacing the banned excipient and submission of revised formulation along with all relevant supporting pharmaceutical development and stability study data. | |
| 88 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Pacific Pharmaceutical Ltd** 30 km Multan Road Lahore **(000295)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DYW-P1P-5Z1W, 2024-08-26) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-20, |
| | The proposed proprietary name / brand name | **Sofosbuvir 400mg film coated Tablet** |
| | Label Claim | Each film coated Tablet contains:<br>Sofosbuvir.....400mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 28s-As per SRO |
| | Shelf Life (Unit) | 3 Year(s)below 30°C |
| | For generic drugs (me-too Status) | Fosbu Tablet 400mg by Highnoon Pharma |
| | Pharmacotherapeutic Group of (API) | Antivirals for systemic use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zhejiang Hongyuan Pharmaceutical Co Ltd Chem & API Industrial Zone Linhai, Zhejiang P.R. China |
| | Detail of stability batches of drug product | 03 batches having batch size of 2200 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of commercial invoice cleared by AD (I&E) DRAP dated 09-06-2020 specifying 04kg Sofosbuvir |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE & CDP studies performed against Sovaldi 400mg tablets |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | stability study data of drug substance as per zone IV till 12th months is submitted |
| | The status in reference regulatory authorities | Sovaldi 400 mg film coated tablets by Gilead Sciences Limited USFDA Approved |
| | GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 15-07-2025. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of renewal of DML dated 31-07-2025 specifying Tablet Section (General). |
| | **Evaluation Remarks** | |
| | Shortcomings | Firm's Response |
| | Clarification shall be submitted as manufacturer's specifications have been applied despite the availability of monograph for the applied product in the International Pharmacopoeia (IP). Provide a comparative table demonstrating that the proposed specifications are equal to or more | Firm has submitted revised finished product specifications and analytical procedure as per International Pharmacopoeia (IP) along with submission of Rs. 9400/- on deposit slip#792266244682. |

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| | stringent than the IP specifications. Otherwise, revise the specifications in accordance with the IP monograph and submit the applicable fee. | |
| | Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer issued by Linhai Medical and Chemical Industry Administration China valid upto 09-03-2028 |
| | Stability study data of three batches of API as per zone IV till claimed shelf life shall be submitted | We respectfully state that submitted API Stability is as per Zone IV-A conditions. We have formally requested our API manufacturer/supplier to provide the updated stability study data of three production batches covering the claimed shelf life. The supplier is currently in the process of compiling the required data. We hereby undertake and commit that the complete updated stability study data will be submitted to DRAP immediately upon receipt from the API manufacturer/supplier. |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of following;<br><br>1. Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin<br>2. Stability study data of three batches of API as per zone IV till claimed shelf life | |
| 89 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Herbion Pakistan (Pvt.) Ltd.** Industrial Triangle, Kahuta road, Humak, Islamabad **(000795)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QGH-LDW-EH3R, 2024-07-18) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-20, |
| | The proposed proprietary name / brand name | **Lira 2.5 mg Tablet** |
| | Label Claim | Each film coated tablet contains: Letrozole------ 2.5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 3x10s-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25-30 |
| | For generic drugs (me-too Status) | Femara 2.5 mg Tablet |
| | Pharmacotherapeutic Group of (API) | Aromatase Inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Lianyungang Guike Pharmaceutical Co. Ltd. No.1, Xianfeng Road, Dapu Industry Zone, Economic & Technical Development Area, Lianyungang City, Jiangsu, China. |
| | Detail of stability batches of drug product | 3 batches having batch size 1000 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of form 6 issued dated 07-03-2023 specifying 500gm Letrozole. Firm has also submitted copy of invoice, packing list, form 3, form 7, airway bill and goods declaration |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Femara 2.5mg tablets by M/s Novartis Pharma |

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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | stability study data of 03 batches of drug substance as per zone IV is submitted |
| | The status in reference regulatory authorities | Femara film coated Tablet 2.5 mg by Novartis Approved by USFDA Approved |
| | GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 02-07-2024. |
| | Evidence of approval of manufacturing facility | Renewal of DML submitted specifying tablet general section |
| | **Evaluation Remarks** | |
| | Shortcomings | Firm's Response |
| | Details of Sacubitril sodium and valsartan are given in table b) Identify available literature reference for the Drug Substance and Drug Product of module II, clarify | The firm submitted that it was Typo error in Module II in substance name. Firm has submitted corrected revised module II. |
| | The statement "As the formulation of Lira 2.5 mg Tablet (Sacubitril Valsartan Sodium) is same to that of the innovator brand "Femra 2.5 mg Tablet" is written in section 3.2. P.2.1.1 Active Pharmaceutical Ingredient module III, clarify | The firm submitted that it was Typo error in Module III in substance name. |
| | Pictorial evidence of innovator's product/comparator's product including details of name of MAH, batch number, manufacturing date and expiry date against which CDP studies has been submitted is required | Pictorial evidence of innovator's product/comparator's product is submitted Product Name; Femaar2.5mg tablet Batch#TJC77; Mfg date; 10-2020; Exp date; 09-2025 Name of MAH; Novartis Pharma Switzerland |
| | Clarification shall be submitted for not including uniformity of dosage units i.e. content uniformity in finished product specifications as per USP monograph | The Content Uniformity test as per USP was already included in the testing method and is being performed during analysis. However, it was unintentionally missed while preparing the finished product specification document. This omission was only a documentation oversight and does not affect product quality or compliance. The product has been evaluated according to the required standards. The specification has now been corrected to include the Content Uniformity parameter. |
| | **Decision** | |
| | **Approved** | |
| 90 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Helix Pharma (Pvt)., Ltd.** Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 **(000030)** |
| | Application Form Dy. No / Tracking ID & date of submission | (56W-1D4-EJE5, 2024-10-22) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-30, 2024-10-10 |
| | The proposed proprietary name / brand name | **TAPENDA IR Tablets 50mg** |
| | Label Claim | Each film coated tablet contains: Tapentadol HCl eq. to Tapentadol ..... 50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's,10's,14's,20's,2-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store below 30C |
| | For generic drugs (me-too Status) | Available ; Tapento IR Tablets by SAMI Pharma |

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| | Pharmacotherapeutic Group of (API) | Opiate analgesics. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Ami Lifesciences Private Limited (ALPL) |
| | Detail of stability batches of drug product | 03 batches having batch size of 1000 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | form has submitted copy of form 6, commercial invoice, packing list, form 3, form 7 and airway bill for procurement of API. Firm has also submitted copy of goods declaration |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE & CDP performed against Tapento IR Tablet 50mg |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| | The status in reference regulatory authorities | Nucynta® Tablets 50mg approved by USFDA |
| | GMP status of the firm | Firm has submitted copy of cGMP certificate based on inspection dated 07-03-2024 |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of regularization of section dated 28-12-2020 specifying Tablet (General) Section. |
| | **Evaluation Remarks** | |
| | Shortcomings | Firm's Response |
| | Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer valid upto14-04-2028. |
| | Pictorial evidence of innovator's product/comparator's product including details of name of MAH, batch number, manufacturing date and expiry date against which PE & CDP studies has been submitted is required | Pictorial evidence of innovator's product/comparator's product is submitted. Product Name; Tapento IR Batch#001K; Mfg date; 01-2023; Exp date; 12-2024 Name of MAH; Sami Pharmaceuticals |
| | The application fulfils codal formalities is submitted for consideration of Registration Board | |
| | **Decision** | |
| | **Approved** | |
| 91 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Hi-Med Pharmaceuticals** 208C Sundar industrial estate Raiwind Road Lahore **(000884)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NMR-4WU-J7R2, 2024-10-31) |
| | Detail of Fee Submitted | 30000.0,<br>2023-06-15, |
| | The proposed proprietary name / brand name | **Thiomed** |
| | Label Claim | Each Capsule Contains Thiocolchicoside....4mg<br>As per Innovators Specs |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 20s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Not More Than 30 Degree |
| | For generic drugs (me-too Status) | Relxo 4mg Capsule Reg No. 092216 |
| | Pharmacotherapeutic Group of (API) | Muscle Relaxant |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Sarv Bio Labs |
| | Detail of stability batches of drug product | 3 batches having batch size of 34000 capsule each |
| | Documents for the procurement of API with approval from DRAP | Firm has submitted copy of invoice cleared by AD I&E DRAP dated 24-11-2021 specifying |

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| (in case of Import) | 02kg Thiocolchicoside. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against Relxo 4mg capsule by M/s Medpharm Research Lab |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per Zone II till 6th months |
| The status in reference regulatory authorities | RRA Approved |
| GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 23-09-2024. |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 13-06-2018 specifying Capsule (General) Section. |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
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| Copy of executed BMR is required | Not submitted |
| Analytical method verification of drug substance performed by drug product manufacturer is required | Not Submitted |
| Submit stability study data of API as per Zone IV conditions till claimed shelf life, shall be submitted | Submit stability study data of 03 batches of API at accelerated conditions is submitted only |
| CDP studies of applied product against the innovator/comparator's product is required | PE report is submitted instead of CDP studies |
| Chromatograms submitted in pharmaceutical equivalence study, method validation and stability study data contains name of Zhejiang university, clarify | The chromatograms submitted as part of the Pharmaceutical Equivalence Study, Analytical Method Validation, and Stability Study contain the name Zhejiang University because the chromatographic software used for data acquisition and processing was developed by Zhejiang University. The software automatically displays the developer's name on all chromatograms and printed reports as a standard feature. As previously stated, screenshots of the software interface are attached for your kind reference. The presence of the name "Zhejiang University" on the chromatograms is solely related to the software developer and does not indicate that the studies were performed by or affiliated with Zhejiang University. All analytical studies were conducted by our laboratory in accordance with the approved analytical procedures, and the validity and integrity of the submitted data remain unaffected. |
| Clarification is required for not including dissolution test in finished product specifications for applied product | As the company format had already been established, the dissolution test was unintentionally omitted from the report. However, the dissolution test results are included in the summary sheets, which are attached for your kind reference. |
| Compliance Record of HPLC Software 21CFR & Audit Trail Reports on Product Testing is required | The HPLC software currently used in our laboratory does not support the generation of audit trail reports or full compliance with 21 CFR Part 11 requirements. Therefore, audit trail reports for the submitted product testing data cannot be provided. |

**Decision**

**Rejected**

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| | The Registration Board rejected the application as the firm has submitted that the HPLC software is not compliant with 21 CFR and audit trail reports cannot be provided. | |
| 92 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UQQ-E4J-UAEJ, 2024-08-20) |
| | Detail of Fee Submitted | 75000.0,<br>2024-04-23, |
| | The proposed proprietary name / brand name | **Ferrimal** |
| | Label Claim | Each capsule contains: Iron (as Ferric Maltol) ..... 30mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x 10's-As per SRO,7 x 8's -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | Accrufol 30mg Capsule by M/s Pharmedic Laboratories |
| | Pharmacotherapeutic Group of (API) | Iron Supplement |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Global Calcium Private Limited & Address: Unit-III Plot No. 19 & 19 B, SIPCOT Industrial Complex, Hosur - 635 126, India |
| | Detail of stability batches of drug product | 3 batches having batch size of 1000 capsule each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | form 6 submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Feraccru 30mg Hard Capsules by M/s Norgine Pharmaceuticals |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| | The status in reference regulatory authorities | Medical and Healthcare Products Regulatory Agency(MHRA) |
| | GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 20-11-2024. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of renewal of DML dated 03-03-2023 specifying Capsule (General) Section. |
| | **Evaluation Remarks** | |

| Shortcomings | Firm's Response |
|---|---|
| Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted cop of cGMP certificate of API manufacturer valid upto 31-12-2028 |
| Pictorial evidence of innovator's product/comparator's product including details of name of MAH, batch number, manufacturing date and expiry date against which PE and CDP studies has been submitted is required | Firm has submitted pictorial evidence of innovator's product/comparator's product; Product Name; Feraccru 30mg Name of MAH; Norgine B.V Antonio Vivaldistraat, Amsterdam Niederland Batch number; 9011; Expiry date; 09/2022 |
| Justify the assay method of applied product by titration | The assay method for Ferrimal® (Iron as Ferric Maltol) Capsules 30 mg is based on a validated iodometric redox titration utilizing standardized 0.1 N Sodium Thiosulfate with starch indicator |

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| | | for endpoint detection. The method quantitatively determines ferric iron content through a stoichiometric oxidation-reduction reaction, whereby ferric ions oxidize iodide ions to liberate iodine, which is subsequently titrated with standardized sodium thiosulfate solution The volume of sodium thiosulfate consumed is directly proportional to the amount offerric iron present in the sample, thereby enabling accurate quantification of the active ingredient. The scientific principle and application of oxidation-reduction titrations are recognized in USP General Chapter Titrimetry, which describes redox titration as an official quantitative analytical technique and includes thiosulfate-based titration systems for assay determination. A copy of USP General Chapter is enclosed for reference. (Attached as Annexure V) This titrimetric method provides a direct, specific, accurate, precise, and robust determination of iron content and is particularly suitable for ironcontaining pharmaceutical products, where the assay is based on elemental iron quantification. Therefore, the use of iodometric titration for assay determination of Ferrimal Capsules is scientifically justified and appropriate for routine quality control testing. Furthermore, the analytical procedure has been validated in accordance with USP General Chapter Validation of Compendial Procedures. The complete method validation data have already been submitted in the dossier: however, a copy of USP General Chapter is also attached for reference. |
| | Clearance certificate for procurement of API shall be submitted or submit copy of commercial invoice, packing list, goods declaration and airway bill. | Firm has submitted copy of form 6 dated 04-11-2021 specifying 01kg Ferric Maltol. Firm has also submitted copy of invoice, packing list, airway bill. |
| | **Decision** | |
| | **Approved** | |
| 93 | Case Category | New Molecule/Formulation (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (48P-DUW-3JJ7, 2025-09-25) |
| | Detail of Fee Submitted | 75000.0,<br>2025-02-14, |
| | The proposed proprietary name / brand name | **Icosa (Icosapent Ethyl) 1g Soft Gelatin Capsule** |
| | Label Claim | Each Soft Gelatin Capsule Contains: Icosapent Ethyl ..... 1g |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 120's-As per SRO,30's-As per SRO,60;s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30°C in a cool and dry place |
| | For generic drugs (me-too Status) | Not applicable as it is a new drug product |
| | Pharmacotherapeutic Group of (API) | Lipid Regulating Agent |

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| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Shandong Xinhua Pharmaceutical Company Limited ADDRESS:Hutian Chemical Indus- trial Zone, Zibo, Shan- dong, P.R.China |
| Detail of stability batches of drug product | 3 batches having batch size of 1500 capsule each |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted copy of form 6 dated 22-12-2021 specifying 6kg Icosapent Ethyl. Firm has also submitted copy of invoice cleared by AD (I&E) DRAP field office. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against Vascepa 1gm Capsules by M/s Amarin Pharmaceuticals Ireland Ltd. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per zone IV |
| The status in reference regulatory authorities | Vascepa (Icosapentate Ethyl) Capsule 1g USFDA Approved. |
| GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 20-11-2024. |
| Evidence of approval of manufacturing facility | Firm has submitted copy of renewal of DML dated 03-03-2023 specifying Soft Gelatin Capsule (General). |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
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| The applied product is Icosa (Icosapent Ethyl) 1g Soft Gelatin Capsule while submitted fee challan is for Osimer (Osimertinib) 40mg Tablet. Submit fee challan for applied product | Firm has submitted Registration Fee Rs. 75,000/- on deposit slip#739607255 for applied product |
| Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted cop of DML of API manufacturer valid upto 10-11-2030 |
| The applied product is Icosa (Icosapent Ethyl) 1g Soft Gelatin Capsule while executed BMR of Finerenone 20mg tablets, clarify and submit executed BMR of applied product | It is to inform that the BMR of Finerenone 20mg tablet was mistakenly attached with submitted dossier. BMR of Icosa (Icosapent Ethyl) 1g Soft Gelatin Capsule is submitted |
| Drug-excipient compatibility study is required since the qualitative composition of the applied formulation is not similar to innovator / reference product. | Firm has submittd the comparison between Icosapent 1gm Soft Gel Capsule and Vascepa Soft Gel Capsule The innovator has not provided complete details regarding the gelatin shell formulation. However, it is well established that the inclusion of preservatives in gelatin shell formulations is necessary. In this regard we would like to clarify that the preservatives are not part of our fill formulation. Instead, they are incorporated solely into the gelatin shell formulation, as gelatin is more susceptible to microbial contamination and bacterial growth due to its composition and moisture content. The preservatives are therefore included only to maintain the microbiological quality and stability of the gelatin shell throughout the product's shelf life. Accordingly, this formulation difference does not affect the quality, safety, efficacy, or performance of the finished product. |
| Compliance Record of GC software 21CFR & audit trail reports on product testing is required | We acknowledge the query and hereby submit the requested documentation for your review. The Gas Chromatography (GC) software utilized for product testing is compliant with the requirements of 21 CFR Part 11, including provisions for |

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| | | electronic records, electronic signatures, user access control, audit trail functionality, and data integrity management. Furthermore, the relevant audit trail reports generated during product testing are enclosed as supporting evidence. These reports demonstrate complete traceability of analytical activities, including data acquisition, processing, modification history, user actions, and system-generated records, thereby ensuring compliance with applicable regulatory requirements and data integrity principles. The following documents are attached for review: 1. 21 CFR Part 11 Compliance Certificate/Statement of the GC Software. 2. Audit Trail Reports for the relevant product testing batches. (Stability and AMV) |
| | Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation is required | For Icosa (Icosapent Ethyl) 1g Soft Gelatin Capsule, complete RMP approved by the reference regulatory authority (RRA) is not publicly available. However, Summary of risk management plan for Icosapent Ethyl 1g Soft Gelatin Capsule is available on EMA. Complete report & SMPC data along with site link has been attached for your reference (Annexure - VII) https://www.ema.europa.eu/en/documents/rmp-summary/vazkepa-epar-riskmanagement-plan-summary en.pdf https://www.accessdata.fda.gov/drugsatfda docs/label/2017/202057s019lbl.pdf |
| | RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07 is required | RMP for Icosa (Icosapent Ethyl) 1g Soft Gelatin Capsule developed by the applicant is submitted |
| | Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division is required | Evidence confirming establishment of pharmacovigilance unit has been attached and R&I for nomination of qualified person for pharmacovigilance QPPV and backup person has also been attached |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of comparative dissolution profile (CDP) data | |

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| 94 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AB4-46D-BYXY, 2024-10-30) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-28, 2024-10-08 |
| | The proposed proprietary name / brand name | **Olanxetin 3mg/25mg Capsules** |
| | Label Claim | Each capsule contains: Olanzapine.....3mg Fluoxetine as HCl.....25mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Neolepra-F 3mg/25mg capsule, Manufacturer: GeneticsPharmaceuticals |

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| Pharmacotherapeutic Group of (API) | Olanzapine: Antipsychotics Fluoxetine HCl: Selective Serotonin Reuptake Inhibitors (SSRIs) |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Palam Pharma Private. Limited. India,Vision Drugs Private. Limited. India |
| Detail of stability batches of drug product | 3 batches having batch size of 1000 capsule each |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted a request letter for borrowing of API (indicating Fluoxetine HCI 0.5kg) and loan agreement between M/s Solaris life sciences and M/s Seraph pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 07-10-2022 specifying 25kg Fluoxetine HCI in name of M/s Seraph Pharmaceuticals Firm has submitted loan agreement between M/s Solaris life sciences and M/s Global pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 11-01-2024 specifying 05kg Olanzpine in name of M/s Global Pharmaceuticals |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Neolepra-F 3mg/25mg capsule by M/s Genetics Pharmaceuticals |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Olanzapine Firm has submitted stability study data of 3 batches of drug substance as per Zone IV Fluoxetine HCl Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| The status in reference regulatory authorities | Olanzapine and Fluoxetine Hydrochloride 3mg;25mg USFDA Approved |
| GMP status of the firm | New DML issued dated 17-01-2024 |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Capsule Section-I (General). |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
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| Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for olanzapine issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer of olanzapine valid upto 03-05-2027 |
| The real time storage conditions of zone IV-A mentioned on stability summary sheets of drug substance Fluoxetine HCl have different font size and writing style compared to other information written on the sheets making it questionable, clarification is required. Submit stability study data of Fluoxetine HCl as per Zone IV conditions till claimed shelf life, duly signed by the API manufacturer on their letterhead. | Stability studies of Fluoxetine HCl manufactured by M/S: Palam Pharma Private. Limited is included in CTD from DMF, provided by Manufacturer. The font size was different due to batch number was mentioned separately in bold with scan sheet. Revised Module-III including complete stability studies and Complete DMF is submitted. |
| Clarification is required, as the batch analysis report provided by the drug product manufacturer and loan agreement mentions the material name as olanzapine citrate, whereas the drug substance manufacturer has identified it as olanzapine. | Olanzapine USP is used for development and manufacturing of this drug as mentioned on COA, stability studies and other clearance documents. Olanzapine citrate is not available as drug and it is mentioned mistakenly in analysis report, and loan agreement the corrected report and loan letter from global Pharmaceuticals is enclosed in revised module-III. |
| Clarification is required, as the batch number of olanzapine mentioned in the clearance certificate | The batch number of olanzapine USP is OLA0431223 as mentioned on Manufacturer |

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| | differs from the batch number provided in the API batch analysis report. | COA and clearance documents. On QC testing report was mentioned incorrectly that was corrected and the revised corrected test report is attracted in Module-III for your kind consideration. |
| | It has been observed that the batch number of the Olanzapine API was initially submitted as FLU1851123 in the API COA, whereas the subsequently submitted COA by API manufacturer mentions the batch number as OLA0431223. Clarify | The batch number of olanzapine USP is OLA0431223 as mentioned on Manufacturer COA provided with clearance documents enclosed in revised Module-III. However, On QC testing report is was mentioned incorrectly due to confusion with batch number of fluoxetine mentioned in clearance documents. The Clearance documents, provided by Global pharmaceutical for Olanzapine mentioned both API i.e. FLUOXETINE HCl batch number FLU1851123 and Olanzapine batch number OLA0431223. The batch number FLU1851123 was mistakenly mentioned on QC test reports and COA was corrected by analyst accordingly. The correct COA provided by API manufacturer with batch Number OLA0431223 is enclosed in revised module-III, and the Clearance documents are enclosed for your kind consideration. |
| | **Decision** | |
| | **Approved**<br><br>Registration Board further decided that the Registration Letter shall be issued after verification of the loan documents of API. | |
| 95 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R83-D72-GYG7, 2024-12-19) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-28, 2024-10-08 |
| | The proposed proprietary name / brand name | **Olanxetin 6mg/25mg Capsules** |
| | Label Claim | Each capsule contains: Olanzapine.....6mg Fluoxetine as HCl.....25mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Neolepra-F 6mg/25mg capsule, Manufacturer: GeneticsPharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Olanzapine: Antipsychotics Fluoxetine HCl: Selective Serotonin Reuptake Inhibitors (SSRIs) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Palam Pharma Private. Limited. India,Vision Drugs Private. Limited. India |
| | Detail of stability batches of drug product | 3 batches having batch size of 1000 capsule each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted a request letter for borrowing of API (indicating Fluoxetine HCI 0.5kg) and loan agreement between M/s Solaris life sciences and M/s Seraph pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 07-10-2022 specifying 25kg Fluoxetine |

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| | HCI in name of M/s Seraph Pharmaceuticals Firm has submitted loan agreement between M/s Solaris life sciences and M/s Global pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 11-01-2024 specifying 05kg Olanzpine in name of M/s Global Pharmaceuticals |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Neolepra-F 6mg/25mg capsule by M/s Genetics Pharmaceuticals |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Olanzapine Firm has submitted stability study data of 3 batches of drug substance as per Zone IV Fluoxetine HCl Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| The status in reference regulatory authorities | Olanzapine and Fluoxetine Hydrochloride 6mg;25mg USFDA Approved |
| GMP status of the firm | New DML issued dated 17-01-2024 |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Capsule Section-I (General). |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
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| Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for olanzapine issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer of olanzapine valid upto 03-05-2027 |
| The real time storage conditions of zone IV-A mentioned on stability summary sheets of drug substance Fluoxetine HCl have different font size and writing style compared to other information written on the sheets making it questionable, clarification is required. Submit stability study data of Fluoxetine HCl as per Zone IV conditions till claimed shelf life, duly signed by the API manufacturer on their letterhead. | Stability studies of Fluoxetine HCl manufactured by M/S: Palam Pharma Private. Limited is included in CTD from DMF, provided by Manufacturer. The font size was different due to batch number was mentioned separately in bold with scan sheet. Revised Module-III including complete stability studies and Complete DMF is submitted. |
| Clarification is required, as the batch analysis report provided by the drug product manufacturer and loan agreement mentions the material name as olanzapine citrate, whereas the drug substance manufacturer has identified it as olanzapine. | Olanzapine USP is used for development and manufacturing of this drug as mentioned on COA, stability studies and other clearance documents. Olanzapine citrate is not available as drug and it is mentioned mistakenly in analysis |

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| | | report, and loan agreement the corrected report and loan letter from global Pharmaceuticals is enclosed in revised module-III. |
| | Clarification is required, as the batch number of olanzapine mentioned in the clearance certificate differs from the batch number provided in the API batch analysis report. | The batch number of olanzapine USP is OLA0431223 as mentioned on Manufacturer COA and clearance documents. On QC testing report was mentioned incorrectly that was corrected and the revised corrected test report is attracted in Module-III for your kind consideration. |
| | It has been observed that the batch number of the Olanzapine API was initially submitted as FLU1851123 in the API COA, whereas the subsequently submitted COA by API manufacturer mentions the batch number as OLA0431223. Clarify | The batch number of olanzapine USP is OLA0431223 as mentioned on Manufacturer COA provided with clearance documents enclosed in revised Module-III. However, On QC testing report is was mentioned incorrectly due to confusion with batch number of fluoxetine mentioned in clearance documents. The Clearance documents, provided by Global pharmaceutical for Olanzapine mentioned both API i.e. FLUOXETINE HCl batch number FLU1851123 and Olanzapine batch number OLA0431223. The batch number FLU1851123 was mistakenly mentioned on QC test reports and COA was corrected by analyst accordingly. The correct COA provided by API manufacturer with batch Number OLA0431223 is enclosed in revised module-III, and the Clearance documents are enclosed for your kind consideration. |
| | **Decision** | |
| | **Approved**<br><br>Registration Board further decided that the Registration Letter shall be issued after verification of the loan documents of API. | |
| 96 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XPW-7HM-LSJ6, 2024-12-20) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-28, 2024-10-08 |
| | The proposed proprietary name / brand name | **Olanxetin 12mg/25mg Capsules** |
| | Label Claim | Each capsule contains: Olanzapine.....12mg Fluoxetine as HCl.....25mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Neolepra-F 12mg/25mg capsule, Manufacturer: GeneticsPharmaceuticals |

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|---|---|
| Pharmacotherapeutic Group of (API) | Olanzapine: Antipsychotics Fluoxetine HCl: Selective Serotonin Reuptake Inhibitors (SSRIs) |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Palam Pharma Private. Limited. India,Vision Drugs Private. Limited. India |
| Detail of stability batches of drug product | 3 batches having batch size of 1000 capsule each |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted a request letter for borrowing of API (indicating Fluoxetine HCI 0.5kg) and loan agreement between M/s Solaris life sciences and M/s Seraph pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 07-10-2022 specifying 25kg Fluoxetine HCI in name of M/s Seraph Pharmaceuticals Firm has submitted loan agreement between M/s Solaris life sciences and M/s Global pharmaceuticals for API loan. Firm has submitted copy of clearance certificate dated 11-01-2024 specifying 05kg Olanzpine in name of M/s Global Pharmaceuticals |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Neolepra-F 12mg/25mg capsule by M/s Genetics Pharmaceuticals |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Olanzapine Firm has submitted stability study data of 3 batches of drug substance as per Zone IV Fluoxetine HCl Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| The status in reference regulatory authorities | Olanzapine and Fluoxetine Hydrochloride 12mg;25mg USFDA Approved |
| GMP status of the firm | New DML issued dated 17-01-2024 |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 17-01-2024 specifying Capsule Section-I (General). |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
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| Valid copy of cGMP certificate / DML of the Drug Substance manufacturer for olanzapine issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer of olanzapine valid upto 03-05-2027 |
| The real time storage conditions of zone IV-A mentioned on stability summary sheets of drug substance Fluoxetine HCl have different font size and writing style compared to other information written on the sheets making it questionable, clarification is required. Submit stability study data of Fluoxetine HCl as per Zone IV conditions till claimed shelf life, duly signed by the API manufacturer on their letterhead. | Stability studies of Fluoxetine HCl manufactured by M/S: Palam Pharma Private. Limited is included in CTD from DMF, provided by Manufacturer. The font size was different due to batch number was mentioned separately in bold with scan sheet. Revised Module-III including complete stability studies and Complete DMF is submitted. |
| Clarification is required, as the batch analysis report provided by the drug product manufacturer and loan agreement mentions the material name as olanzapine citrate, whereas the drug substance manufacturer has identified it as olanzapine. | Olanzapine USP is used for development and manufacturing of this drug as mentioned on COA, stability studies and other clearance documents. Olanzapine citrate is not available as drug and it is mentioned mistakenly in analysis report, and loan agreement the corrected report and loan letter from global Pharmaceuticals is enclosed in revised module-III. |
| Clarification is required, as the batch number of olanzapine mentioned in the clearance certificate | The batch number of olanzapine USP is OLA0431223 as mentioned on Manufacturer |

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| | differs from the batch number provided in the API batch analysis report. | COA and clearance documents. On QC testing report was mentioned incorrectly that was corrected and the revised corrected test report is attracted in Module-III for your kind consideration. |
| | It has been observed that the batch number of the Olanzapine API was initially submitted as FLU1851123 in the API COA, whereas the subsequently submitted COA by API manufacturer mentions the batch number as OLA0431223. Clarify | The batch number of olanzapine USP is OLA0431223 as mentioned on Manufacturer COA provided with clearance documents enclosed in revised Module-III. However, On QC testing report is was mentioned incorrectly due to confusion with batch number of fluoxetine mentioned in clearance documents. The Clearance documents, provided by Global pharmaceutical for Olanzapine mentioned both API i.e. FLUOXETINE HCl batch number FLU1851123 and Olanzapine batch number OLA0431223. The batch number FLU1851123 was mistakenly mentioned on QC test reports and COA was corrected by analyst accordingly. The correct COA provided by API manufacturer with batch Number OLA0431223 is enclosed in revised module-III, and the Clearance documents are enclosed for your kind consideration. |
| | Clarification is required regarding the batch size of the drug product, as 1000 capsules are mentioned in the BMR, whereas 500 capsules are reported in the batch analysis report and stability summary sheet. | The Batch Size of all batches is 1000 capsules as mentioned in the BMR. It was mentioned 500 capsules are in the QC test report and stability sheet mistakenly. The QC test reports and Stability sheets are corrected and included in revised module-III for your kind consideration |
| | **Decision** | |
| | **Approved**<br><br>Registration Board further decided that the Registration Letter shall be issued after verification of the loan documents of API. | |
| 97 | Case Category | Export Facilitation (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MX9-NUG-RJH9, 2025-02-19) |
| | Detail of Fee Submitted | 30000.0, 8700<br>2024-09-12, 2026-06-24 |
| | The proposed proprietary name / brand name | **Tofanib 5mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains:<br>Tofacitinib.....5mg (equivalent to 8mg tofacitinib citrate) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's 5's 7's 10's 14'-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30o C |
| | For generic drugs (me-too Status) | Jakjanz 5mg Tablet by Atco Laboratories Limited |
| | Pharmacotherapeutic Group of (API) | Janus kinase (JAK) inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | 3 batches having batch size of 2500 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of form 6 issued dated 22-09-2023 specifying 0.25kg Tofacitinib Citrate. |

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| | | Firm has also submitted copy invoice, packing list, form 3, form 7. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Jakjanz 5mg Tablet by Atco Laboratories Limited |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per Zone IV |
| | The status in reference regulatory authorities | Xeljanz Tablet 5mg, 10mg USFDA Approved |
| | GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 09-01-2024. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of grant of sections (Amendments)-Approval dated 21-02-2018 specifying Tablets (General) Section (Revised) |
| | **Evaluation Remarks** | |
| | Shortcomings | Firm's Response |
| | Submit the differential fee of registration for the applied product and update the details of submitted fee in relevant field of e-app interphase (online portal). | Firm has submitted differential fee Rs. 8700/- on deposit slip#981168835328 for applied product |
| | Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer issued by Liaoning Fuxin Management Committee For Fluoride Industrial Development Zone valid upto 31-08-2026 |
| | Clearance certificate for procurement of API shall be submitted or submit copy of goods declaration and airway bill. | The duly issued DRAP Form 6 is attached for your reference. Please note that the API consignment was imported and cleared by Pakistan Customs against the attached DRAP Form 6. At the time of import clearance, the Clearance Certificate was not a regulatory requirement, and customs clearance was granted solely on the basis of the DRAP Form 6. Subsequently, with the implementation of the Pakistan Single Window (PSW) system, the Clearance Certificate became a mandatory requirement to be obtained through the PSW portal prior to the filing of the GD. Since the subject consignment was imported before the implementation of this revised procedure, no separate Clearance Certificate was issued for this consignment. Therefore, the attached DRAP Form 6 serves as the clearance certificate for the import of the API. |
| | **Decision** | |
| | **Approved**<br><br>Registration Board further decided that the Registration Letter shall be issued after submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin | |
| 98 | Case Category | Export Facilitation (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **PHARMEVO (PVT) LTD.** A-29, NORTH WESTERN INDUSTRIAL ZONE, PORT QASSIM KARACHI. **(000504)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2MW-UAM-69H4, 2025-02-19) |
| | Detail of Fee Submitted | 30000.0,<br>2024-09-12, |
| | The proposed proprietary name / brand name | **Tofanib 10mg Tablet** |

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| Label Claim | Each Film Coated Tablet Contains:<br>Tofacitinib.....10mg (equivalent to 16mg tofacitinib citrate) |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 1's 5's 7's 10's 14'-De-Controlled |
| Shelf Life (Unit) | 2 Year(s)Store below 30o C |
| For generic drugs (me-too Status) | Tofajak Tablet 10mg by hiranis pharma |
| Pharmacotherapeutic Group of (API) | Janus kinase (JAK) inhibitors |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical Co., Ltd. |
| Detail of stability batches of drug product | 3 batches having batch size of 2500 tablets each |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of form 6 issued dated 22-09-2023 specifying 0.25kg Tofacitinib Citrate. Firm has also submitted copy invoice, packing list, form 3, form 7. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies performed against Actinib Tablet 10mg by The Searle Company |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A |
| The status in reference regulatory authorities | Xeljanz Tablet 5mg, 10mg USFDA Approved |
| GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 09-01-2024. |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of grant of sections (Amendments)-Approval dated 21-02-2018 specifying Tablets (General) Section (Revised) |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
|---|---|
| Submit the differential fee of registration for the applied product and update the details of submitted fee in relevant field of e-app interphase (online portal). | Firm has submitted differential fee Rs. 8700/- on deposit slip#2440130527 for applied product |
| Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer issued by Liaoning Fuxin Management Committee For Fluoride Industrial Development Zone valid upto 31-08-2026 |
| Clearance certificate for procurement of API shall be submitted or submit copy of goods declaration and airway bill. | The duly issued DRAP Form 6 is attached for your reference. Please note that the API consignment was imported and cleared by Pakistan Customs against the attached DRAP Form 6. At the time of import clearance, the Clearance Certificate was not a regulatory requirement, and customs clearance was granted solely on the basis of the DRAP Form 6. Subsequently, with the implementation of the Pakistan Single Window (PSW) system, the Clearance Certificate became a mandatory requirement to be obtained through the PSW portal prior to the filing of the GD. Since the subject consignment was imported before the implementation of this revised procedure, no separate Clearance Certificate was issued for this consignment. Therefore, the attached DRAP Form 6 serves as the clearance certificate for the import of the API. |

**Decision**

**Approved**

Registration Board further decided that the Registration Letter shall be issued after submission of valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin

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| 99 | Case Category | Routine (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000900)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N53-R5X-Q7T8, 2024-07-18) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-31, |
| | The proposed proprietary name / brand name | **Komplet 3MIU Injection** |
| | Label Claim | Each vial contains: Colistimethate Sodium 3MIU eq. to Colistimethate Sodium.....255mg (3MIU of Colistimethate Sodium is eq. to Colistin Base Activity 102mg (approx.) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 25°C |
| | For generic drugs (me-too Status) | Colistim 3MIU Injection by M/s Pharmasol (Pvt) Ltd. |
| | Pharmacotherapeutic Group of (API) | Antibacterials for systemic use, other antibacterials, polymyxins. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Livzon group Fuzhou fuxing pharmaceutical Co, Ltd. |
| | Detail of stability batches of drug product | 3 batches having batch size of 450 vials each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of clearance certificate dated 19-09-2022 specifying 01kg Colistimethate Sodium in the name of Aulton Pharmaceuticals. Firm has submitted copy of loan letter from M/s Aulton pharma |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against COLISTIM 3MIU BY M/S BIOPHARMASEUTICA. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per zone IV |
| | The status in reference regulatory authorities | Colistamethate sodium (3.M.I.U and 1.M.I.U) powder for solution for injection (IV) MHRA Approved |
| | GMP status of the firm | Firm has submitted copy of routine GMP inspection report of the firm dated 03-04-2023 concluding the firm is operating at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of issuance of DML dated 05-03-2019 specifying Dry Powder Vial (General) Section. |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
|---|---|
| Copy of cGMP certificate or GMP inspection report conducted within last three years is required | Firm has submitted copy of routine GMP inspection report of the firm dated 03-04-2023 concluding the firm is operating at satisfactory level of GMP compliance. |

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|---|---|---|
| | Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required | Firm has submitted written confirmation for active substances exported to EU issued by Fujian Medical Products Administration valid upto 21-09-2025 |
| | Pictorial evidence of innovator's product/comparator's product including details of name of MAH, batch number, manufacturing date and expiry date against which PE & CDP studies has been submitted is required | We respectfully submit that the PE study was conducted using a commercially available comparator product and all comparative testing was performed in accordance with applicable pharmacopoeial requirements using validated and verified analytical methods. The comparator product details, including product name, batch number, manufacturing date and expiry date, were documented in the Pharmaceutical Equivalence study report submitted with the dossier. The comparator product was procured from the commercial market and evaluated under identical analytical conditions alongside the test product. It is respectfully submitted that pictorial evidence of the comparator product is not available in the study records. At the time of study execution, photographic documentation of comparator product packaging was not maintained as part of the study documentation package. The study records were prepared and maintained primarily to document the scientific and analytical evidence necessary to establish pharmaceutical equivalence between the test and comparator products. |
| | Protocols for analytical method validation/verification studies shall be submitted | Not submitted |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of following;<br><br>1. Copy of cGMP certificate or GMP inspection report conducted within last three years<br>2. Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin<br>3. Protocols for analytical method validation/verification studies<br>4. Revised Pharmaceutical equivalence report of the applied product with the innovator / reference / comparator product along with pictorial evidence | |
| 100 | Case Category | Export Facilitation (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QRR-8QL-2BT9, 2026-03-03) |
| | Detail of Fee Submitted | 75000,<br>2025-11-19, |
| | The proposed proprietary name / brand name | **OLOMET NASAL SPRAY** |
| | Label Claim | Each Spray (100 microliters) contains: Olopatadine 600mcg (as Olopatadine Hydrochloride) and Mometasone Furoate 25mcg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 bottle of 30ml with 240 actuations.-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store between 20°C to 25°C, excursion permitted between 15°C to 30°C. |

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| For generic drugs (me-too Status) | N/A |
| Pharmacotherapeutic Group of (API) | Nasal Corticosteroids Combination |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Avik Pharmaceutical Limited,Beijing Lianben Pharm-Chemicals Tech Co., Ltd |
| Detail of stability batches of drug product | 3 batches having batch size of 2L (66 packs) each |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of final clearance certificate dated 15-03-2025 specifying 04kg Olopatadine HCl. Firm has submitted copy of final clearance certificate dated 18-02-2025 specifying 02kg Mometasone Furoate. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against Ryalt ris Nasal Spray by M/s Glen Mark Pharmaceutical. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Olopatadin Firm has submitted stability study data of 3 batches of drug substance as per zone II Mometasone Firm has submitted stability study data of 3 batches of drug substance as per zone IV |
| The status in reference regulatory authorities | RYALTRIS Glenmark Pharmaceuticals US FDA Approved. |
| GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 24-01-2024. |
| Evidence of approval of manufacturing facility | Firm has submitted copy of letter of renewal of DML dated 20-09-2021 specifying Ear/Nasal Drops (General). |

**Evaluation Remarks**

| Shortcomings | Firm's Response |
|---|---|
| Standardize the label claim in section 1.5.2 as per reference formulation along with submission of applicable fee | Label claim mentioned in section 1.5.2 is already aligned with the reference formulation. |
| Valid copy of cGMP certificate or DML of API manufacturer for olopatadine issued by relevant regulatory authority of country of origin is required | Firm has submitted copy of cGMP certificate of API manufacturer issued by Beijing Food and Drug Administration China (China Food and Drug Administration) valid upto 10-12-2029. However, the certificate could not be verified from NMPA website |
| Stability study data of three batches of API olopatadine as per zone IV till claimed shelf life shall be submitted | Zone II stability study data is submitted. With reference to the observation regarding submission of stability study data of three batches of Olopatadine API as per Zone IVA, we respectfully submit that the API manufacturer has been asked to provide the required stability data. As soon as it is received from the API manufacturer, the same shall be submitted to DRAP at the earliest. (Undertaking attached) |
| Pictorial evidence of innovator's product/comparator's product including details of name of MAH, batch number, manufacturing date and expiry date against which PE studies has been submitted is required | Pictorial evidence of innovator's product/comparator's product is submitted Product Name; Ryaltis nasal spray Batch#12240741A; Exp date; 06-2027 Name of MAH; Glenmark Pharmaceuticals UK |
| Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation is required | Submitted |
| RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices | Submitted |

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| | for Registration Holders, Document No. PHSR/GL/PV/07 is required | |
| | Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division is required | Receiving of application submitted in DRAP is submitted |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of following;<br><br>1. Valid copy of cGMP certificate or DML of API manufacturer for olopatadine issued by relevant regulatory authority of country of origin<br>2. Stability study data of three batches of API olopatadine as per zone IV till claimed shelf life | |
| 101 | Case Category | Any Other (Farooq Aslam) |
| | 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 | (NLS-H9R-HBGM, 2026-03-03) |
| | Detail of Fee Submitted | 313500,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **Eltrombopag Olamine** |
| | Label Claim | Each film coated tablet contains: Eltrombopag as Olamine.....50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 28 (4*7)-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)This Medicine does not require any storage condition |
| | For generic drugs (me-too Status) | Revolade by Novartis |
| | Pharmacotherapeutic Group of (API) | Antithemorrhagics, other systemic hemostatic , ATC Code : B02BX (attach in Module 1) |
| | Name, address of Manufacturing site: | Synthon Haspania S.L- c/ castello, 1, 08830 Sant Boi de Llobregat, Barcelona, Spain-Spain |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attach in Module 3 |
| | Name, address of Marketing Authorization Holder: | Synthon Hispania S.L, C/Castello n'1, Sant Boi de Liobregat 08830, Barcelona Spain, Spain |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP certificate issued on the basis of inspection conducted on 17-20th April, 2023. The scope includes the manufacturing of tablets. |
| | Details of Authorization Letter : | CoPP: Copy of CoPP No. 3637 dated 20-11-2025 is submitted. The applied product is available in free sale in exporting country and the facilities and operations conform WHO-GMP as per submitted CoPP. DSL: DSL valid till 07-03-2028 is submitted. LOA: product specific LOA dated 13-11-2025 is submitted. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and ad 72 months real time stability data according to zone-II is submitted. |
| | The status in reference regulatory authorities | USFDA Approved |
| | **Evaluation Remarks** | |

| | | |
|---|---|---|
| | The application has been processed on priority as per decision of 220th meeting of DRAP Authority regarding imported drug products. | |
| | The firm was asked to provide Pharmaceutical equivalence studies and CDP of the applied strength i.e 50mg film coated tablet. | |
| | The firm has submitted the bioequivalence study report of their 75mg strength against the innovator's product i.e Revolade 75mg, film coated tablet. The firm has referred EMA guidelines on investigation of Bioequivalense. As per Section 4.1.6 of guideline, following criteria is mentioned. | |
| | General biowaiver criteria The following general requirements must be met where a waiver for additional strength(s) is claimed: a) the pharmaceutical products are manufactured by the same manufacturing process, b) the qualitative composition of the different strengths is the same, c) the composition of the strengths are quantitatively proportional,e. the ratio between the amount of each excipient to the amount of active substance(s) is the same for all strengths (for immediate release products coating components, capsule shell, colour agents and flavours are not required to follow this rule), | |
| | If there is some deviation from quantitatively proportional composition, condition c is still considered fulfilled if condition i) and ii) or i) and iii) below apply to the strength used in the bioequivalence study and the strength(s) for which a waiver is considered | |
| | i. the amount of the active substance(s) is less than 5 % of the tablet core weight, the weight of the capsule content ii. the amounts of the different core excipients or capsule content are the same for the concerned strengths and only the amount of active substance is changed iii. the amount of a filler is changed to account for the change in amount of active substance. The amounts of other core excipients or capsule content should be the same for the concerned strengths | |
| | d) appropriate in vitro dissolution data should confirm the adequacy of waiving additional in vivo bioequivalence testing | |
| | The firm has provided PE studies against the biobatch (i.e. test product) 75mg and innovator's product Revolade 75mg tablet for the applied strength of 50mg tablet. | |
| | Submitted for consideration by the Board. | |
| | **Decision** | |
| | **Approved**<br><br>as per import policy for inspection of manufacturer abroad subject to submission of apostille/legalized CoPP. | |
| 102 | Case Category | Routine (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 | (G2Z-LS7-RDHR, 2024-04-17) |
| | Detail of Fee Submitted | 300000.0,<br>2024-03-22, |
| | The proposed proprietary name / brand name | **Sterile Water for Injection IP** |
| | Label Claim | Each ampoule contains: Sterile Water for Injection..... 0.5mL |
| | Reference to Finished product specifications | The International Pharmacopeia |
| | Proposed Pack Size | 50 ampoules, each fi-As per SRO |
| | Shelf Life (Unit) | 60 Month(s)Below 30 °C |
| | For generic drugs (me-too Status) | Water for Injection (Registration number: 024873) Amson Vaccines & Pharma (Pvt) Ltd. |
| | Pharmacotherapeutic Group of (API) | Diluent |
| | Name, address of Manufacturing site: | SERUM INSTITUTE OF INDIA PVT. LTD,- Room No. 1, first floor, Survey No. 46/1-4, Kadaiya village, Nani Daman C/O Sovereign |

| | | |
|---|---|---|
| | | Pharma Pvt Ltd., Survey No. 46/1-4, Kadaiya village, Nani Daman-India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | N.A |
| | Name, address of Marketing Authorization Holder: | Amson Vaccines & Pharma (Pvt) Ltd., Plot # 115,Industrial Triangle Kahuta Road Islamabad, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | The facilities and operations conform WHO-GMP as per submitted CoPP. GMP certificate valid till 13-122-2027 is submitted. |
| | Details of Authorization Letter : | CoPP: Copy of legalized CoPP No. DD/L458/2022/1-1-203 valid till 14-11-2024. The applied product is available in free sale in the exporting country and the facilities and operations conform WHO-GMP as per submitted CoPP. Letter of Authorization: Copy of product specific Marketing Authorization letter valid till 30-04-2025 is submitted. DSL: DSL no. DHO-ISB-1352 dated 01-12-2023 is submitted. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 72 months real time (25oC and 60%RH) and 06 months accelerated stability data is submitted for 03 batches. |
| | The status in reference regulatory authorities | USFDA Approved |
| | **Evaluation Remarks** | |
| | The product license holder has acquired the manufacturing license on loan basis. Product License holder: Serum Institute of India Pvt. Ltd., Room No. 1, first floor, Survey No. 46/1-4, Kadaiya village, Nani Daman Manufacturer on loan license: Sovereign Pharma Pvt Ltd., Survey No. 46/1-4, Kadaiya village, Nani Daman | |
| | **Decision** | |
| | **Deferred**<br><br>for policy decision regarding loan license. | |
| 103 | Case Category | Export Facilitation (Farooq Aslam) |
| | Name, address of Applicant. | **Atco Laboratories Limited** B-18 SITE KARACHI **(000188)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EH6-5GW-AST6, 2026-02-03) |
| | Detail of Fee Submitted | 38700,<br>2025-11-13, |
| | The proposed proprietary name / brand name | **ROVATOR EZ Tablet** |
| | Label Claim | Each film coated tablet contains: Rosuvastatin (as Rosuvastatin Calcium) ..... 10mg Ezetimibe ..... 10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 strip x 10 Tablets-De-Controlled,2 strips x 10 Tablets-De-Controlled,3 strips x 10 Tablets-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Donot store and transport above 30 degree centigrade. |
| | For generic drugs (me-too Status) | Crestat EZ 10/10mg tablets manufactured by CCL Pharmaceutical (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Rosuvastatin Calcium is “Hyperlipidemic Agent”. Ezetimibe is “Selective Cholesterol-Absorption |

| | | |
|---|---|---|
| | | Inhibitors” |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Enaltec Labs Private Limited. ,Zhejiang Tianyu Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | 06 Months Accelerated Stability Data and 06 months Long-Term Stability according to zone IV-B. Batch size: 2000 tablets |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate dated 25-10-2022 for 100kg material is submitted, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence Report and Comparative Dissolution Profile against the comparator's product i.e. RolipEze by M/s Hilton Pharma is submitted. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months Accelerated Stability Data of Rosuvastatin Calcium and 36 months Long-Term Stability Data of Rosuvastatin Calcium. 06 months Accelerated Stability Data of Ezetimibe and 36 months Long-Term Stability Data of Ezetimibe according to zone IV-B. |
| | The status in reference regulatory authorities | HPRA Ireland approved |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 23-07-2024. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved. |
| | **Evaluation Remarks** | |
| | The application has been processed under export priority. The storage conditions for Rosuvastatin are: | |
| | As per BP | USP |
| | In an airtight container, protected from light, at a temperature of 2 °C to 8 °C. The DS used for product development is tested according to BP. | Preserve in well-closed containers, protected from light. Store at controlled room temperature. |
| | The applied product is approved in different reference regulatory authorities as film coated bilayer tablet but HPRA Ireland has approved film coated tablet as a single core in strengths of 40/10mg, 20/10mg and 10/10mg respectively for Rosuvastatin/ezetimibe. | |
| | The reference product by M/s Sanofi Aventis Ireland was checked and it was found that the product has been developed with a single core. The pictures of the product and relevant literature is upload in online application. | |
| | https://assets.hpra.ie/products/Human/18202/33562aa6-f524-4cee-a5c9-329de6e3d3ba.pdf | |
| | https://www.medicines.ie/medicines/suvezen-40-mg-10-mg-film-coated-tablets-34831/license-info | |
| | https://www.hpra.ie/find-a-medicine/for-human-use/authorised-medicines?data=eyJpZCI6bnVsbCwic2tpcCI6MCwidGFrZSI6MTAsInF1ZXJ5Ijoic3V2ZXplbiIsIm9yZGVyIjoi | |
| | The reference product by M/s Sanofi Aventis Ireland was checked and it was found that the product has been developed with a single core. The pictures of the product and relevant literature is upload in online application. | |
| | The applicant has applied for 20/10mg, 10/10mg and 5/10mg tablets. | |
| | **Decision** | |
| | **Approved** | |
| 104 | Case Category | Export Facilitation (Farooq Aslam) |
| | Name, address of Applicant. | **Atco Laboratories Limited** B-18 SITE KARACHI **(000188)** |
| | Application Form Dy. No / Tracking ID & date of submission | (G8N-NW1-ARP3, 2026-02-03) |

| | |
|---|---|
| Detail of Fee Submitted | 38700,<br>2025-11-13, |
| The proposed proprietary name / brand name | **ROVATOR EZ Tablet** |
| Label Claim | Each film coated tablet contains: Rosuvastatin (as Rosuvastatin Calcium) ..... 5mg Ezetimibe ..... 10mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 1 strip x 10 Tablets-De-Controlled,2 strips x 10 Tablets-De-Controlled,3 strips x 10 Tablets-De-Controlled |
| Shelf Life (Unit) | 24 Month(s)Donot store and transport above 30 degree centigrade. |
| For generic drugs (me-too Status) | Crestat EZ 5/10mg tablets manufactured by CCL Pharmaceutical (Pvt.) Ltd. |
| Pharmacotherapeutic Group of (API) | Rosuvastatin Calcium is “Hyperlipidemic Agent”. Ezetimibe is “Selective Cholesterol-Absorption Inhibitors” |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Enaltec Labs Private Limited. ,Zhejiang Tianyu Pharmaceutical Co., Ltd. |
| Detail of stability batches of drug product | 06 Months Accelerated Stability Data and 06 months Long-Term Stability according to zone IV-B. Batch size: 2000 tablets |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate dated 25-10-2022 for 100kg material is submitted, |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence Report and Comparative Dissolution Profile against the comparator's product i.e. RolipEze by M/s Hilton Pharma is submitted. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months Accelerated Stability Data of Rosuvastatin Calcium and 36 months Long-Term Stability Data of Rosuvastatin Calcium. 06 months Accelerated Stability Data of Ezetimibe and 36 months Long-Term Stability Data of Ezetimibe according to zone IV-B. |
| The status in reference regulatory authorities | Eklipo 5mg/10mg Tablet manufactured by Elpen Pharmaceutical Co. Inc. |
| GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 23-07-2024. |
| Evidence of approval of manufacturing facility | Tablet General Section is approved. |

**Evaluation Remarks**

The application has been processed under export priority. The storage conditions for Rosuvastatin are:

| | |
|---|---|
| As per BP | USP |
| In an airtight container, protected from light, at a temperature of 2 °C to 8 °C. The DS used for product development is tested according to BP. | Preserve in well-closed containers, protected from light. Store at controlled room temperature. |

The applied product is approved in different reference regulatory authorities as film coated bilayer tablet but HPRA Ireland has approved film coated tablet as a single core in strengths of 40/10mg, 20/10mg and 10/10mg respectively for Rosuvastatin/ezetimibe.

The reference product by M/s Sanofi Aventis Ireland was checked and it was found that the product has been developed with a single core. The pictures of the product and relevant literature is upload in online application.

| | | |
|---|---|---|
| | https://assets.hpra.ie/products/Human/18202/33562aa6-f524-4cee-a5c9-329de6e3d3ba.pdf | |
| | https://www.medicines.ie/medicines/suvezen-40-mg-10-mg-film-coated-tablets-34831/license-info | |
| | https://www.hpra.ie/find-a-medicine/for-human-use/authorised-medicines?data=eyJpZCI6bnVsbCwic2tpcCI6MCwidGFrZSI6MTAsInF1ZXJ5Ijoic3V2ZXplbiIsIm9yZGVyIjoi | |
| | The reference product by M/s Sanofi Aventis Ireland was checked and it was found that the product has been developed with a single core. The pictures of the product and relevant literature is upload in online application. | |
| | The applicant has applied for 20/10mg, 10/10mg and 5/10mg tablets. However, the strength of 5/10mg is not approved by HPRA Ireland but it is approved by other reference regulatory authorities as bilayer tablet. | |
| | **Decision** | |
| | **Deferred**<br><br>for evidence of approval of the applied product in reference regulatory authorities as defined by Registration Board in its 275th meeting. | |
| 105 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **GT Pharma Pvt. Ltd** 713- Sundar Industrial Estate, Sundar Raiwind Road, **(000829)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GQ2-JDE-YVP4, 2024-06-03) |
| | Detail of Fee Submitted | 30000.0, 9400<br>2024-05-16, 2026-03-31 |
| | The proposed proprietary name / brand name | **Boxyfer Injection** |
| | Label Claim | Each 10ml Glass vial contains: Ferric Carboxymaltose equivalent to Iron.....500mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Controlled Room |
| | For generic drugs (me-too Status) | Feservoir Injection by M/s Cunningham Pharma |
| | Pharmacotherapeutic Group of (API) | Iron preparations |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Nanjing Hencer Pharmaceutical Co., Ltd |
| | Detail of stability batches of drug product | 03 batches : 100 vials |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan letter request dated 06-09-2023 is submitted from M/s Cunningham Pharma for 500 gram material. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against the comparator's product i.e. Feservoir by M/s Martin Dow. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 06 months real time stability data of 03 batches according to zone IV-A. |
| | The status in reference regulatory authorities | MHRA |
| | GMP status of the firm | Last inspection report dated 17-11-2023 is submitted. |
| | Evidence of approval of manufacturing facility | Liquid injectable (General) section for ampoules and vials is approved. |
| | **Evaluation Remarks** | |
| | The firm has submitted extract of 357th meeting of Registration Board. The stability data is already approved with the following details: | |
| | Name of applicant: M/s Jenner Pharmaceuticals Pvt. Ltd, Sheikhupura. | |
| | Name of manufacturer: M/s GT Pharma (Pvt) Ltd., Lahore | |

| | | |
|---|---|---|
| | Product: Each 10mL contains: Ferric carboxy Maltose eq. to Iron.....500mg | |
| | Application ID: DT8-9M7-QX8L dated 11-09-2024. | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 106 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y3D-9AN-B4D7, 2024-10-10) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-25, |
| | The proposed proprietary name / brand name | **THD 50mg CAPSULE** |
| | Label Claim | Each Capsule Contains: Thalidomide-50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1x10-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | Teramide 50mg Capsule by M/s Seraph Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | immunomodulator |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Laurus Labs Limited |
| | Detail of stability batches of drug product | 03 batches : 3100 capsules each 06 months accelerate and 06 months real time according to zone IV-A. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate dated 18-07-2023 for 1.5kg material is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been submitted against the comparator's product ie Teramide 50mg capsule by M/s Seraph Pharmaceuticals. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 60 months real time stability data according to zone IV-A. |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 24th to 25-05-202. |
| | Evidence of approval of manufacturing facility | Capsule General Section is approved. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 107 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GS4-LY7-U3Z2, 2024-10-24) |
| | Detail of Fee Submitted | 75000.0, 18000.0<br>2024-06-05, 2024-10-09 |
| | The proposed proprietary name / brand name | **Lotepred Eye Drops** |

| | | |
|---|---|---|
| | Label Claim | Each ml of ophthalmic suspension contains: Loteprednol Etabonate.....5mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | as per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | Product Name: Lotepred Opthalmic Suspension Strength: 5mg/ml Manufactured By: Sante Pharmaceuticals Reg. No.: 008230-EX |
| | Pharmacotherapeutic Group of (API) | Corticosteroid indicated for inflammatory conditions of eyes |
| | Name, address of Manufacturing site: | Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi- |
| | Name & address of API manufacturer | Flax Laboraotires |
| | Detail of stability batches of drug product | 03 batches Batch Size: 14,000 vials accelerated and real time stability data according to zone IV-A. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | AD attested invoice issued on 21-06-2021 for 3kg material (Winthrox). |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against the comparator's product Loteprad 5mg/mL eye drop by M/s Sante (Private) Ltd. |
| | 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 | Lotemax eye suspension, TGA Australia approved |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 10-06-2024. (Winthrox) |
| | Evidence of approval of manufacturing facility | Sterile eye drops (General) Section is approved. (Winthrox) |
| | **Evaluation Remarks** | |
| | The firm was asked to provide scientific justification for: | |
| | Manufacturing method includes preparation of part A by mixing Loteprednol and Tyloxapol in water. The resultant solution cannot be sterilized by filtration because Loteprednol is not dissolved but it is suspended in Part A of suspension mixture. This step produces an unsterilized suspension mixture which is not acceptable in sterile products' manufacturing. The step could have been performed by dissolving Tyloxapol in water as per SOP, then filtered for sterilizing the solution and then the sterile Loteprednol should have been added for preparation suspension i.e. Part A. Clarification is required. | |
| | Reply: Tyloxapol containing suspension are difficult to sterilize by membrane filtration because the drug particles are larger than the 0.22micro meter filter pore size. Sterilize the Part A suspension separately usually by terminal sterilization by using autoclaving (121 °C) than after mixing sterilize Loteprednol to make suspension and add into main bulk mixture. | |
| | The manufacturer is already manufacturing the product. (Registration Number: .86738). | |
| | **Decision** | |
| | **Deferred**<br><br>The Board deferred the case considering for following innovator's manufacturing method of the applied product. | |
| 108 | Case Category | Any Other (Farooq Aslam) |

| | | |
|---|---|---|
| | Name, address of Applicant. | **Martin Dow Limited** Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan **(000267)** |
| | Application Form Dy. No / Tracking ID & date of submission | (47T-BLE-DEND, 2026-02-12) |
| | Detail of Fee Submitted | 38700,<br>2025-11-07, |
| | The proposed proprietary name / brand name | **Tadivra Tablets 5mg** |
| | Label Claim | Each film-coated tablet contains: Tadalafil .....5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-As per SRO,2's-As per SRO,20's-As per SRO,28's-As per SRO,4's-As per SRO,8's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Ciafil Tablet 5mg (Mfg. By AGP Limited) |
| | Pharmacotherapeutic Group of (API) | Drugs used in erectile dysfunction |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Stability data of 3 batches on Zone IV provided (Batch size: 3000 tablets) |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate dated 27-02-2025 for 0.426kg is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE & CDP performed against innovator product "CIALIS film-coated tablets by Lilly USA, LLC " |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A. |
| | The status in reference regulatory authorities | CIALIS tablets (Mfg By. Lilly USA, LLC) - USFDA Approved |
| | GMP status of the firm | GMP (Valid till 02-08-2027) |
| | Evidence of approval of manufacturing facility | Section Approval dated 15-Sep-2021 mentions the availability of Tablet (General) Section |
| | **Evaluation Remarks** | |
| | Shortcomings were communicated to the firm. In response the firm has requested for withdrawal of the application. | |
| | **Decision** | |
| | **Rejected**<br><br>As withdrawn by the applicant. | |
| 109 | Case Category | Any Other (Farooq Aslam) |
| | Name, address of Applicant. | **Martin Dow Limited** Plot no. 37, Sector 19, Korangi Industrial Area, Karachi-74900, Pakistan **(000267)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QSH-QHJ-W7ZB, 2026-02-12) |
| | Detail of Fee Submitted | 38700,<br>2025-11-07, |
| | The proposed proprietary name / brand name | **Tadivra Tablets 20mg** |
| | Label Claim | Each film-coated tablet contains: Tadalafil .....20mg |

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|---|---|---|
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-As per SRO,2's-As per SRO,20's-As per SRO,28's-As per SRO,4's-As per SRO,8's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Ciafil Tablet 5mg (Mfg. By AGP Limited) |
| | Pharmacotherapeutic Group of (API) | Drugs used in erectile dysfunction |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Stability data of 3 batches on Zone IV provided (Batch size: 3000 tablets) |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate dated 27-02-2025 for 0.426kg is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE & CDP performed against innovator product "CIALIS film-coated tablets by Lilly USA, LLC " |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 60 months real time stability data of 03 batches according to the conditions of zone IV-A. |
| | The status in reference regulatory authorities | CIALIS tablets (Mfg By. Lilly USA, LLC) - USFDA Approved |
| | GMP status of the firm | GMP (Valid till 02-08-2027) |
| | Evidence of approval of manufacturing facility | Section Approval dated 15-Sep-2021 mentions the availability of Tablet (General) Section |
| | **Evaluation Remarks** | |
| | Shortcomings were communicated to the firm. In response the firm has requested for withdrawal of the application. | |
| | **Decision** | |
| | **Rejected**<br><br>As withdrawn by the applicant. | |
| 110 | Case Category | Export Facilitation (Farooq Aslam) |
| | Name, address of Applicant. | **Atco Laboratories Limited** B-18 SITE KARACHI **(000188)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZNM-EVH-T56B, 2025-09-30) |
| | Detail of Fee Submitted | 37000.0,<br>2025-05-06, |
| | The proposed proprietary name / brand name | **BYNEVOL-V TABLET** |
| | Label Claim | Each film coated tablet contains: Nebivolol as Hydrochloride.....5mg Valsartan.....80mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Do not store and transport above 30 degree centigrade |
| | For generic drugs (me-too Status) | Gneb-V Tablet by Genix Pharma |
| | Pharmacotherapeutic Group of (API) | Beta Adrenergic blocker and Angiotensin II Receptor blocker |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | SECOND PHARMA CO., LTD., NO.33 WEIWU ROAD, HANGZHOU GULF FINE CHEMICAL ZONE, SHANGYU CITY,ZHEJIANG |

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|---|---|---|
| | | PROVINCE 312369,P.R OF CHINA,SMAART PHARMACEUTICALS., B-23,MIDC, AJANTHA ROAD, |
| | Detail of stability batches of drug product | 03 batches having batch size of 3000tabelts accelerated and long term study for 6months provided. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Nebivolol: Clearance certificate No: E-1238184826941 dated 21-03-2023. Valsartan: Clearance certificate No: E-4500309991283 dated 20-05-2022. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence and CDP studies have been performed against the comparator's product i.e. Gneb-V Tablet by Genix Pharma |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Nebivolol: 06 months accelerated and 36 months real time stability data of 03 batches according to zone Iv-B. Valsartan: 06 months accelerated and 48 months real time stability data according to zone IV-B. |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | GMP Certificate No. 166 /2024-DRAP (K)enclosed valid till 22/07/2027 |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved. |
| | **Evaluation Remarks** | |
| | The application is processed under exports facilitation letter dated 30 April 2026. | |
| | **Decision** | |
| | **Approved** | |
| 111 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **jupiter Pharma** Plot No 25 Street S-6 RCCI Rawat Rawalpindi **(000838)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RD1-EV8-NLBR, 2024-06-13) |
| | Detail of Fee Submitted | 75000.0, 2024-02-02, |
| | The proposed proprietary name / brand name | **Dexxo 30mg Capsule** |
| | Label Claim | Each Capsule Contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole.....30MG |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°c |
| | For generic drugs (me-too Status) | Dexxo Capsule by Weather Folds Pharma. |
| | Pharmacotherapeutic Group of (API) | PPI |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar.- |
| | Name & address of API manufacturer | Winbrains Research Laboratories |
| | Detail of stability batches of drug product | Batches: T001, T002, T003 (Batch size: 5000 packs (1*14's)) 06 months accelerated and 06 months real time stability data is submitted according to zone IV-A. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Pellets have been procured locally against invoice no. 27 dated 13-01-2021 from M/s Winbrains Research Laboraoties. |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been submitted against Dexilent 30mg delayed release capsule by M/s Takeda. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 36 months real time stability data of 03 batches is submitted according to zone IV-A. |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 12-10-2022 (Weather folds) |
| | Evidence of approval of manufacturing facility | Capsule General Section is approved as per submitted GMP certificate. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 112 | Case Category | New License (Farooq Aslam) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L5E-6V5-B9L5, 2025-11-10) |
| | Detail of Fee Submitted | 38700,<br>2025-09-05, |
| | The proposed proprietary name / brand name | **BETAPIME 500mg INECTION** |
| | Label Claim | Each vial contains: Cefepime as Hydrochloride Monohydrate (with L-arginine) .....500mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Cefstar Injection 500mg Barrett Hodgson Pakistan (Pvt) Ltd., F/423 SITE Karachi., Karachi Registration No: 0309543 |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Kopran Research Laboratories Limited. Parijat House 1076,Dr. E. Moses Road, Worli, Mumbai-400 018,India |
| | Detail of stability batches of drug product | Batches: CMP16T, CMP17T, CMP18T (Batch size: 1000 vials) 06 months real time and 06 months accelerated stability data according to the conditions of zone IV-A. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan letter from M/s Alton Pharmaceuticals for 10kg material is submitted. Clearnce certificate dated 01-11-2024 is submitted (M/s Alton Pharmaceuticals) |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against Cefstar 500mg injection by M/s Barret Hodgson. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | The data is not as per zone IV-A. |
| | The status in reference regulatory authorities | Regulatory Authority USFDA (Maxipime 500mg Powder for Solution for Injection or Infusion, Hospira, Inc. Lake Forest, IL 60045 USA.) |
| | GMP status of the firm | New License (w.e.f. 02-06-2021) |

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| | Evidence of approval of manufacturing facility | Dry vial injection section (Ceph) is approved. |
| | **Evaluation Remarks** | |

| Observations | Response |
|---|---|
| Clarification since you have not imported USP reference standard and the working standard from the API manufactured has been used in analysis which is not according to the guidelines. | For trial batches we have used API manufacturer's provided reference standard. We shall import reference standard for the commercial batches. |
| Provide stability studies for drug substance according to the conditions of zone IV-A for 03 batches. | The firm could not provide the stability data of DS according to the conditions of zone IV-A. However, the firm has submitted forced degradation studies as per the decision of 297th meeting of Registrtaion Board. |
| Submit BMRs of stability batches. | Submitted. |

As per the submitted Chromatograms, the submitted forced degradation studies were performed in March, 2025 whereas the query regarding the stability data was forwarded in December, 2025. The firm was asked to submit clarifictaion:

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| For the second query it is to clarify that our HPLC system is equipped with auto sampler and we normally perform the studies as a whole project taking advantage of auto sampling facility. Once the complete project is run, we process all the data of project at the same time. Moreover, as no excipients are involved in Cefepime injection and the same lot is used for both 500mg and 1g injections having same qualitative formulation, analyzed using the same stability indicating method results appear same and close to each other having same chromatographic profiles. |

The case was deferred in 358th meeting for verification of audit trail report from 18th to 20th March, 2025. The audit trail report has been submitted.

**Decision**

**Approved**

| | | |
|---|---|---|
| 113 | Case Category | New License (Farooq Aslam) |
| | Name, address of Applicant. | **Acumen Healthcare (Pvt.) Ltd** plot#, 39, 40 Street S2, Rawat Industrial Estate, Islamabad **(000932)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VQM-778-PPN8, 2025-11-10) |
| | Detail of Fee Submitted | 38700,<br>2025-09-05, |
| | The proposed proprietary name / brand name | **BETAPIME 1G INECTION** |
| | Label Claim | Each vial contains: Cefepime as Hydrochloride Monohydrate (with L-Arginine).....1000mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Room Temprature |
| | For generic drugs (me-too Status) | Cefstar Injection 1000mg Barrett Hodgson Pakistan (Pvt) Ltd., F/423 SITE Karachi., Karachi Registration No: 030954 |
| | Pharmacotherapeutic Group of (API) | Third generation cephalosporins |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Kopran Research Laboratories Limited. Parijat House 1076,Dr. E. Moses Road, Worli, Mumbai-400 018,India |
| | Detail of stability batches of drug product | Batches: CMP19T, CMP20T, CMP21T (Batch size: 1000 vials) 06 months real time and 06 months accelerated stability data according to the conditions of zone IV-A. |

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| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan letter from M/s Alton Pharmaceuticals for 10kg material is submitted. Clearnce certificate dated 01-11-2024 is submitted (M/s Alton Pharmaceuticals) |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against Cefstar 1000mg injection by M/s Barret Hodgson. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | The data is not as per zone IV-A. |
| | The status in reference regulatory authorities | Regulatory Authority USFDA (Maxipime 1000mg Powder for Solution for Injection or Infusion, Hospira, Inc. Lake Forest, IL 60045 USA.) |
| | GMP status of the firm | New License (w.e.f. 02-06-2021) |
| | Evidence of approval of manufacturing facility | Dry vial injection section (Ceph) is approved. |
| | **Evaluation Remarks** | |
| | Submitted. | |
| | As per the submitted Chromatograms, the submitted forced degradation studies were performed in March, 2025 whereas the query regarding the stability data was forwarded in December, 2025. The firm was asked to submit clarifictaion: | |
| | For the second query it is to clarify that our HPLC system is equipped with auto sampler and we normally perform the studies as a whole project taking advantage of auto sampling facility. Once the complete project is run, we process all the data of project at the same time. Moreover, as no excipients are involved in Cefepime injection and the same lot is used for both 500mg and 1g injections having same qualitative formulation, analyzed using the same stability indicating method results appear same and close to each other having same chromatographic profiles. | |
| | The case was deferred in 358th meeting for verification of audit trail report from 18th to 20th March, 2025. The audit trail report has been submitted. | |
| | **Decision** | |
| | **Approved** | |
| 114 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2NN-E9S-JE59, 2024-06-10) |
| | Detail of Fee Submitted | 75000.0,<br>2024-04-23, |
| | The proposed proprietary name / brand name | **Diclom** |
| | Label Claim | Each hard gelatin capsule contains: Diclofenac sodium (as MR pellets) .....75mg Omeprazole (as enteric coated pellets).....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 30's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place. Below 30 oC |
| | For generic drugs (me-too Status) | could not be confirmed |
| | Pharmacotherapeutic Group of (API) | NSAID/PPI |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Vision Pharmaceuticals (Pvt.) Ltd, Address: Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad- Pakistan,M/s Alphamed Formulations Private Limited, Address: Sy.no.225, sampanbole village, shamirpet mandal,medchal- malkajgiri |

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|---|---|
| | district, telangana 500101, sampanbole village, shamirpet mandal, medchal - mal |
| Detail of stability batches of drug product | Batches: TF-01, TF-02, TF-03 (Batch size: 500 capsules) 06 months acc and 06 months RT stability data according to zone IV-A. |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Diclofenac Sodium MR Pellets: Form 6 dated 22-12-2021 for 1kg material is submitted along with AD attested invoice. Omeprazole pellets: Invoice from M/s Vision Pharma dated 21-04-2023 for 1 kg material is submitted. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been performed against the product i.e. DicloDuo Combi by M/s Haupt Pharma Amareg GmbH. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Omeprazole ECP: 06 months accelerated and 24 months real time stability data of 03 batches according to the conditions of zone IV-A. Diclofenac Sodium: 06 months accelerated and 36 months real time stability data according to zone IV-A for 03 batches. |
| The status in reference regulatory authorities | MHRA Approved (Diclopram MR hard capsules) |
| GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 03-01-2023. |
| Evidence of approval of manufacturing facility | Capsule General Section is approved. |

**Evaluation Remarks**

| Observation | Response |
|---|---|
| As per the literature of innovator's product, the hard capsule contains 25mg of gastro resistant pellets and 50mg prolonged release pellets, therefore, the submitted testing of drug substance should support the innovator's formulation as per the dissolution test of drug substance for 25mg of gastro resistant pellet, the test on acidic medium has not been performed, please clarify with scientific justifications. Furthermore, there should be separate development studies along with testing method and stability studies etc for 25mg (gastro resistant) and 50mg (prolonged release pellets) whereas in your application, the submitted studies support the formulation of only one type of pellets i.e. prolonged release. Please submit scientific clarification with supporting data. | During stability studies of the capsule, dissolution in 0.1N HCl has been performed for confirming the enteric coating of Omeprazole pellets in respect of acid resistance. As per submitted chromatograms: No Diclofenac Sodium peak was detected in acid stage dissolution testing confirming the no release of Diclofenac prolonged release pellets and gastro resistant pellets in acidic medium. |

The case was deferred in 353rd meeting for submission of dissolution data in acidic medium for gastro-resistant pellets (DS) for verification of two distinct release profiles of the two pellets i.e. 25mg gastro resistant and 50mg prolonged release pellets.

Reply: Dissolution of Diclofenac Sodium pellets 25mg gastro resistant and 50mg prolonged released pellets in single capsule (including 20mg Omeprazole), was performed on initial testing of TF-01, TF-02 and TF-03. The Chromatograms and Calculation Sheets along with Testing Method are attached for your reference.

Remarks: The testing has been performed in acid stage i.e 0.01N HCl and sampling point of 2 hours has been selected. As per submitted chromatograms no peak of Diclofenac has been detected. However a peak for Omeprazole is visible confirming that there is no release of Diclofenac n acidic medium upto 02 hours.

**Decision**

| | | |
|---|---|---|
| | **Approved** | |
| 115 | Case Category | Contract Manufacturing (Farooq Aslam) |
| | Name, address of Applicant. | **Danas Pharmaceuticals (Pvt) Ltd.** 312-Industrial Triangle, Kahuta road,Islamabad. **(000569)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BDW-VVU-E5TQ, 2024-02-26) |
| | Detail of Fee Submitted | 75000.0, 75000.0<br>2023-11-08, 2023-11-08 |
| | The proposed proprietary name / brand name | **Dancef Injection 1g** |
| | Label Claim | Each Vial contains ceftriaxone (as sodium).....1g |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1,s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Ceftriaxone for injection sterile powder should be |
| | For generic drugs (me-too Status) | Rocephin Injection 1g I.V Martin Dow Limited Plot No.37, Sector 19, Korangi Industrial Area, Karach |
| | Pharmacotherapeutic Group of (API) | Cephalosporin |
| | Name, address of Manufacturing site: | Evolution Pharmaceuticals (Pvt.)Ltd-Plot #: 25 & 26, Street #: S-3 RCCI, National Industrial Zone Rawat, Islamabad - Pakistan - |
| | Name & address of API manufacturer | SinopharmWeiqida Pharmaceutical Co., Ltd |
| | Detail of stability batches of drug product | 16500 vials: 3 batches |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | 03-02-2023: clearance certificate submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Oxidil Injection of Sami: PE studies performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 3 batches as per Zone IV-A |
| | The status in reference regulatory authorities | Rocephin Injection 1g I.V,Hoffmann-La Roche, Ltd.; Basel, Switzerland: |
| | GMP status of the firm | (Evolution pharma: 11-01-2023: GMP certificate |
| | Evidence of approval of manufacturing facility | (Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section |
| | **Evaluation Remarks** | |
| | The applicant was asked to clarify the following on 12.03.2025: 1) Submit specifications of API from drug product manufacturer in section 3.2.S.4.2 2) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability is approximately 5413495, while peak area for the same concentration solutin in linearity studies is 11162684. Justify how such huge difference can exist is peak areas of same concentration solution. 3) Justify the precision studies of the drug substance in which results are mentioned in % instead of peak areas. 4) Justify the specificity test in the light of ICH / WHO guidelines. 5) The acceptance criteria for assay specified by API manufacturer is >84%, while the drug product manufacturer has used assay limit as NLT795ug/ml. Justify how drug product manufacturer can adopt difference assay limits. 6) Justify how your drug substance qualifies USP specs while the assay limit adopted by API manufacturer is different than USP. 7) Specify the fill weight of API per vial in 3.2.P.1 8) Submt compatibility studies of the drug product with diluent in section 3.2.P.2.6 9) USP monograph for "ceftriaxone for injection" specifies two different assay tests while you have mentioned only 1 test in your specifications. Clarification is required in this regard. 10) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug | |

product. Justify how such difference can exist while no formulation is involved in this product. 11) Submit summary of stability study data in section 3.2.P.8.1 12) Submit stability study data sheets of all batches as per the template given in CTD guidance document in section 3.2.P.8.3 so that assessment of results of stability studies can be made. The raw data of stability studies shall be provided in the Point No. 4 of the 6-points checklist of stability study data. 13) Submit complete 6 months stability study data. 14) Submit COA of API along with its clearance certificate which is used in the manufacturing of batches for which stability study data has been submitted, since you have provided clearance certificate of 2023 while batches were manufactured in 2022. The applicant submitted incomplete response on 24.04.2025 and was asked to submit complete response on the same date. On 30.04.2025 the applicant submitted complete response which was evaluated and still found deficient of the following which was communicated to applciant in July, 2025: 1) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability and precision is approximately 5413495, while peak area for the same concentration solution in linearity studies is 11162684. Justify how such huge difference can exist is peak areas of same concentration solution. Reconduct the analytical verification studies with correct injection volume and submit detailed report (including raw data sheet and chromatograms) accordingly Furthermore values of Peak areas in chromatograms of intermediate precision do not correspond to raw data. 2) Specify the fill weight (600mg ) as provided is not justifiable w.r.t salt factor since there is no excipient has been added in finished product formulation. 3) Submit compatibility studies of the drug product with diluent in section 3.2.P.2.6 4) USP monograph for "ceftriaxone for injection" specifies two different sample solutions (A and B or C). Perform analysis of finished product as per USP monograph and submit report accordingly. 5) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug product. Justify how such difference can exist while no formulation is involved in this product. Otherwise re conduct the product verification studies and submit the report accordingly. 6) Re conduct stability studies using sample volume/injection volume as per USP i.e 20 ul . On 21.08.2025, the applicant was sent a reminder to submit replies. The applicant submitted following on 19.09.2025: Subject: Clarification on Our Submission for Ceftriaxone Sodium Injection Respected Concerns, This letter is to clarify a possible confusion in our application for Ceftriaxone Sodium Injection. 1. The Mistake in Our First Submission:We imported two different medicines in one shipment: Ceftriaxone Sodium and Cefotaxime Sodium.In our first documents, we accidentally sent the quality certificate (COA) for a different Ceftriaxone batch and also included the certificate for Cefotaxime (Batch S012102005).This was our error. We are sorry for the confusion. 2. The Correct Information:The correct batches of Ceftriaxone Sodium we used are: Batch Q012105066 Batch Q012105067We are now attaching the official quality certificates (COAs) for these exact batches.The product meets all USP quality standards. 3. Stability Study Batches:Our stability studies were done using the correct batches of Ceftriaxone Sodium listed above (Q012105066 and Q012105067).The Cefotaxime batch (S012102005) was never used for any Ceftriaxone stability studies. We hope this clear explanation resolves any questions. Please let us know if you need more information. Sincerely, Danas Pharmaceutical Pvt Ltd

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| The case was deferred in 353rd meeting for PSI for verification of authenticity of submitted stability data. |
| However, the Board rejected the stability data of the same manufacturer i.e. M/s Evolution Pharmaceuticals against application ID No. GQR-21L-2GXT, 2024-02-28 (Applicant: M/s Sawera Pharmaceuticals) and the applicant was advised to submit complete product development data and stability studiesusing appropriate and pharmacopeia-compliant specifications with ceftriaxone for Injection, including defined lower and upper acceptance criteria in line with USP requirements. |
| Submitted for consideration by the Board. |

**Decision**

**Deferred**

The Board rejected the submitted stability data and directed the applicant to submit complete drug product development data and stability studies using appropriate and pharmacopoeial compliant specifications for Ceftriaxone for Injection, including defined lower and upper acceptance criteria in-line with USP requirements.

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| 116 | Case Category | Contract Manufacturing (Farooq Aslam) |

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| Name, address of Applicant. | **Danas Pharmaceuticals (Pvt) Ltd.** 312-Industrial Triangle, Kahuta road,Islamabad. **(000569)** |
| Application Form Dy. No / Tracking ID & date of submission | (3TE-9SJ-A842, 2024-02-26) |
| Detail of Fee Submitted | 75000.0,<br>2023-11-08, |
| The proposed proprietary name / brand name | **Dancef Injection 500 mg IV** |
| Label Claim | Each Vial Contains: Ceftriaxone Sodium Equivalent to ceftriaxone.....500mg |
| Reference to Finished product specifications | United States Pharmacopeia |
| Proposed Pack Size | 1,s-As per SRO |
| Shelf Life (Unit) | 2 Year(s)Ceftriaxone for injection sterile powder should be stored at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature] and protected from light. After reconstitution, protection from normal ligh |
| For generic drugs (me-too Status) | Oxidil |
| Pharmacotherapeutic Group of (API) | Cephalosporin |
| Name, address of Manufacturing site: | Evolution Pharmaceuticals (Pvt.)Ltd-Plot #: 25 & 26, Street #: S-3 RCCI, National Industrial Zone Rawat, Islamabad - Pakistan - |
| Name & address of API manufacturer | SinopharmWeiqida Pharmaceutical Co., Ltd |
| Detail of stability batches of drug product | 16500 vials: 3 batches |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | 03-02-2023: clearance certificate submitted |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Oxidil Injection of Sami: PE studies performed |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 3 batches as per Zone IV-A |
| The status in reference regulatory authorities | USFDA Approved |
| GMP status of the firm | (Evolution pharma: 11-01-2023: GMP certificate |
| Evidence of approval of manufacturing facility | (Evolution pharma) 10-07-2017: Issuance of DML letter specifies Dry vial injection (Cephalosporin) section |

**Evaluation Remarks**

The applicant was asked to clarify the following on 12.03.2025: 1) Submit specifications of API from drug product manufacturer in section 3.2.S.4.2 2) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability is approximately 5413495, while peak area for the same concentration solutin in linearity studies is 11162684. Justify how such huge difference can exist is peak areas of same concentration solution. 3) Justify the precision studies of the drug substance in which results are mentioned in % instead of peak areas. 4) Justify the specificity test in the light of ICH / WHO guidelines. 5) The acceptance criteria for assay specified by API manufacturer is >84%, while the drug product manufacturer has used assay limit as NLT795ug/ml. Justify how drug product manufacturer can adopt difference assay limits. 6) Justify how your drug substance qualifies USP specs while the assay limit adopted by API manufacturer is different than USP. 7) Specify the fill weight of API per vial in 3.2.P.1 8) Submt compatibility studies of the drug product with diluent in section 3.2.P.2.6 9) USP monograph for "ceftriaxone for injection" specifies two different assay tests while you have mentioned only 1 test in your specifications. Clarification is required in this regard. 10) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug product. Justify how such difference can exist while no formulation is involved in this product. 11) Submit summary of stability study data in section 3.2.P.8.1 12) Submit stability study data sheets of

all batches as per the template given in CTD guidance document in section 3.2.P.8.3 so that assessment of results of stability studies can be made. The raw data of stability studies shall be provided in the Point No. 4 of the 6-points checklist of stability study data. 13) Submit complete 6 months stability study data. 14) Submit COA of API along with its clearance certificate which is used in the manufacturing of batches for which stability study data has been submitted, since you have provided clearance certificate of 2023 while batches were manufactured in 2022. The applicant submitted incomplete response on 24.04.2025 and was asked to submit complete response on the same date. On 30.04.2025 the applicant submitted complete response which was evaluated and still found deficient of the following which was communicated to applciant in July, 2025: 1) The peak areas for standard solution (0.3mg/ml solution of ceftriaxone) in analytical method verification studies in system suitability and precision is approximately 5413495, while peak area for the same concentration solution in linearity studies is 11162684. Justify how such huge difference can exist is peak areas of same concentration solution. Reconduct the analytical verification studies with correct injection volume and submit detailed report (including raw data sheet and chromatograms) accordingly Furthermore values of Peak areas in chromatograms of intermediate precision do not correspond to raw data. 2) Specify the fill weight (600mg ) as provided is not justifiable w.r.t salt factor since there is no excipient has been added in finished product formulation. 3) Submit compatibility studies of the drug product with diluent in section 3.2.P.2.6 4) USP monograph for "ceftriaxone for injection" specifies two different sample solutions (A and B or C). Perform analysis of finished product as per USP monograph and submit report accordingly. 5) The peak areas observed in verification studies of API are entirely different from those observed in verification studies of drug product. Justify how such difference can exist while no formulation is involved in this product. Otherwise re conduct the product verification studies and submit the report accordingly. 6) Re conduct stability studies using sample volume/injection volume as per USP i.e 20 ul . On 21.08.2025, the applicant was sent a reminder to submit replies. The applicant submitted following on 19.09.2025: Subject: Clarification on Our Submission for Ceftriaxone Sodium Injection Respected Concerns, This letter is to clarify a possible confusion in our application for Ceftriaxone Sodium Injection. 1. The Mistake in Our First Submission:We imported two different medicines in one shipment: Ceftriaxone Sodium and Cefotaxime Sodium.In our first documents, we accidentally sent the quality certificate (COA) for a different Ceftriaxone batch and also included the certificate for Cefotaxime (Batch S012102005).This was our error. We are sorry for the confusion. 2. The Correct Information:The correct batches of Ceftriaxone Sodium we used are: Batch Q012105066 Batch Q012105067We are now attaching the official quality certificates (COAs) for these exact batches.The product meets all USP quality standards. 3. Stability Study Batches:Our stability studies were done using the correct batches of Ceftriaxone Sodium listed above (Q012105066 and Q012105067).The Cefotaxime batch (S012102005) was never used for any Ceftriaxone stability studies. We hope this clear explanation resolves any questions. Please let us know if you need more information. Sincerely, Danas Pharmaceutical Pvt Ltd

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| The case was deferred in 353rd meeting for PSI for verification of authenticity of submitted stability data. |
| However, the Board rejected the stability data of the same manufacturer i.e. M/s Evolution Pharmaceuticals against application ID No. 87M-R7Y-P82M, 2024-02-28 (Applicant: M/s Sawera Pharmaceuticals) and the applicant was advised to submit complete product development data and stability studiesusing appropriate and pharmacopeia-compliant specifications with ceftriaxone for Injection, including defined lower and upper acceptance criteria in line with USP requirements. |
| Submitted for consideration by the Board. |

**Decision**

**Deferred**

The Board rejected the submitted stability data and directed the applicant to submit complete drug product development data and stability studies using appropriate and pharmacopoeial compliant specifications for Ceftriaxone for Injection, including defined lower and upper acceptance criteria in-line with USP requirements.

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| 117 | Case Category | Any Other (Farooq Aslam) |
| | Name, address of Applicant. | **Skymed Healthcare Private Limited** House No:2, Gor-1 near Chamba House Lahore, |

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| | | Pakistan. **(05-352-0063-038947D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PV2-1TQ-DX2R, 2026-02-17) |
| | Detail of Fee Submitted | 313500,<br>2025-10-27, |
| | The proposed proprietary name / brand name | **Clarivist injection 7.5mL** |
| | Label Claim | Each mL contains: Gadobutrol.....604.72 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 36 Month(s)Below 30°C |
| | For generic drugs (me-too Status) | Gadoray injection by Graton Pharma (106838) registered as PFS |
| | Pharmacotherapeutic Group of (API) | Contrast media |
| | Name, address of Manufacturing site: | Hainan Poly Pharm. Co., Ltd. -Guilinyang Economic Development zone, Haikou, Hainan 571127, China-China |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Provided |
| | Name, address of Marketing Authorization Holder: | Hainan Poly Pharm. Co., Ltd. , Guilinyang Economic Development zone, Haikou, Hainan 571127, China, China |
| | Details of Certificates (CoPP/FSC/cGMP): | DML No. Qiong20150024 valid till 03-08-2030 is submitted with scope of manufacturing of small volume injections. |
| | Details of Authorization Letter : | CoPP: Apostille CoPP No. 4TMM-SHSP valid till 10-07-2027 is submitted, issued by USFDA. The applied product is available in free sale in US. The facilities and operations conform to WHO-GMP at the time of inspection as per submitted CoPP. DSL: DSL valid till 14-01-2028 is submitted. LOA: Apostille LOA dated 04-08-2025 is submitted. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 48 months real time stability studies of 03 batches according to zone II. |
| | The status in reference regulatory authorities | US FDA approved |
| | **Evaluation Remarks** | |
| | The application has been processed on priority in compliance to the decision of DRAP Authority. | |
| | The firm has submitted separate CoPPs for both filled volumes. The applied product is available in USFDA approved drug product database with different filled volumes (i.e. 7.5mL, 15mL, 2mL, 10mL, 30mL, 65mL) with a strength of 604.72mg/mL. The submitted CoPPs of both strengths does not show the filled volumes. | |
| | https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=217480 | |
| | **Decision** | |
| | **Approved**<br><br>as per import policy for inspection of manufacturer abroad. | |
| 118 | Case Category | Any Other (Farooq Aslam) |
| | Name, address of Applicant. | **Skymed Healthcare Private Limited** House No:2, Gor-1 near Chamba House Lahore, Pakistan. **(05-352-0063-038947D)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (JLL-J17-DAN4, 2026-02-17) |
| | Detail of Fee Submitted | 313500,<br>2025-10-24, |
| | The proposed proprietary name / brand name | **Clarivist injection 15mL** |
| | Label Claim | Each mL contains: Gadobutrol.....604.72 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 36 Month(s)Below 30°C |
| | For generic drugs (me-too Status) | Gadoray injection by Graton Pharma |
| | Pharmacotherapeutic Group of (API) | Contrast media |
| | Name, address of Manufacturing site: | Hainan Poly Pharm. Co., Ltd. -Guilinyang Economic Development zone, Haikou, Hainan 571127, China-China |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Provided |
| | Name, address of Marketing Authorization Holder: | Hainan Poly Pharm. Co., Ltd. , Guilinyang Economic Development zone, Haikou, Hainan 571127, China, China |
| | Details of Certificates (CoPP/FSC/cGMP): | DML No. Qiong20150024 valid till 03-08-2030 is submitted with scope of manufacturing of small volume injections. |
| | Details of Authorization Letter : | CoPP: Apstille CoPP No. PJHT-8KRM valid till 10-07-2027 is submitted issued by USFDA. The applied product is available in free sale in US. The facilities and operations conform to WHO-GMP at the time of inspection as per submitted CoPP. DSL: DSL valid till 14-01-2028 is submitted. LOA: Apostille LOA dated 04-08-2025 is submitted. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 48 months real time stability studies of 03 batches according to zone II. |
| | The status in reference regulatory authorities | US FDA approved |
| | **Evaluation Remarks** | |
| | The application has been processed on priority in compliance to the decision of DRAP Authority. | |
| | The firm has submitted separate CoPPs for both filled volumes. The applied product is available in USFDA approved drug product database with different filled volumes (i.e. 7.5mL, 15mL, 2mL, 10mL, 30mL, 65mL) with a strength of 604.72mg/mL. The submitted CoPPs of both strengths does not show the filled volumes. | |
| | https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=217480 | |
| | **Decision** | |
| | **Approved**<br><br>as per import policy for inspection of manufacturer abroad. | |
| 119 | Case Category | Contract Manufacturing (Farooq Aslam) |
| | Name, address of Applicant. | **The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YTN-2PM-LP37, 2024-10-28) |

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| | Detail of Fee Submitted | 93000.0,<br>2024-10-23, |
| | The proposed proprietary name / brand name | **Ros-Ez 5mg/10mg Tablet** |
| | Label Claim | Each Film Coated tablet contains: Rosuvastatin Calcium Equivalent to Rosuvastatin .....5mg<br>Ezetimibe.....1 |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2x7's, 1x10's, 2x10'-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 °C. |
| | For generic drugs (me-too Status) | Rovista EZ (rosuvastatin and ezetimibe) 5mg/10mg Tablet by Getz Pharma |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road, Lahore.- |
| | Name & address of API manufacturer | CTX Lifesciences Pvt. Ltd. Address: Block No. 251-252, Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230, Gujarat, INDIA,Saptagir Laboratories Pvt Ltd Address: Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana, India-502 247 |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | USFDA Approved: Roszet (rosuvastatin and ezetimibe) 5mg/10mg Tablets |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The applied product Approved was approved on form 5F via TID Application HJM-SAV-AT2V, in 352nd meeting. The firm shall submit the applicable fee for changing the status of the data approved. | |
| | **Decision** | |
| | **Approved** | |
| 120 | Case Category | Contract Manufacturing (Farooq Aslam) |
| | Name, address of Applicant. | **The Searle Company Limited** Plot No. F-319, Sindh Industrial Trading Estate (SITE) **(000016)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9LQ-6EL-MUWZ, 2024-11-01) |
| | Detail of Fee Submitted | 93000.0,<br>2024-10-23, |
| | The proposed proprietary name / brand name | **Ros-Ez 10mg/10mg Tablet** |
| | Label Claim | Each Film Coated tablet contains: Rosuvastatin Calcium Equivalent to Rosuvastatin |

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|---|---|---|
| | | .....10mg<br>Ezetimibe.....1 |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2x7's, 1x10's, 2x10'-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 °C. |
| | For generic drugs (me-too Status) | Rovista EZ (rosuvastatin and ezetimibe) 10mg/10mg Tablet by Getz Pharma |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Raiwind Road, Lahore.- |
| | Name & address of API manufacturer | CTX Lifesciences Pvt. Ltd. Address: Block No. 251-252, Sachin- Magdalla Road GIDC, Sachin, Surat – 394 230, Gujarat, INDIA,Saptagir Laboratories Pvt Ltd Address: Sy.No. Parts of 27, 46 & 50 to 56, Ananthasagar (Vill), Chegunta (Mandal), Medak (Dist.), Telangana, India-502 247 |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Roszet (rosuvastatin and ezetimibe) 10mg/10mg Tablets by Althera Pharmaceuticals LLC, Morristown, NJ 07960 |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The applied product Approved was approved on form 5F via TID Application 5A6-7SN-12EW, in 352nd meeting. The firm shall submit the applicable fee for changing the status of the data approved. | |
| | **Decision** | |
| | **Approved** | |
| 121 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (S26-P4S-8W4W, 2024-07-19) |
| | Detail of Fee Submitted | 75000.0,<br>2024-06-11, |
| | The proposed proprietary name / brand name | **Metolaz** |
| | Label Claim | Each tablet contains: Metolazone..... 10mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place. Below 30 °C |
| | For generic drugs (me-too Status) | Available (Scotmann) |

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| | Pharmacotherapeutic Group of (API) | Thiazide diuretic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s. Azico Biophore India Address: Plot No.40/A, Sy Nos:13,15,16,51,52 & 182, Jawaharlal Nehru Pharma City, Thanam (V), Parawada Mandal Visakhapatnam District- 531 021, Andhra Pradesh, India. |
| | Detail of stability batches of drug product | 03 Batches : 400 tablets 06 months accelerated and 24 months real time stability data is submitted. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | AD attested invoice No, 02326042021 dated 26-04-2021 issued on 25-05-2021 for 15 grams of material. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been performed against Zor. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. |
| | The status in reference regulatory authorities | Food and Drug Administration (FDA) USA |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 03-01-2023. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 122 | Case Category | Export Facilitation (Farooq Aslam) |
| | Name, address of Applicant. | **Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) **(000837)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T85-MVG-ZP8Z, 2025-05-09) |
| | Detail of Fee Submitted | 37000.0, 2024-12-30, |
| | The proposed proprietary name / brand name | **BEMPY-Z 180/10MG TABLET** |
| | Label Claim | Each Film coated tablet contains: Bempedoic acid..... 180mg Ezetimibe ..... 10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10s-As per SRO,15s-As per SRO,4x10s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C. |
| | For generic drugs (me-too Status) | BEMPEX-Z 180/10MG TABLET by M/s HORIZON PHARMACEUTICALS PVT.LTD |
| | Pharmacotherapeutic Group of (API) | Anti-hyperlipidemic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Glenmark Lifesciences Ltd,Metrochem API private Limited |
| | Detail of stability batches of drug product | 03 batches : 4000 tablets 06 months real time and 06 months accelerated stability data acc to zone IV-A. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Ezetimibe: Clearance certificate dated 05-04-2023 is submitted for 15kg material. Bempedoic acid: Form 6 dated 17-09-2023for 3.3kg material. |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been performed against the reference product i.e. Nustendi film coated tablet by M/s Daiichi Sankyo UK Limited. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Ezetimibe: 06 months accelerated and 24 month real time stability data of 03 batches according to zone IV-B. Bembedoic acid: Stability data of 03 batches according to zone II is submitted. |
| | The status in reference regulatory authorities | NEXLIZET 180/10MG TABLET by ESPERION THERAPS INC USA |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 22-02-2023. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved. |
| | **Evaluation Remarks** | |
| | Under exports facilitation as per letter dated 12 August 2025 | |
| | **Decision** | |
| | **Approved** | |
| 123 | Case Category | Any Other (Farooq Aslam) |
| | Name, address of Applicant. | **Al Habib Pharmaceuticals.** Plot 81 SMCHS BLOCK B **(0414)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZDV-H44-6YQ9, 2026-02-04) |
| | Detail of Fee Submitted | 313500,<br>2025-11-10, |
| | The proposed proprietary name / brand name | **K-DAZA 100mg Lyo. Powder for Injection** |
| | Label Claim | Each vial contains : Azacitidine ..... 100 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1s-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | HIMMEL PHARMACEUTICALS (PVT.) LTD Brand name : Azalid AqVida Injection 100mg Lyophilized Powder Strength: 100mg Composition : Each Vial Contains 100mg of Azacitidine. Registration n |
| | Pharmacotherapeutic Group of (API) | SHIVALIK RASAYAN LIMITED Corporate Office Address : 1506, CHIRANJIV TOWER, 43, NEHRU PLACE, NEW DELHI – 110019 Manufacturing Site Address: D-2/CH/41/A, DAHEJ-II, INDUSTRIAL ESTATE V-VADDALA T-VAGRA CITY: BHARUCH; STATE/PROVINCE: GJ (GUJARAT); COUNTRY: INDIA; ZIP/POSTAL CODE: 392140 |
| | Name, address of Manufacturing site: | KWALITY PHARMACEUTICALS LTD. -Plot No.1-A, Industrial Area, Raja Ka Bagh, Distt. Kangra 176201, Himachal Pradesh.-India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been submitted against Azadual for injection by M/s MSN Laboratories Private Limited. |
| | Name, address of Marketing Authorization Holder: | Al Habib Pharmaceuticals, Plot 81, Block B, SMCHS, Karachi , Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP certificate valid till 26-06-2027 is submitted. Dosage forms included are cytotoxic lyophilized injections. |

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| | Details of Authorization Letter : | CoPP: Apostille CoPP No. DCA/DML/KPL/2025/171 valid till 26-06-2027 is submitted. the applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted COPP. DSL: DSL valid till 08-05-2029 is submitted. LOA: LOA dated 23-08-2024 is submitted or the applied product. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated stability data at 25°C ± 2°C / 60±5% RH and 24 months' real time stability data at 5°C ± 3°C |
| | The status in reference regulatory authorities | VIDAZA AZACITIDINE 100MG/VIAL POWDER;INTRAVENOUS, SUBCUTANEOUS New Drug Application (NDA): 050794 Company: BRISTOL-MYERS US FDA APPROVED |
| | **Evaluation Remarks** | |
| | The application has been processed on priority in compliance to the decision of DRAP Authority. | |
| | The firm has submitted stability data of drug product for exhibit batches while data of commercial batches is required. | |
| | **Decision** | |
| | **Deferred**<br><br>for submission of stability data of drug product for 03 commercial batches till claimed shelf life. | |
| 124 | Case Category | Any Other (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 | (MZW-WQD-9HWE, 2025-09-30) |
| | Detail of Fee Submitted | 300000.0,<br>2025-06-25, |
| | The proposed proprietary name / brand name | **BORTADE 3.5mg/Vial** |
| | Label Claim | Each Vial cotains: Bortezomib.... 3.5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store below 30°C. Protect from light and moisture. |
| | For generic drugs (me-too Status) | Bortezomib 3.5mg/Vial MAH: Himont Pharmaceuticals (Pvt)Ltd. |
| | Pharmacotherapeutic Group of (API) | Other antineoplastic agents |
| | Name, address of Manufacturing site: | Kindos Pharmaceuticals Co., Ltd. -No.8-9 Kexin Road. Chengdu Hi-Tech Comprehensive Bonded Zone.Chengdu, Sichuan, 611731, P. R. China - China |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | A comparative analysis of Bortezomib for Injection (3.5 mg/vial) showed that the test product by Kindos Pharmaceuticals is comparable to the reference product by Millennium Pharmaceuticals. Both appeared as white lyophilized powder and met assay specifications (Kindos: 102.0%, Reference: 97.7%). Identification tests for the test product conformed |

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| | | by UV and HPLC. Overall, the test product meets pharmacopeial standards. |
| | Name, address of Marketing Authorization Holder: | Meitheal Pharmaceuticals Inc., , 8700 West Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631 United States of America , United States of America |
| | Details of Certificates (CoPP/FSC/cGMP): | .... |
| | Details of Authorization Letter : | CoPP: The firm has submitted CoPP No. TF2k-36x9 valid till 11-07-2027. The applied product is available in free sale and, the facilities and operations conform to WHO-GMP as per submitted CoPP. DSL: DSL is valid till 15-08-2029. LOA: LOA from Manjing King-Friend Biochemical Pharmaceutical Co., Ltd., grants distribution the rights on behalf of M/s Meitheal Pharmaceuticals Inc, USA (MAH abroad) to the applicant. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability studies of Bortezomib are carried out by drug substance manufacturer, under long term conditions, (25°C ± 2°C, 60%±5% RH for 60 months) and accelerated conditions, (40°C ± 2°C , 75% ± 5% RH for 6 months) as per ICH guidelines. |
| | The status in reference regulatory authorities | Velcade Bortezomib 3.5 mg/Vial Millennium Pharmaceuticals, USFDA Approved |
| | **Evaluation Remarks** | |
| | The application has been processed in compliance to the decision of DRAP Authority. The firm shall submit stability data of drug product signed and stamped by authorized personnel on letter head of the manufacturer. | |
| | The case was deferred in 358th meeting for further deliberations on storage conditions of drug substance. The stability data of drug substance, the submitted real time stability data is at 25°C and accelerated stability data is at 40°C whereas the innovator has mentioned the storage conditions as -20°C. | |
| | The firm has submitted declaration from drug substance manufacturer. The firm has stated that they are manufacturing proprietary novel polymorphic form SB. The crystal structure is different from the innovator; it is not required to adopt the same storage conditions. | |
| | The firm has submitted 06 months accelerated and 60 months real time stability data according to zone II. | |
| | The declaration further states that API adopts optimized synthetic and purification technology with stringent impurity control, making storage at 25'C feasible. The innovator's -20 ·c storage requirement is only due to its outdated manufacturing process and unstable crystal form, rather than an inherent mandatory requirement of the Bortezomib molecule itself. | |
| | The stability data of drug product is submitted till 36 months according to zone IV-A. Submitted for consideration by the Board. | |
| | **Decision** | |
| | **Deferred**<br><br>The firm shall submit the evidence of approval of the polymorphic form SB used in the manufacturing of the applied product in reference regulatory authorities validating the storage conditions as described by the applicant in the instant application. | |
| 125 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (LTQ-T4P-5H9R, 2024-07-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-29, |
| | The proposed proprietary name / brand name | **Proxet CR 12.5mg Tablets** |
| | Label Claim | Each enteric film coated, extended-release tablet contains: Paroxatine HCl equivalent to Paroxetine.....12.5mg (USP Spec's) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Paraxyl CR 12.5 mg Tablets, Manufacturer: CCL Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Anti-depressant |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zheijiang Haisen Pharmaceutical Co. Ltd |
| | Detail of stability batches of drug product | 03 batches : 1500 tablets The firm has adopted USP test I for dissolution. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan request letter dated 08-01-2024 along with agreemet from M/s Seraph Pharmaceuticals is submitted for 0.5lg material. Clearance certificate dated 13-12-2023 is submitted (Seraph Pharmaceuticals) |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been performed against the comparator's product i.e. Paraxyl CR tablet by M/s CCL.. |
| | 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 | Paxil CR 12.5mg Tablets, Manufacturer: Apotex Pharmaceutical corporation (Registered in USA) |
| | GMP status of the firm | NEW DML granted w.e.f 17-01-2024. |
| | Evidence of approval of manufacturing facility | Tablet general Section I and II are approved. |
| | **Evaluation Remarks** | |
| | The submitted chromatograms bear the name of analyst which is not included in the list of employees of the applicant. | |
| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the case for submission of employment details of analyst mention in the submitted chromatograms. | |
| 126 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (G8E-NN3-5Y9T, 2024-07-16) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-29, |
| | The proposed proprietary name / brand name | **Proxet CR 25mg Tablets** |
| | Label Claim | Each enteric film coated, extended-release tablet contains: Paroxetine HCl equivalent to |

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| | | Paroxetine.....25mg (USP Spec's) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Paraxyl CR 25mg Tablets, Manufacturer: CCL Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Anti-depressant |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zheijiang Haisen Pharmaceutical Co. Ltd |
| | Detail of stability batches of drug product | 03 batches : 1500 tablets The firm has adopted USP test I for dissolution. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan request letter dated 08-01-2024 along with agreemet from M/s Seraph Pharmaceuticals is submitted for 0.5lg material. Clearance certificate dated 13-12-2023 is submitted (Seraph Pharmaceuticals) |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been performed against the comparator's product i.e. Paraxyl CR tablet by M/s CCL.. |
| | 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 | Paroxetine HCl 25mg Controlled-Release Tablets, Manufacturer: Apotex Pharmaceutical corporation (Registered in USA) |
| | GMP status of the firm | NEW DML granted w.e.f 17-01-2024. |
| | Evidence of approval of manufacturing facility | Tablet general Section I and II are approved. |
| | **Evaluation Remarks** | |
| | The submitted chromatograms bear the name of analyst which is not included in the list of employees of the applicant. | |
| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the case for submission of employment details of analyst mention in the submitted chromatograms. | |
| 127 | Case Category | Any Other (Farooq Aslam) |
| | 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 | (372-ZW8-6T9J, 2026-02-17) |
| | Detail of Fee Submitted | 313500,<br>2025-10-27, |
| | The proposed proprietary name / brand name | **Milrinone injection** |
| | Label Claim | Each 10mL vial contains: Milrinone.....10mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 36 Month(s)Below 30°C |
| | For generic drugs (me-too Status) | Milron injection by Atco laboratories |
| | Pharmacotherapeutic Group of (API) | ATC code: C01CE02, Cardiac therapy, Phosphodiesterase inhibitor |

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| | Name, address of Manufacturing site: | Shanghai Xudong Haipu Pharmaceutical Co., Ltd. -No. 879, Jinhu Road, China (Shanghai) Pilot Free Trade Zone-China |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been submitted against RLD Primacor by Sanofi, MHRA. |
| | Name, address of Marketing Authorization Holder: | Shanghai Xudong Haipu Pharmaceutical Co., Ltd., No. 879, Jinhu Road, China (Shanghai) Pilot Free Trade Zone, China |
| | Details of Certificates (CoPP/FSC/cGMP): | DML No. 20160003 valid till 31-12-2030 is submitted with the manufacturing scope of small volume injections. |
| | Details of Authorization Letter : | CoPP: Apostille CoPP No. Shnaghai20250180 valid till 08-06-2027 is submitted. The applied product is available in free sale in exporting country and, the facilities and operations conform to WHO-GMP. LOA: Apostille LOA dated 29-06-2025 is submitted. DSL: Valid copy of DSL is submitted (Validity till 14-01-2028) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 36 months real time stability data of 03 batches according to zone II. |
| | The status in reference regulatory authorities | UK-MHRA |
| | **Evaluation Remarks** | |
| | The application has been processed on priority in compliance to the decision of DRAP Authority (220th meeting) regarding imported drug products. | |
| | The product has been developed according to Chinese Pharmacpoeial specifications whereas the product is compendial. The firm was asked to provide justification. In reply, the firm has submitted a comparison of specifications as defined in USP and CP. The limits are either equal or more stringent in CP but the method is different. | |
| | The firm has submitted stability data of drug product according to zone IV-A for exhibit batches. | |
| | **Decision** | |
| | **Deferred**<br><br>for submission of stability data of drug product for commercial batches till claimed shelf life. | |
| 128 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8GY-497-L8EL, 2024-12-02) |
| | Detail of Fee Submitted | 75000.0,<br>2024-11-06, |
| | The proposed proprietary name / brand name | **Eslicar Oral Suspension** |
| | Label Claim | Each ml contains: Eslicarbazepine acetate.....50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 60ml, 120ml, 200ml/A-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30OC at a dry place, protect from light and heat. |
| | For generic drugs (me-too Status) | Carlep Oral Suspension by M/s Genix (Reg. No. 123457) |
| | Pharmacotherapeutic Group of (API) | Anti-epileptic |
| | Name, address of Manufacturing site: | Self Manufacturing |

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| | Name & address of API manufacturer | M/s Ami Lifesciences Private Limited. Address: Block No.82/B, ECP Road, AT & Post: Karakhadi- 391450, Taluka: Padra, District Vadodara. Gujarat, India |
| | Detail of stability batches of drug product | 03 batches : 50 bottles 200mL each 06 months accelerated and 06 months real time stability studies according to zone IV-A. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | AD attested invoice vide dy. No. 0777 dated 11-03-2020 for 10 Kg material is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against the reference product i.e. Zebinex Oral Suspension. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. |
| | The status in reference regulatory authorities | MHRA Approved; ZEBINIX 50 MG/ML ORAL SUSPENSION;Bial Pharma UK Ltd, Admiral House, St Leonards Road, Windsor, SL4 3BL, UK. |
| | GMP status of the firm | GMP certificate issued on the basis on inspection conducted on 14-12-2023. |
| | Evidence of approval of manufacturing facility | Liquid Syrup General Section is approved. |
| | **Evaluation Remarks** | |
| | The firm has submitted copy of intimation letter submitted to DRAP dated 30-04-2026. | |
| | The firm has submitted Risk management plan for Eslicarbazepine tablets and suspension. | |
| | **Decision** | |
| | **Approved** | |
| 129 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Benson Pharmaceuticals** Plot No.03, Main Road, National Industrial Zone, RCCI, Rawat, Rawalpindi **(000447)** |
| | Application Form Dy. No / Tracking ID & date of submission | (21U-SBH-5R25, 2024-10-29) |
| | Detail of Fee Submitted | 75000.0, 2024-09-20, |
| | The proposed proprietary name / brand name | **Bentoril Tablet 12.5 mg** |
| | Label Claim | Each Tablet Contains: Captorpril ..... 12.5 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 30-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Below 30 Degree Centigrade |
| | For generic drugs (me-too Status) | Available |
| | Pharmacotherapeutic Group of (API) | Diuretic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zhejiang Huahai Pharmaceutical Co., Ltd, Xunqiao, Linhai, Zhejiang, 317024 |
| | Detail of stability batches of drug product | 03 batches : Batch size: 500 tablets 06 months accelerated and 06 months real time stability data according to zone IV-A. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate dated 02-03-2022 for 25kg material is submitted. |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against the comparator's product i.e. Capril tablet by M/s Maple Pharma. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 48 months real time stability data according to zone IV-A for 03 batches. |
| | The status in reference regulatory authorities | US FDA Approved |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 15-05-2025. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved. |
| | **Evaluation Remarks** | |
| | GMP certificate of drug substance manufacturer is expired. | |
| | **Decision** | |
| | **Approved**<br><br>subject to submission of valid GMP/DML of drug substance manufacturer. | |
| 130 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Kohinoor Industries** 159-160/B Small Industrial Estate, Sahiwal **(000197)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JRX-H6V-218X, 2025-10-20) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-02, |
| | The proposed proprietary name / brand name | **Pulmodox Liquid Syrup** |
| | Label Claim | Each 5ml contains: Doxofylline.....100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30 CG |
| | For generic drugs (me-too Status) | Fylod 100mg |
| | Pharmacotherapeutic Group of (API) | Aarey Drugs and pharmaceuticals pvt.Ltd. 1227, Hubtown Solaris,12th Floor, N.S. Phadke Marg, Opp-Telli Galli, Andheri Flyover Bridge, Andheri East, Mumbai. India |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Aarey Drugs and pharmaceuticals pvt.Ltd. |
| | Detail of stability batches of drug product | 03 batches : 50 bottles (120mL) 06 month accelerated and 06 months real time. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan letter dated 28-08-2024 for 400grams of material is submitted from M/s Jinnah Pharma. Clerance certificate dated 29-12-2023 is submitted (Jinnah Pharma). |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against the comparator's product i.e. Unifying by M/s Platinum. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 60 month real time stability data of 03 batches according to zone IV-A. |
| | The status in reference regulatory authorities | AIFA Italy approved (20mg/mL) |
| | GMP status of the firm | New Section |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |

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| | Chromatograms under accuracy (80%, 100%, 120%) have been submitted with different values of different parameters but the time acquired is same. Similarly, the chromatograms submitted under repeatability and specificity parameter have different values but time for acquiring is same. | |
| | **Decision** | |
| | **Rejected**<br><br>The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified data by the applicant, the Board decided to reject the case. | |
| 131 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Kohinoor Industries** 159-160/B Small Industrial Estate, Sahiwal **(000197)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AD7-JLS-5V1J, 2025-10-02) |
| | Detail of Fee Submitted | 37000.0, 1700.0<br>2025-03-11, 2025-08-27 |
| | The proposed proprietary name / brand name | **ONKAT** |
| | Label Claim | Each 5ml contains: Ondansetron HCl Dihydrate eq. To Ondansetron.....4mg (USP Specification). |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 25ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30 CG |
| | For generic drugs (me-too Status) | Onset 4mg/5ml Oral Solution |
| | Pharmacotherapeutic Group of (API) | Anti-Emetic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | SYMED LABS LIMITED, UNIT –VI , SY NO:744,745,750,751,752&753Mandollagudem(vi Choutu (Mandal) Yadadri(District)-508252Telangana(India). |
| | Detail of stability batches of drug product | 03 batches: 70 bottles (50mL) 06 months real time and 06 months acc stability data is submitted. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan letter dated 01-07-2024 for 2kg material is submitted from M/s Neutro Pharam Pvt. Ltd.. Clearance certificate dated 04-08-2023 (Neutro Pharma). |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies have been performed against the comparator's product i.e. Emesson Oral solution by M/s Highnoon. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 36moths real time stability data of 03 batches according to zone IV-A. |
| | The status in reference regulatory authorities | ZOFRAN Oral solution |
| | GMP status of the firm | New Section |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | The submitted chromatograms have same acquired data and time under accuracy studies (80%, 100% and 120%). The same observation has been noted in chromatograms submitted under linearity and repeatability parameters of AMV studies. | |
| | **Decision** | |
| | **Rejected** | |

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| | The Board, upon deliberation, emphasized that the integrity and authenticity of submitted information is a basic requirement for the fair proceeding. In light of the submission of falsified data by the applicant, the Board decided to reject the case. | |
| 132 | Case Category | Any Other (Farooq Aslam) |
| | Name, address of Applicant. | **Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)** |
| | Application Form Dy. No / Tracking ID & date of submission | (URW-J1H-4L1L, 2026-01-29) |
| | Detail of Fee Submitted | 38700,<br>2026-01-21, |
| | The proposed proprietary name / brand name | **TADALO TABLET 20MG** |
| | Label Claim | Each Film coated tablet contains Tadalafil.....20mg. |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's, 20's, 30's & 10x10's-As per SRO |
| | Shelf Life (Unit) | 3 Year(s)Room Condition |
| | For generic drugs (me-too Status) | Manufacturer Name Company Name: CCL Pharmaceuticals Pvt Ltd Generic Name Tadalafil Brand Name Product Name: Tadala 20mg Tablet Registration Number: 132219 |
| | Pharmacotherapeutic Group of (API) | Phosphodiesterase inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s. RAKSHIT PHARMACEUTICALS LIMITED Address: PLOT NO.: 68/A, JAWAHARLAL NEHRU PHARMA CITY, PARAWADA (MANDAL), ANAKAPALLI (DIST), ANDHRA PRADESH. INDIA. 531021 |
| | Detail of stability batches of drug product | Batch No TC001 Mfg date 05/2025 Batch No TC002 Mfg date 05/2025 Batch No TC003 Mfg date 05/2025 Batch size: 1000 tablets 06 months real time and 06 months accelerated according to zone IV-A |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6 dated 17-02-2025 for 500grams of material is submitted along with airway bill no. 960-00362994. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP studies have been performed against Cialis 20mg Tablet Manufacturer Name: Lilly Del Caribe Inc. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Batch Number TD/21/028 TD/21/029 TD/21/030 Storage Condition (˚c, %RH) 40°C±2°C & 75% ±5%RH Storage Condition (˚c, %RH) 30°C ±2°C & 75%±5%RH 06 months accelerated and 60 months real time. |
| | The status in reference regulatory authorities | USFDA approved |
| | GMP status of the firm | Last inspection report for renewal of DMP dated 27,29th May,-16th July, 2026 is submitted. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved. |
| | **Evaluation Remarks** | |
| | The case has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs. | |
| | **Decision** | |
| | **Approved** | |

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| 133 | Case Category | New Molecule/Formulation (Farooq Aslam) |
| | Name, address of Applicant. | **Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6QA-537-6NX7, 2026-02-09) |
| | Detail of Fee Submitted | 38700,<br>2026-01-31, |
| | The proposed proprietary name / brand name | **Cenomate 12.5mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains: Cenobamate .....12.5mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months |
| | For generic drugs (me-too Status) | Brand Name of Approved Medicines o Product Name:: Cenomate 12.5mg Manufacturer o Company Name: Kaizen Pharmaceuticals (Pvt) Ltd Strength 12.5mg Composition Each Film Coated Tablet Contains: Cenobamate |
| | Pharmacotherapeutic Group of (API) | Dipeptidyl Peptidase-4 (DPP-4) Inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches as per Zone IV-A |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | 3.2.S.8.3 Stability Data: Attached in Serial No. 3 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | 3.2.P.2.2 FINISHED PHARMACEUTICAL EQUIVALENCE STUDY ATTACHED |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability Perform According to Zone IV-A (Attached) 2.3.P.8.3 |
| | The status in reference regulatory authorities | https://www.pmda.go.jp/files/000153594.pdf |
| | GMP status of the firm | Valid GMP |
| | Evidence of approval of manufacturing facility | General Tablet Section |
| | **Evaluation Remarks** | |
| | The Board had previously decided that all the strengths of Cenobamate should be presented at one time in the meeting for a decision. The firm has submitted 03 strengths under the category of new molecule and the other strengths under export priority. | |
| | **Decision** | |
| | **Not Applicable**<br><br>The Board discussed the recommended dosage and titration, which should not be exceeded because of the potential for serious adverse reactions, directed PE&R division to process all the recommended strengths by reference country for presenting before the Board in next meeting. | |
| 134 | Case Category | New Molecule/Formulation (Farooq Aslam) |
| | Name, address of Applicant. | **Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PVD-VPZ-SHHJ, 2026-02-12) |

| | | |
|---|---|---|
| | Detail of Fee Submitted | 38700,<br>2026-01-31, |
| | The proposed proprietary name / brand name | **Cenomate 25mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains: Cenobamate .....25mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearReal time: 30°C ± 2°C / 65% ± 5%RH<br>Accelerated: 40°C ± 2°C / 75% ± 5%RH |
| | For generic drugs (me-too Status) | Brand Name of Approved Medicines o Product Name:: Cenomate 25mg Manufacturer o Company Name: Kaizen Pharmaceuticals (Pvt) Ltd Strength 25mg Composition Each Film Coated Tablet Contains: Cenobamate…… |
| | Pharmacotherapeutic Group of (API) | Dipeptidyl Peptidase-4 (DPP-4) Inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches as per Zone IV-A |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | 3.2.S.8.3 Stability Data: Attached in Serial No. 3 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | 3.2.P.2.2 FINISHED PHARMACEUTICAL EQUIVALENCE STUDY ATTACHED |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability Perform According to Zone IV-A (Attached) 2.3.P.8.3 |
| | The status in reference regulatory authorities | https://www.pmda.go.jp/files/000153594.pdf |
| | GMP status of the firm | Valid GMP |
| | Evidence of approval of manufacturing facility | General Tablet Section |
| | **Evaluation Remarks** | |
| | The Board had previously decided that all the strengths of Cenobamate should be presented at one time in the meeting for a decision. The firm has submitted 03 strengths under the category of new molecule and the other strengths under export priority. | |
| | **Decision** | |
| | **Not Applicable**<br><br>The Board discussed the recommended dosage and titration, which should not be exceeded because of the potential for serious adverse reactions, directed PE&R division to process all the recommended strengths by reference country for presenting before the Board in next meeting. | |
| 135 | Case Category | New Molecule/Formulation (Farooq Aslam) |
| | Name, address of Applicant. | **Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)** |
| | Application Form Dy. No / Tracking ID & date of submission | (27N-VXG-UGQS, 2026-02-04) |
| | Detail of Fee Submitted | 38700,<br>2026-01-31, |
| | The proposed proprietary name / brand name | **Cenomate 50mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains: Cenobamate eq. to Cenobamate.....50mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |

| | | |
|---|---|---|
| | Shelf Life (Unit) | 2 YearStability study conditions: Real time: 30°C ± 2°C / 65% ± 5%RH for 24 months Accelerated: 40°C ± 2°C / 75% ± 5%RH for 6 months |
| | For generic drugs (me-too Status) | pproved Medicines o Product Name:: Cenomate 50mg Manufacturer o Company Name: Kaizen Pharmaceuticals (Pvt) Ltd Strength 50mg Composition Each Film Coated Tablet Contains: Cenobamate……..50mg Registr |
| | Pharmacotherapeutic Group of (API) | Dipeptidyl Peptidase-4 (DPP-4) Inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches as per Zone IV-A |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | 3.2.S.8.3 Stability Data: Attached in Serial No. 3 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | 3.2.P.2.2 FINISHED PHARMACEUTICAL EQUIVALENCE STUDY ATTACHED |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability Perform According to Zone IV-A (Attached) 2.3.P.8.3 |
| | The status in reference regulatory authorities | https://www.pmda.go.jp/files/000153594.pdf |
| | GMP status of the firm | Valid GMP |
| | Evidence of approval of manufacturing facility | General Tablet Section |
| | **Evaluation Remarks** | |
| | The Board had previously decided that all the strengths of Cenobamate should be presented at one time in the meeting for a decision. The firm has submitted 03 strengths under the category of new molecule and the other strengths under export priority. | |
| | **Decision** | |
| | **Not Applicable**<br><br>The Board discussed the recommended dosage and titration, which should not be exceeded because of the potential for serious adverse reactions, directed PE&R division to process all the recommended strengths by reference country for presenting before the Board in next meeting. | |
| 136 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R4H-JZM-RUAY, 2024-10-21) |
| | Detail of Fee Submitted | 75000.0,<br>2024-09-16, |
| | The proposed proprietary name / brand name | **Roxtin 70mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Roxadustat.....70mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°c |
| | For generic drugs (me-too Status) | Available |
| | Pharmacotherapeutic Group of (API) | indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Jiangxi Synergy Pharmaceutical Co., Ltd., |

| | | |
|---|---|---|
| | Detail of stability batches of drug product | PE and CDP studies have been submitted against Everenzo 70mg tablet by M/s Astellas Pharma Japan. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | GD NO. IPAF-4464-2022 Date: 19-12-2022 for 1.5kg material unattested invoice no. JXSG221063 dated 04-12-2022 along with packing list is submitted. Form 6 is not submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted against the reference product by M/s Atellas Pharma, Japan |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 08-08-2025. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 137 | Case Category | Routine (Farooq Aslam) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1AZ-LQ6-2LP8, 2024-10-23) |
| | Detail of Fee Submitted | 75000.0, 2024-09-16, |
| | The proposed proprietary name / brand name | **Roxtin 100mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Roxadustat.....100MG |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°c |
| | For generic drugs (me-too Status) | Available |
| | Pharmacotherapeutic Group of (API) | indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Jiangxi Synergy Pharmaceutical Co., Ltd., |
| | Detail of stability batches of drug product | 03 batches : 1200 tablets 06 months real time and 06 months accelerated stability data according to zone IV-A. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | GD NO. IPAF-4464-2022 Date: 19-12-2022 for 1.5kg material unattested invoice no. JXSG221063 dated 04-12-2022 along with packing list is submitted. Form 6 is not submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted against the reference product by M/s Atellas Pharma, Japan |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months accelerated and 18 months real time stability data of 03 batches according to zone IV-A. |
| | The status in reference regulatory authorities | MHRA Approved |

| | | |
|---|---|---|
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 08-08-2025. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 138 | Case Category | Export Facilitation (Farooq Aslam) |
| | Name, address of Applicant. | **Atco Laboratories Limited** B-18 SITE KARACHI **(000188)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EV5-5SZ-NHJG, 2026-02-03) |
| | Detail of Fee Submitted | 38700,<br>2025-11-13, |
| | The proposed proprietary name / brand name | **ROVATOR EZ Tablet** |
| | Label Claim | Each film coated tablet contains: Rosuvastatin (as Rosuvastatin Calcium) ..... 20mg Ezetimibe ..... 10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 strip x 10 Tablets-De-Controlled,2 strips x 10 Tablets-De-Controlled,3 strips x 10 Tablets-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Donot store and transport above 30 degree centigrade. |
| | For generic drugs (me-too Status) | Crestat EZ 20/10mg tablets manufactured by CCL Pharmaceutical (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Rosuvastatin Calcium is “Hyperlipidemic Agent”. Ezetimibe is “Selective Cholesterol-Absorption Inhibitors” |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Enaltec Labs Private Limited. ,Zhejiang Tianyu Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | 06 Months Accelerated Stability Data and 06 months Long-Term Stability according to zone IV-B. Batch size: 2000 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate dated 25-10-2022 for 100kg material is submitted, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence Report and Comparative Dissolution Profile against the comparator's product i.e. RolipEze by M/s Hilton Pharma is submitted. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 months Accelerated Stability Data of Rosuvastatin Calcium and 36 months Long-Term Stability Data of Rosuvastatin Calcium. 06 months Accelerated Stability Data of Ezetimibe and 36 months Long-Term Stability Data of Ezetimibe according to zone IV-B. |
| | The status in reference regulatory authorities | Eklipo 20mg/10mg Tablet manufactured by Elpen Pharmaceutical Co. Inc. |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 23-07-2024. |
| | Evidence of approval of manufacturing facility | Tablet General Section is approved. |

**Evaluation Remarks**

The application has been processed under export priority. The storage conditions for Rosuvastatin are:

| As per BP | USP |
|---|---|
| In an airtight container, protected from light, at a temperature of 2 °C to 8 °C. The DS used for product development is tested according to BP. | Preserve in well-closed containers, protected from light. Store at controlled room temperature. |

The applied product is approved in different reference regulatory authorities as film coated bilayer tablet but HPRA Ireland has approved film coated tablet as a single core in strengths of 40/10mg, 20/10mg and 10/10mg respectively for Rosuvastatin/ezetimibe.

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| The reference product by M/s Sanofi Aventis Ireland was checked and it was found that the product has been developed with a single core. The pictures of the product and relevant literature is upload in online application. |
| https://assets.hpra.ie/products/Human/18202/33562aa6-f524-4cee-a5c9-329de6e3d3ba.pdf |
| https://www.medicines.ie/medicines/suvezen-40-mg-10-mg-film-coated-tablets-34831/license-info |

https://www.hpra.ie/find-a-medicine/for-human-use/authorised-medicines?data=eyJpZCI6bnVsbCwic2tpcCI6MCwidGFrZSI6MTAsInF1ZXJ5Ijoic3V2ZXplbiIsIm9yZGVyIjoi

| |
|---|
| The reference product by M/s Sanofi Aventis Ireland was checked and it was found that the product has been developed with a single core. The pictures of the product and relevant literature is upload in online application. |
| The applicant has applied for 20/10mg, 10/10mg and 5/10mg tablets. |

**Decision**

**Approved**

| 139 | | |
|---|---|---|
| | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **TABROS PHARMA (PVT). LTD.** Plot No. L-20/B, Sector 22, F.B. Industrial Area **(000106)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z37-33V-WPX3, 2024-08-19) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-26, |
| | The proposed proprietary name / brand name | **Tripxen 85/500mg Tablet** |
| | Label Claim | Each film coated tablet contains: Sumatriptan Succinate equivalent to Sumatriptan.....85mg Naproxen Sodium.....500mg Innovator's Specification |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-De-Controlled,2's-De-Controlled,6's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30 Degree |
| | For generic drugs (me-too Status) | Synflex-M Tablet 85/500mg, M/s Martin Dow Ltd., Pakistan |
| | Pharmacotherapeutic Group of (API) | Anti-migraine |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Divi's Laboratories Limited., Unit No. 2, Chippada Village Annavaram Post, Beemunipatnam Mandal Visakhapatnam District Andhra Pradesh, India,Maithili Life Sciences Pvt. Ltd., Plot No. 2, APIIC Industrial Estate, Gajulamandyam (V), Renugunta (M), Tirupati, Andhra Pradesh, India |
| | Detail of stability batches of drug product | Submitted |

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|---|---|---|
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 submitted by firm. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Treximet, Currax Pharmaceuticals LLC, USFDA Approved |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 28th march 2024 |
| | Evidence of approval of manufacturing facility | Section approval letter by CLB submitted by firm. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 140 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M46-846-S57Q, 2024-08-21) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-27, |
| | The proposed proprietary name / brand name | **Rifaximin** |
| | Label Claim | Each Film coated Tablet contains: Rifaximin, BP.....200mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | As per DPC-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Nimixa Tablet 200mg |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Optimus Drugs Private Limited |
| | Detail of stability batches of drug product | Submitted for three batches both accelerated and real time |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Approved in USFDA, Xifaxan Tablet 200mg |
| | GMP status of the firm | Attached inside dossier |
| | Evidence of approval of manufacturing facility | Attached inside dossier |
| | **Evaluation Remarks** | |
| | GMP certificate of drug substance manufacturer is not valid and for export purpose of drug only. | |
| | **Decision** | |
| | **Approved** | |

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|---|---|---|
| | Approved subject to submission of valid GMP certificate of drug substance manufacturer. | |
| 141 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Platinum Pharmaceuticals** A-20,North Western Industrial Zone Bin Qasim,Karachi **(000415)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3GZ-NNS-S5SZ, 2024-10-15) |
| | Detail of Fee Submitted | 75000.0,<br>2024-09-12, |
| | The proposed proprietary name / brand name | **TEDOLID** |
| | Label Claim | Each film-coated tablet contains: Tedizolid 200mg. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 6's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 °C |
| | For generic drugs (me-too Status) | Delzaquin 200mg Tablet (Reg. No. 134171) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Yibin Hongguang Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | Submitted for three batches |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6 is submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | US-FDA (SIVEXTRO 200MG TABLET) (NDA: 205435) |
| | GMP status of the firm | Submitted |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General section is submitted by firm |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 142 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)** |
| | Application Form Dy. No / Tracking ID & date of submission | (78S-QQU-6D4Q, 2024-04-02) |
| | Detail of Fee Submitted | 75000.0,<br>2023-12-21, |
| | The proposed proprietary name / brand name | **Linux 600mg/300ml Infusion** |
| | Label Claim | Each ml contains: Linezolid.....2mg (300 ml Infusion contains Linezolid .....600mg) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30 degree centigrade |
| | For generic drugs (me-too Status) | Barizold 600mg/300ml Infusion (Barrett Hodgson Pakistan Pvt. Ltd.) |

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|---|---|---|
| | Pharmacotherapeutic Group of (API) | J01XX08: ANTIBACTERIALS FOR SYSTEMIC USE |
| | Name, address of Manufacturing site: | Variant Pharmaceuticals (Pvt) Ltd.- PLOT # 5, M-2, PHARMAZONE, 26 KM MAIN SHARAQPUR ROAD DISTRICT SHEIKHUPURA.PAKISTAN- |
| | Name & address of API manufacturer | Optrix Laboratories Private Limited, Address: Survey No. 145/A & 147, Ramalingampally (V), Bommalaramaram (M) Yadadri-Bhuvanagiri (Dist)-508126 Telangana, India |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate is submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE; Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | USFDA Approved (Linezolid 2mg/ml solution for infusion) Milpharm Limited UK |
| | GMP status of the firm | Submitted by firm |
| | Evidence of approval of manufacturing facility | CLB letter indicating liquid Injectable ampoule and vial section is submitted by firm |
| | **Evaluation Remarks** | |
| | Name of drug substance manufacturer is Optrix Laboratories Private Limited on dossier and Optimus Drugs Private Limited on GMP certificate and invoice. Address of drug substance manufacturer is also not same. | |
| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the case for clarification regarding the difference in the name of the drug substance manufacturer. The dossier identifies the manufacturer as M/s. Optrix Laboratories Private Limited, whereas the GMP certificate and commercial invoice identify the manufacturer as M/s. Optimus Drugs Private Limited. Furthermore, the address of the drug substance manufacturer provided in the dossier does not correspond with the address stated in the GMP certificate and the commercial invoice. | |
| 143 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5NR-RNT-6WR9, 2024-10-29) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2023-11-10, 2024-10-24 |
| | The proposed proprietary name / brand name | **Flexible 500/20 mg Tablet** |
| | Label Claim | Each Modified release Tablet contains: Naproxen ..... 500mg Esomeprazole as Magnesium Trihydrate.....20mg (as Immediate Release Coat) (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 3'10s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30C |
| | For generic drugs (me-too Status) | Eznepo 500/20mg (by Wnsfeild Pharmaceuticals) |
| | Pharmacotherapeutic Group of (API) | NSAID/PPI |

| | | |
|---|---|---|
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Divi's Laboratoires Limited ,Metrochem API private Limited |
| | Detail of stability batches of drug product | -- |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | -- |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | -- |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | -- |
| | The status in reference regulatory authorities | Vimovo 500/20mg DR Tablets (USA-FDA Approved) |
| | GMP status of the firm | -- |
| | Evidence of approval of manufacturing facility | -- |
| | **Evaluation Remarks** | |
| | Application was evaluated and shortcomings were conveyed to the firm, In response firm has submitted that due to ongoing higher prices of API, and market fluctuations, we want to withdraw our product | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as withdrawn. | |
| 144 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **FAAS Pharmaceuticals (Pvt)Ltd** F-748 L, S.I.T.E, Karachi **(000767)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3R9-7PV-SSSN, 2024-07-08) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-04, |
| | The proposed proprietary name / brand name | **Cynofen 500mcg/ml Injection** |
| | Label Claim | Each ml contains: Mecobalamin .....500mcg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30 C. |
| | For generic drugs (me-too Status) | Brand Name: Flench Injection 500mcg/ml injection Registration holder: TABROS PHARMA (PVT). LTD |
| | Pharmacotherapeutic Group of (API) | Coenzyme B12 |
| | Name, address of Manufacturing site: | Seraph Pharmaceutical-Plot # 210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan- |
| | Name & address of API manufacturer | Mahima Life Sciences Pvt. Ltd. |
| | Detail of stability batches of drug product | -- |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | -- |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | -- |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | -- |
| | The status in reference regulatory authorities | Approved in PMDA |

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|---|---|---|
| | GMP status of the firm | GMP certificate issued to manufacturer (M/s. Seraph) based on inspection conducted on 11.10.2022, and to applicant M/s. Faas based on inspection conducted on 9th January 2024. |
| | Evidence of approval of manufacturing facility | CLB letter indicating Liquid Injectable Ampoule (General) is submitted by firm. |
| | **Evaluation Remarks** | |
| | In response to shortcomings firm has submitted this product is already approved in the name of M/s. Evolution Pharma contract manufactured by M/s. Seraph in 351st meeting of Registration Board. And instant product is also manufactured by M/s. seraph on contract. | |
| | **Decision** | |
| | **Approved**<br><br>Registration Board Approved the product subject to submission of undertaking that the Applicant will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website | |
| 145 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (44S-W9M-HUS3, 2024-10-21) |
| | Detail of Fee Submitted | 75000.0,<br>2024-09-20, |
| | The proposed proprietary name / brand name | **Estadol-C 120mg Tablet** |
| | Label Claim | Each Chewable Tablet contains Acetaminophen .....120mg (As per USP specs.) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30°C in Cool & Dry Place. |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Antipyretic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Citi Pharma Limited |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Submitted (local purchase invoice from Citi Pharma) |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | submitted |
| | The status in reference regulatory authorities | Registered drug by TGA (Panadol Chewable Tablets 120mg) |
| | GMP status of the firm | Submitted by firm |
| | Evidence of approval of manufacturing facility | GMP certificate indicating tablet general section is submitted by firm |
| | **Evaluation Remarks** | |
| | **Decision** | |

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| | **Approved** | |
| 146 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (H49-PX8-NX66, 2024-08-29) |
| | Detail of Fee Submitted | 75000.0,<br>2024-05-24, |
| | The proposed proprietary name / brand name | **Unizolide** |
| | Label Claim | Each film coated tablet contains: Tedizolid Phosphate.....200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 30's-As per SRO,6's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C in a cool and dry place. |
| | For generic drugs (me-too Status) | Delzaquin 200mg Tablet (Reg. No. 134171) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Yibin Hongguang Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | Submitted for three batches |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6 is submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Approved in USFDA |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 1.01.2023. |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General section is Submitted by firm |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 147 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W9V-UB5-12XR, 2024-10-29) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-13, 2024-09-25 |
| | The proposed proprietary name / brand name | **Desolra Tablets 5mg** |
| | Label Claim | Each film coated tablet contains;<br>Desloratidine.....5mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |

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|---|---|---|
| | For generic drugs (me-too Status) | Destina 5mg tablets, Manufacturer: M/s Hilton Pharma Limited |
| | Pharmacotherapeutic Group of (API) | Antiallergic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Stability studies submitted for three batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted loan agreement between M/s. Solaris and M/s. Caliph |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Approved in USFDA, Clarinex 5mg tablets, Manufacturer: Scheing Corporation (NDA): 021165 |
| | GMP status of the firm | GMP certificate is issued to the firm based on inspection conducted on 15.01.2025 |
| | Evidence of approval of manufacturing facility | CLB letter indicating tablet general section is attached inside dossier |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 148 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M9T-R7V-9AU1, 2024-06-25) |
| | Detail of Fee Submitted | 75000.0, 2024-05-29, |
| | The proposed proprietary name / brand name | **Barinib 2mg Tablet** |
| | Label Claim | Each film coated tablet contains Baricitinib ..... 2mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x10’s, 2x7’s, 2x10’-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool & Dry place below 30 |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Immunomodulator |
| | Name, address of Manufacturing site: | Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore- |
| | Name & address of API manufacturer | Lianyungang Jari Pharmaceutical Co., Ltd, Add: No. 18 Zhenhua Road, Lianyungang City, Jiangsu Province, China |
| | Detail of stability batches of drug product | -------- |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | ----- |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | ---- |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | ---- |

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| | The status in reference regulatory authorities | OLUMIANT 2mg tablet of M/s Lilly USA, LLC Indianapolis, IN 46285, USA (USFDA Approved) |
| | GMP status of the firm | GMP certificate issued to the manufacturer (M/s. Wimits) based on inspection conducted on 03.04.2023. |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General section of manufacturer (M/s. Wimits) is submitted by the firm. |
| | **Evaluation Remarks** | |
| | Barimit 2mgTablet of M/s. Wimit already approved in 347th Registration Board as per copy of minutes uploaded by firm, & Firm has submitted following undertaking: We hereby declare that we will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website | |
| | **Decision** | |
| | **Approved** | |
| 149 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EVP-2PB-HHHV, 2024-06-26) |
| | Detail of Fee Submitted | 75000.0,<br>2024-05-29, |
| | The proposed proprietary name / brand name | **Barinib 4mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Baricitinib ..... 4mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x10’s, 2x7’s, 2x10’-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool & Dry place below 30 |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Immunomodulator |
| | Name, address of Manufacturing site: | Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore- |
| | Name & address of API manufacturer | Lianyungang Jari Pharmaceutical Co., Ltd, Add: No. 18 Zhenhua Road, Lianyungang City, Jiangsu Province, China |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | OLUMIANT 4mg tablet of M/s Lilly USA, LLC Indianapolis, IN 46285, USA (USFDA Approved) |
| | GMP status of the firm | GMP certificate issued to the manufacturer (M/s. Wimits) based on inspection conducted on 03.04.2023. |

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| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General section of manufacturer (M/s. Wimits) is submitted by the firm. |
| | **Evaluation Remarks** | |
| | Barimit 4 mgTablet of M/s. Wimit already approved in 347th Registration Board as per copy of minutes uploaded by firm, & Firm has submitted following undertaking: We hereby declare that we will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website | |
| | **Decision** | |
| | **Approved** | |
| 150 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **fozan pharmaceuticals Industries (Pvt) Ltd** 36-A hayatabad Industrial estate, Peshawar **(000567)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ABQ-BXX-RHQ7, 2024-11-18) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-08, |
| | The proposed proprietary name / brand name | **Floxar** |
| | Label Claim | Each Tablet Contains:<br>Paracetamol.....650mg<br>Orphenadrine Citrate.....50mg (Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | as per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C. |
| | For generic drugs (me-too Status) | Nuberol Tablet (Searle Pakistan Ltd) |
| | Pharmacotherapeutic Group of (API) | Analgesic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | CITI Pharma Pvt Ltd,RL fine Chem No.15,Karnataka Housing |
| | Detail of stability batches of drug product | - |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | - |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | - |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | - |
| | The status in reference regulatory authorities | iNOVA Pharmaceuticals (Australia TGA Approved) |
| | GMP status of the firm | - |
| | Evidence of approval of manufacturing facility | - |
| | **Evaluation Remarks** | |
| | Deficiencies were conveyed to firm and in response firm has submitted that Due to Recent shifts in Market Dynamics (Higher API Prices from many Supplier) and an internal portfolio reassessment, we want to withdraw our product. | |
| | **Decision** | |

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| | **Rejected**<br><br>Rejected as withdrawn. | |
| 151 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)** |
| | Application Form Dy. No / Tracking ID & date of submission | (A89-N1H-XZ8D, 2024-06-26) |
| | Detail of Fee Submitted | 75000.0,<br>2024-05-29, |
| | The proposed proprietary name / brand name | **Pzole 100mg DR Tablet** |
| | Label Claim | Each Delayed-Release Tablet contains:<br>Posaconazole.....100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x10's, 2x10's, 2x7'-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool & Dry place below 30 |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Antifungal |
| | Name, address of Manufacturing site: | Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore- |
| | Name & address of API manufacturer | Bright Gene Bio-Medical Technology Co., Ltd. Add: Building C25, No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, 215123, China. |
| | Detail of stability batches of drug product | - |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Posaconazole 100mg DR Tablet of M/s Merck Sharp & Dohme LLC (118446553) (USFDA Approved). Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons** |
| | GMP status of the firm | GMP certificate issued to the manufacturer (M/s. Wimits) based on inspection conducted on 03.04.2023. |
| | Evidence of approval of manufacturing facility | GMP certificate issued to the manufacturer (M/s. Wimits) based on inspection conducted on 03.04.2023 indicate tablet General section of firm |
| | **Evaluation Remarks** | |
| | Noxamit 100mg DR Tablet of M/s. Wimit already approved in 353rd Registration Board meeting as per copy of minutes uploaded by firm, & Firm has submitted following undertaking: We hereby declare that we will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website | |
| | **Decision** | |

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| | **Approved** | |
| 152 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GN5-WSD-WYVR, 2024-10-29) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-02, |
| | The proposed proprietary name / brand name | **Naprox 550mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Naproxen Sodium.....550mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1x10's, 2x7's, 2x10'-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool & Dry place below 30 |
| | For generic drugs (me-too Status) | Synflex Tablet 550mg of M/s Martin Dow Limited |
| | Pharmacotherapeutic Group of (API) | NSAID |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | DIVI'S LABORATORIES LIMITED (Unit-2) Add: Chippada Village, Annavaram Post – 531 162, Bheemunipatnam Mandal Visakhapatnam District, Andhra Pradesh, INDIA |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | NAPROXEN SODIUM tablet 550mg of M/s AvPAK AvKARE Inc., Pulaski, TN 38478 (USFDA Approved) |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 03.04.2023. |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet general section is submitted by the firm |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 153 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ULM-6RE-7GY6, 2024-07-16) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-02, |
| | The proposed proprietary name / brand name | **Neoprox** |
| | Label Claim | Neoprox Oral Suspension 125mg/5ml Each 5ml contains: Naproxen.....125 mg. (USP Specification) |

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| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 120ml-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Proxen Oral suspension by Martin Dow |
| | Pharmacotherapeutic Group of (API) | NSAID |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | DIVIS LABORATORIES LIMITED (Unit-2) Chippada Village Annavaram Post – 531 162 Bheemunipatnam Mandal Visakhapatnam District Andhra Pradesh INDIA |
| | Detail of stability batches of drug product | Stability data for three batches is submitted by firm. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearence certificate submitted by the firm. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE; Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Approved in MHRA & TGA |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 15th to 16th June 2024 |
| | Evidence of approval of manufacturing facility | CLB letter indicating liquid syrup general section i submitted by firm |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 154 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3ZT-U8B-42DD, 2024-08-19) |
| | Detail of Fee Submitted | 30000.0, 2024-07-25, |
| | The proposed proprietary name / brand name | **NEPLOX-S TABLET** |
| | Label Claim | Each Film Coated Tablet: Naproxen Sodium...500mg & Sumatriptan Succinate eq. to Succinate ...85mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 X 2'S-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)25 degree |
| | For generic drugs (me-too Status) | SYNFLEX-M Tablet BY Martin Dow Limited |
| | Pharmacotherapeutic Group of (API) | Anti migrain agent |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | AZAKEM LABS PVT LTD,Plot No: 97 & 98, IDA Kolar, Bidar Mandal & District, Karnataka. India ,Divi's Laboratories Ltd.Unit-2,Annavaram Post, Chippada Village, Bheemunipatnam Mandal,Visakhapatnam District – 531 162,Andhra Pradesh, India. |

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| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clarence certificate submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per zone II |
| | The status in reference regulatory authorities | https://www.accessdata.fda.gov/scripts/cder/daf/index.event=overview.process&ApplNo=021926 |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 05.01.2024 |
| | Evidence of approval of manufacturing facility | GMP certificate issued to the firm based on inspection conducted on 05.01.2024 indicate Tablet General section of firm. |
| | **Evaluation Remarks** | |
| | Firm was advised to submit stability studies for Sumatriptin as per conditions of Zone IV a, firm in response submitted same studies by changing conditions to zone IVa only in stability study protocol. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected due to concerns related to data integrity concerns in submitted stability studies of drug substance Sumatriptan. | |
| 155 | Case Category | Export Facilitation (Haleema Sharif) |
| | Name, address of Applicant. | **Surge Laboratories (Pvt.) Ltd.** 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. **(000484)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1B8-ESS-HRNT, 2025-06-17) |
| | Detail of Fee Submitted | 75000.0,<br>2025-01-06, |
| | The proposed proprietary name / brand name | **Feveral** |
| | Label Claim | Each 50ml vial contains:<br>Paracetamol.....500mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml x 1's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)store below 30°C |
| | For generic drugs (me-too Status) | Febrol 500mg/50ml Infusion IV |
| | Pharmacotherapeutic Group of (API) | Analgesic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Citi Pharma |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Local purchase by Citi Pharma. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE; submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Approved in MHRA |

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| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 27.09.2024. |
| | Evidence of approval of manufacturing facility | submitted in dossier (Liquid Inject abl including blow fill seal) |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of valid GMP certificate of drug product manufacturer. | |
| 156 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MEX-32H-4E54, 2024-10-03) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-09, |
| | The proposed proprietary name / brand name | **Dislep Tablets 50mg** |
| | Label Claim | Each tablet contains: Levosulpiride.....50mg (Innovator Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Sulvorid Tablets 50mg, Manufacturer: High- Q Pharma (Pvt.) Limited |
| | Pharmacotherapeutic Group of (API) | Antipsychotic drugs |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Submitted for three batches |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan agreement with M/s. Caliph is submitted by firm. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Levosulpiride50mgTablets, Manufacturer: Aristo Pharma GmbH, Germany Approved |
| | GMP status of the firm | DML issued to the firm on 17.01.2024 |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General section is submitted by firm. |
| | **Evaluation Remarks** | |
| | Despite repeated communications firm still has not submitted following: 1. Valid GMP certificate of drug substance manufacturer. 2. Link to verify that the excipient of applied product are similar to reference product OR drug excipient compatibility studies. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for the following:<br><br>1. Valid GMP certificate of drug substance manufacturer. | |

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| | 2. Link to verify that the excipient of applied product are similar to reference product OR drug excipient compatibility studies. | |
| 157 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7BN-H58-YD4P, 2024-10-03) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-09, |
| | The proposed proprietary name / brand name | **Dislep Tablets 25mg** |
| | Label Claim | Each tablet contains: Levosulpiride.....25mg (Innovator Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Sulvorid Tablets, Manufacturer: High- Q Pharma (Pvt.) Limited |
| | Pharmacotherapeutic Group of (API) | Antipsychotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan agreement with M/s. Caliph is submitted by firm. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Levopraid 25 mg tablets, Manufacturer: M/s TEOFARMA, Italy Approved |
| | GMP status of the firm | DML issued to the firm on 17.01.2024 |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General section is submitted by firm. |
| | **Evaluation Remarks** | |
| | Neither excipients of applied product are similar to reference product nor drug excipient compatibility studies are performed by firm. Despite repeated communications firm still has not submitted drug excipient compatibility studies. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for the following:<br><br>1. Valid GMP certificate of drug substance manufacturer.<br><br>2. Link to verify that the excipient of applied product are similar to reference product OR drug excipient compatibility studies. | |
| 158 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ANV-HLU-91S5, 2024-10-10) |

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| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-07-30, 2024-09-13 |
| | The proposed proprietary name / brand name | **Sinaxamol-D** |
| | Label Claim | Each film coated tablet contains:<br>Paracetamol.....500.0mg<br>Diphenhydramine HCl.....25.0mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's, 14's, 20's, 28-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30ºC. Protect from light. |
| | For generic drugs (me-too Status) | Panadol Night by Haleon Pakistan Limited |
| | Pharmacotherapeutic Group of (API) | Analgesic/anti allergic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Saakh Pharm (Pvt) Ltd.,Supriya Lifescience Ltd. |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Paracetamol; Local Purchase, Diphenhydramine; Form 6 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Panadol Night by Haleon UK Trading Limited |
| | GMP status of the firm | GMP Certificate is issued to the firm based on evaluation conducted on 12th June, 2023, |
| | Evidence of approval of manufacturing facility | CLB letter indicating tablet general section is submitted by the firm |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 159 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EVM-TPT-Q1AS, 2024-10-21) |
| | Detail of Fee Submitted | 75000.0,<br>2024-09-23, |
| | The proposed proprietary name / brand name | **Estadol 500mg capsule** |
| | Label Claim | Each capsule contains Acetaminophen .....500 mg (As per USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Antipyretic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Citi Pharma Limited |
| | Detail of stability batches of drug product | Stability data for three batches is submitted by firm |
| | Documents for the procurement of API with approval from DRAP | Firm has purchased API locally by M/s. Citi Pharma. |

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| | (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted inside dossier. |
| | The status in reference regulatory authorities | Approved in MHRA |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 13.04.2021 |
| | Evidence of approval of manufacturing facility | GMP certificate issued to the firm based on inspection conducted on 13.04.2021 indicate Capsule General Section. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of RMP (Risk Management Plan). | |
| 160 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Surge Laboratories (Pvt.) Ltd.** 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. **(000484)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1LY-63Q-W3TV, 2026-02-06) |
| | Detail of Fee Submitted | 75000,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **Feveral Duo IV Solution for Infusion 1000mg/300mg** |
| | Label Claim | Each 100ml vial contains: Paracetamol BP.....1000mg Ibuprofen Sodium Dihydrate corresponding to Ibuprofen.....300mg (Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | Clear Glass Vial 100ml, USP Type-II in a pack of 1's & 10s vials.-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30ºC |
| | For generic drugs (me-too Status) | Acetamol Plus 1000mg/300mg IV Infusion |
| | Pharmacotherapeutic Group of (API) | Other Analgesics and Antipyretics, Anilides. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Citi Pharma (Pvt.) Ltd., Address: 3 Kilometer, Head Balloki Road, Phool Nagar, Kasur -55050 Punjab, Pakistan,Solara Active Pharma Sciences Limited Address: A1/B SIPCOT Industrial Complex Kudikado Village Cuddalore – 607 005, Tamil Nadu, India |
| | Detail of stability batches of drug product | Submitted stability study data of 3 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 3 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 3 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Paracetamol: Submitted copy of commercial invoice dated 17-01-2025, specifying quantity 2,000 Kg of Ibuprofen Sodium Dihydrate: |

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|---|---|---|
| | | Submitted copy of commercial invoice dated 13-02-2025 with Clearance Certificate dated 20-03-2025 issued by AD, DRAP, Karachi. specifying quantity 0.6000 Kg of Ibuprofen Sodium Dihydrate. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted pharmaceutical equivalence of our product against the product COMBOVAL 10mg/ml & 3mg/ml by EVER Pharma GmbH, Germany. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Paracetamol: Submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 60 months. Ibuprofen Sodium Dihydrate: Submitted stability study data of 3 batches of drug substance at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The real time stability data is conducted at 30°C ± 2°C / 75% ± 5% RH for 60 months. |
| | The status in reference regulatory authorities | US FDA Approved (COMBOGESIC IV by S.M. Farmaceutici SRL, Italy and MHRA Approved (Combogesic IV 1000mg / 300mg by AFT Pharma UK Limited, UK) |
| | GMP status of the firm | GMP certificate dated 29-10-2024 based on inspection conducted on 27-09-2024. |
| | Evidence of approval of manufacturing facility | Manufacturing License issued on 19-12-2020, Renewal applied on 05-08-2025. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of GMP certificate of drug product manufacturer. | |
| 161 | Case Category | New Section (Haleema Sharif) |
| | Name, address of Applicant. | **Bliss Industries(Pvt.) Ltd.** Plot No. G-A-52-A6, National Industrial Park, **(000086)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ML1-5PS-QG2B, 2026-03-02) |
| | Detail of Fee Submitted | 38700,<br>2025-10-17, |
| | The proposed proprietary name / brand name | **Azimax** |
| | Label Claim | Each film coated tablet contains: Azithromycin as Dihydrate ..... 250 mg USP Specifications |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Less than 30 C |
| | For generic drugs (me-too Status) | Mezomed tablet 250 mg by Mediate Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Antibiotics, Macrolides |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Ningixia Taiyicin Biotech Co,Ltd |

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| | Detail of stability batches of drug product | Stability data for three batches submitted by firm |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan letter by M/s. Reign submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached inside dossier |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached inside dossier |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | CLB letter indicating tablet section submitted by firm |
| | **Evaluation Remarks** | |
| | The application was evaluated, and the firm was requested to submit certain documents, including the audit trail report of a 21 CFR Part 11 compliant system. In response, the firm stated that it does not have a 21 CFR Part 11compliant system. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as the firm does not have a 21 CFR Compliant System. | |
| 162 | Case Category | New Section (Haleema Sharif) |
| | Name, address of Applicant. | **Bliss Industries(Pvt.) Ltd.** Plot No. G-A-52-A6, National Industrial Park, **(000086)** |
| | Application Form Dy. No / Tracking ID & date of submission | (55D-QME-JM99, 2026-03-02) |
| | Detail of Fee Submitted | 38700,<br>2025-10-17, |
| | The proposed proprietary name / brand name | **Azimax** |
| | Label Claim | Each Film Coated Tablet Contains: Azithromycin as dihydrate ..... 500 mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Less than 30 C |
| | For generic drugs (me-too Status) | Zetro Tablet 500 mg by Getz Pharma |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Ningixia Taiyicin Biotech Co,Ltd |
| | Detail of stability batches of drug product | stability data for three batches submitted by firm |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan letter by M/s. Reign submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached inside dossier |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted by firm |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | CLB letter indicating tablet general section submitted by firm |
| | **Evaluation Remarks** | |

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|---|---|---|
| | The application was evaluated, and the firm was requested to submit certain documents, including the audit trail report of a 21 CFR Part 11 compliant system. In response, the firm stated that it does not have a 21 CFR Part 11 compliant system. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as the firm does not have a 21 CFR Compliant System. | |
| 163 | Case Category | New Section (Haleema Sharif) |
| | Name, address of Applicant. | **Bliss Industries(Pvt.) Ltd.** Plot No. G-A-52-A6, National Industrial Park, **(000086)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LQW-34Z-WQST, 2026-02-04) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-02-20, 2026-01-09 |
| | The proposed proprietary name / brand name | **Azimax** |
| | Label Claim | Each Capsule Contains: Azithromycin as dihydrate ..... 250 mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Less than 30 C |
| | For generic drugs (me-too Status) | Azomax 250 mg Capsule by AGP Pharma |
| | Pharmacotherapeutic Group of (API) | Antibiotics, Macrolides |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Ningixia Taiyicin Biotech Co,Ltd |
| | Detail of stability batches of drug product | Stability data for three batches submitted |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted loan letter from M/s. Reign |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted in Dossier |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | CLB letter indicating tablet general section submitted by firm. |
| | **Evaluation Remarks** | |
| | The application was evaluated, and the firm was requested to submit certain documents, including the audit trail report of a 21 CFR Part 11 compliant system. In response, the firm stated that it does not have a 21 CFR Part 11 compliant system. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as the firm does not have a 21 CFR Compliant System. | |
| 164 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9ZU-G4U-WX3W, 2024-06-11) |

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|---|---|---|
| | Detail of Fee Submitted | 30000.0,<br>2024-05-08, |
| | The proposed proprietary name / brand name | **Eskita 5mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Escitalopram as Oxalate (USP) ..... 5mg (Product Complies USP Specs) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°c |
| | For generic drugs (me-too Status) | Gentle 5mg Tablet by Wilsons Pharma |
| | Pharmacotherapeutic Group of (API) | Lipid modifying agents. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 Batches Size 1500 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | 00970 dated 13.09.21 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Esperion Pharmaceuticals USA Nexlizet Tablets |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | No F.3-2/2006--Lic(vol-I) dated 11-06-2024 mentioning tablet section |
| | **Evaluation Remarks** | |
| | Firm neither submitted audit trail report of 21 CFR compliant system for chromatogram verification Submitted invoice is not legible. | |
| | **Decision** | |
| | **Rejected**<br><br>The Registration Board decided to reject the application due to the firm's failure to submit the audit trail report generated from a 21 CFR Part 11 compliant system for chromatogram verification. | |
| 165 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8M8-NQ2-SXZ6, 2024-08-07) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-11, |
| | The proposed proprietary name / brand name | **Tazolid** |
| | Label Claim | Each film coated tablet contains: Tedizolid Phosphate ..... 200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7s, 10s, 14s, 20s, 2-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store below 30°C, Protect from heat, light and moisture |
| | For generic drugs (me-too Status) | Delzaquin 200mg Tablet (Reg. No. 134171) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Yibin Hongguang Pharmaceutical Co., Ltd |

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| | Detail of stability batches of drug product | Submitted for three batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted Form 6. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Sivextro 200mg Tablet, Approved in USFDA |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 06.06.2023. |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General of firm. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 166 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)** |
| | Application Form Dy. No / Tracking ID & date of submission | (93T-4PZ-9LG5, 2024-08-16) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-11, |
| | The proposed proprietary name / brand name | **Tedizol** |
| | Label Claim | Each film coated tablet contains: Tedizolid Phosphate ..... 200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7s, 10s, 14s, 20s, 2-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30°C, Protect from heat, light and moisture |
| | For generic drugs (me-too Status) | Delzaquin 200mg Tablet (Reg. No. 134171) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | Genix Pharma Pvt. Ltd.-44, 45-B, Korangi Creek Road, Karachi- |
| | Name & address of API manufacturer | Yibin Hongguang Pharmaceutical Co., Ltd |
| | Detail of stability batches of drug product | submitted for three batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted Form 6. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Sivextro 200mg Tablet, Approved in USFDA |
| | GMP status of the firm | GMP certificate issued to the firm based on inspection conducted on 06.06.2023. |
| | Evidence of approval of manufacturing facility | CLB letter indicating Tablet General Section of firm. |
| | **Evaluation Remarks** | |
| | **Decision** | |

**Approved**

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| 167 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)** |
| | Application Form Dy. No / Tracking ID & date of submission | (H79-VT4-DHQ8, 2024-08-09) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-09, |
| | The proposed proprietary name / brand name | **Topfen** |
| | Label Claim | Each 2ml ampoule contains: Dexketoprofen (as dexketoprofen trometamol) .....50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's, 5's and 10's-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30oC. Protect from heat, light and moisture. |
| | For generic drugs (me-too Status) | Sertofen (Dexketoprofen) Injection 50mg/2ml by Biocare Pharmaceutical 113486 |
| | Pharmacotherapeutic Group of (API) | Analgesic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Metrochem API Private Limited, Unit-IV |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6 submitted by firm |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE; Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Approved in Spain, Dexketoprofen NORMON 50 mg/2 ml solution for injection and infusion EFG by Normon Laboratories SA |
| | GMP status of the firm | GMP certificate is issued to the firm based on inspection conducted on 06.06.2023 |
| | Evidence of approval of manufacturing facility | CLB letter indicating Liquid ampoule vial General section is submitted by firm. |

**Evaluation Remarks**

| Query | Response |
|---|---|
| On attached attested invoice expiry date of drug substance is May 2023 however stability batches are manufactured in November 2023, So it means stability batches are manufactured with expired material, Is it ? | We would like to clarify that the Commercial Invoice is dated 31-Aug-2023, based on which the import process was initiated. Subsequently, the Form-6 Drug Import License was issued by DRAP on 21-Sep-2023. After obtaining the Drug Import License, the product was manufactured, and the manufacturing date is Nov 2025, which is after the issuance of the Form-6 Import License. Sorry for Inconvenience caused. |

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| | No terminal sterilization of applied product? Why | Dexketoprofen trometamol is the pharmacologically active S-enantiomer of Dexketoprofen Trometamol and is responsible for the therapeutic efficacy of the product. Exposure to elevated temperatures during terminal sterilization may promote partial chiral inversion (racemization) of the S-enantiomer to the pharmacologically less active R-enantiomer, potentially reducing the potency and therapeutic performance of the formulation. Therefore, terminal sterilization was not employed during the manufacturing process to minimize the risk of enantiomeric conversion and preserve the stereochemical integrity of the active pharmaceutical ingredient. Sterility assurance was achieved through aseptic manufacturing. Stability studies demonstrated that the infusion maintained its physicochemical properties, and sterility throughout the specified storage period within the established acceptance criteria. |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for the following:<br>• Comparative studies evaluating the quality of the finished product before and after terminal sterilization, including assay, and enantiomeric purity using a validated chiral analytical method. | |
| 168 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **Werrick Pharmaceuticals** Plot No. 216 - 217, I-10/3, Industrial Area Islambad **(000340)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L45-X3X-55TB, 2024-10-30) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-06-04, 2024-09-05 |
| | The proposed proprietary name / brand name | **Flueze Multi Symptom Severe Cold Sachets** |
| | Label Claim | Each sachet contains:- Paracetamol.....500mg, Dextromethorphan HBr.....20mg, Phenylephrine HCl.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-De-Controlled,20's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | Colynol Multi Symptom Severe Cold Sachets (It has different formulation)) |
| | Pharmacotherapeutic Group of (API) | Analgesic/Antipyretic/Antiallergic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Submitted for three batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Dailymed, Theraflu Multi Symptom Severe Cold Sachets |
| | GMP status of the firm | Submitted in Dossier |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |

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|---|---|---|
| | The case was deferred in 359th Registration Board meeting for the following: 1. A Risk Management Plan (RMP) for the proposed new molecule. 2. Differential fee of PKR 38,000/- for new molecule approval, as applicable fee at the time of application submission was 75000/- It is submitted that Me too of instant product has been verified as under : Coldene Fast Sachet (Reg No. 121735) Each Sachet contains:<br>Paracetamol.....500mg<br>Phenylephrine HCl.....10mg<br>Dextromethorphan HBr.....20mg | |
| | **Decision** | |
| | **Approved** | |
| 169 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8XR-JLB-13BM, 2024-10-07) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-27, 2024-10-03 |
| | The proposed proprietary name / brand name | **Sinaxamol Plus** |
| | Label Claim | Each film coated tablet contains: Paracetamol ..... 325mg. Diphenhydramine HCl.....25mg. Phenylephrine HCl.....5mg. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10s, 14s,20s, 28s,30-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Do not store over 30ºC. Protect from direct sunlight, heat & moisture |
| | For generic drugs (me-too Status) | Provas EZ |
| | Pharmacotherapeutic Group of (API) | Analgesic/antiallergic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Divi's Laboratories Limited,,Sakh Pharma (PVT) LTD.,Supriya Lifescience Ltd., Mumbai, INDIA |
| | Detail of stability batches of drug product | Submitted |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | Severe allergy plus sinus headache Tablet, Walmart stores Inc, Human OTC USFDA |
| | GMP status of the firm | Submitted inside dossier |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 170 | Case Category | Routine (Haleema Sharif) |
| | Name, address of Applicant. | **M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LX1-1YP-EQAT, 2024-08-02) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-09, |

| | |
|---|---|
| The proposed proprietary name / brand name | **Skuzid** |
| Label Claim | Each 2ml ampoule contains: Dexketoprofen (as dexketoprofen trometamol) .....50mg. |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 1's, 5's and 10's-As per SRO |
| Shelf Life (Unit) | 24 Year(s)Store below 30oC. Protect from heat, light and moisture. |
| For generic drugs (me-too Status) | Sertofen (Dexketoprofen) Injection 50mg/2ml by Biocare Pharmaceutical 113486 |
| Pharmacotherapeutic Group of (API) | NSAID |
| Name, address of Manufacturing site: | Genix Pharma Pvt Ltd-44، 45-B Genix St, Sector 39 Korangi Creek, Karachi, Karachi - |
| Name & address of API manufacturer | Metrochem API Private Limited, Unit-IV |
| Detail of stability batches of drug product | Submitted |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 submitted by firm |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| The status in reference regulatory authorities | Dexketoprofen NORMON 50 mg/2 ml solution for injection and infusion EFG by Normon Laboratories SA |
| GMP status of the firm | Submitted |
| Evidence of approval of manufacturing facility | CLB letter indicating Tablet General section of Manufacturer is submitted by firm |

**Evaluation Remarks**

| Queries | Response |
|---|---|
| On attached attested invoice expiry date of drug substance is May 2023 however stability batches are manufactured in November 2023, So it means stability batches are manufactured with expired material, Is it ? | We would like to clarify that the Commercial Invoice is dated 31-Aug-2023, based on which the import process was initiated. Subsequently, the Form-6 Drug Import License was issued by DRAP on 21-Sep-2023. After obtaining the Drug Import License, the product was manufactured, and the manufacturing date is Nov 2025, which is after the issuance of the Form-6 Import License. |
| No terminal sterilization of applied product? Why | Dexketoprofen trometamol is the pharmacologically active S-enantiomer of Dexketoprofen Trometamol and is responsible for the therapeutic efficacy of the product. Exposure to elevated temperatures during terminal sterilization may promote partial chiral inversion (racemization) of the S-enantiomer to the pharmacologically less active R-enantiomer, potentially reducing the potency and therapeutic performance of the formulation. Therefore, terminal sterilization was not employed during the manufacturing process to minimize the risk of enantiomeric conversion and preserve the stereochemical integrity of the active pharmaceutical ingredient. Sterility assurance was achieved through aseptic manufacturing. Stability studies demonstrated that the infusion maintained its physicochemical properties, and sterility throughout the specified storage period within the established acceptance criteria. |

**Decision**

**Deferred**

Registration Board deferred the case for the following:

- Comparative studies evaluating the quality of the finished product before and after terminal sterilization, including assay, and enantiomeric purity using a validated chiral analytical method.

| | | |
|---|---|---|
| 171 | Case Category | Import (Haleema Sharif) |
| | Name, address of Applicant. | **Oncovanz Pharmaceuticals Private Limited** C 52 Block 4 Gulshan e Iqbal **(0418)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LUV-7SS-B17P, 2025-09-03) |
| | Detail of Fee Submitted | 300000.0,<br>2025-06-19, |
| | The proposed proprietary name / brand name | **Phosphovanz 0.5g Powder for Injection** |
| | Label Claim | Cyclophosphamide may be used alone or in combination with other chemotherapeutic agents, depending on the indication. Cyclophosphamide is indicated in the treatment of: • Chronic Lymphocytic Leukemia (CLL) • Acute Lymphocytic Leukemia (ALL) • As conditioning for a bone marrow transplantation, in the treatment of Acute Lymphoblastic Leukemia, Chronic Myelogenous Leukemia and Acute Myelogenous Leukemia, in combination with whole body irradiation or busulfan. • Hodgkin's lymphoma, Non-Hodgkin's lymphoma and Multiple Myeloma • Metastatic ovarian, and breast, carcinoma • Adjuvant treatment of breast carcinoma • Ewing's sarcoma • Small cell lung cancer • Advanced or metastatic neuroblastoma, • Life-threatening autoimmune diseases: severe progressive forms of lupus nephritis and Wegener's granulomatosis. |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 30 ml Amber Glass Vial -As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30°C., Protect from light and moisture. |
| | For generic drugs (me-too Status) | Oncofos 500mg Powder for Injection |
| | Pharmacotherapeutic Group of (API) | Alkylating agent |
| | Name, address of Manufacturing site: | Zee Laboratories Limited -Behind 47, Industrial Area, Paonta Sahib-173025 (India)-India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Not Applicable |
| | Name, address of Marketing Authorization Holder: | Oncovanz Pharmaceuticals (Pvt.) Ltd, Plot# C-52, Block 4,Gulshan-e-Iqbal,Karachi, Pakistan, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | Valid & Legalized issued by regulatory body of India |
| | Details of Authorization Letter : | Imported Finished Product. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Accelerated stability studies: 25 ±2°C / 60% RH 5% and Long-term stability studies 5 ±3°C |
| | The status in reference regulatory authorities | Cyclophosphamide for Injection |

**Evaluation Remarks**

Registration Board deferred the case and firm has submitted response.

| Reason | Response |
|---|---|
| Original legalized CoPP. | FSC and GMP certificate provided by firm |
| Analytical Method Verification studies by drug product manufacturer. | Submitted by firm |
| Supporting documents, such as chromatograms, raw data sheets for the authenticity and reliability of the submitted stability studies data. | The assay method employed for the stability studies is based on the BP titration method. Since the analytical procedure is a titrimetric method and not a chromatographic method, chromatograms are not generated during analysis. Therefore, chromatograms cannot be provided as part of the stability backup data. The submitted stability results are supported by the corresponding analytical records generated using the approved titration method |
| The registration letter for the product in country of origin has not been submitted. | Firm has submitted one page document which was valid till 25.2.2020 and it is not valid now |
| Impurity profiling by drug substance and drug product manufacturer as per BP. | Firm has stated that impurity is controlled during manufacturing however neither drug substance manufacturer nor drug product manufacturer has performed impurity profiling as per BP. |

**Decision**

**Deferred**

Registration Board deferred the case for the following:

1.Original legalised CoPP.

2. The registration letter for the product in country of origin has not been submitted.

3. Impurity profiling by drug substance and drug product manufacturer as per BP.

| | | |
|---|---|---|
| 172 | Case Category | Import (Haleema Sharif) |
| | Name, address of Applicant. | **Oncovanz Pharmaceuticals Private Limited** C 52 Block 4 Gulshan e Iqbal **(0418)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZPZ-SX2-NEHW, 2025-08-06) |
| | Detail of Fee Submitted | 300000.0,<br>2025-06-24, |
| | The proposed proprietary name / brand name | **Phosphovanz 1g Powder for Injection** |
| | Label Claim | Cyclophosphamide may be used alone or in combination with other chemotherapeutic agents, depending on the indication. Cyclophosphamide is indicated in the treatment of: • Chronic Lymphocytic Leukemia (CLL) • Acute Lymphocytic Leukemia (ALL) • As conditioning for a bone marrow transplantation, in the treatment of Acute Lymphoblastic Leukemia, Chronic Myelogenous Leukemia and Acute Myelogenous Leukemia, in combination with whole body irradiation or busulfan. • Hodgkin's lymphoma, Non-Hodgkin's lymphoma and Multiple Myeloma • Metastatic ovarian, and breast, carcinoma • Adjuvant treatment of breast carcinoma • Ewing's sarcoma • Small cell lung |

| | |
|---|---|
| | cancer • Advanced or metastatic neuroblastoma, • Life-threatening autoimmune diseases: severe progressive forms of lupus nephritis and Wegener's granulomatosis. |
| Reference to Finished product specifications | British Pharmacopeia |
| Proposed Pack Size | 50 ml Amber Glass Vial -As per SRO |
| Shelf Life (Unit) | 24 MonthStore below 30°C., Protect from light and moisture. |
| For generic drugs (me-too Status) | Oncofos 1g Powder for Injection |
| Pharmacotherapeutic Group of (API) | Alkylating agent |
| Name, address of Manufacturing site: | Zee Laboratories Limited -Behind 47, Industrial Area, Paonta Sahib District Sirmour (H.P.) India.-India |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Not Applicable |
| Name, address of Marketing Authorization Holder: | Oncovanz Pharmaceuticals (Pvt.) Ltd, Plot# C-52, Block 4,Gulshan-e-Iqbal,Karachi, Pakistan, Pakistan |
| Details of Certificates (CoPP/FSC/cGMP): | Valid & Legalized issued by regulatory body of India |
| Details of Authorization Letter : | Attached |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Accelerated stability studies: 25 ±2°C / 60% RH 5% and Long-term stability studies 5 ±3°C |
| The status in reference regulatory authorities | Cyclophosphamide for Injection |

**Evaluation Remarks**

Registration Board deferred the case and firm has submitted response.

| Reason | Response |
|---|---|
| Original legalized CoPP. | FSC and GMP certificate provided by firm |
| Analytical Method Verification studies by drug product manufacturer. | Submitted by firm |
| Supporting documents, such as chromatograms, raw data sheets for the authenticity and reliability of the submitted stability studies data. | The assay method employed for the stability studies is based on the BP titration method. Since the analytical procedure is a titrimetric method and not a chromatographic method, chromatograms are not generated during analysis. Therefore, chromatograms cannot be provided as part of the stability backup data. The submitted stability results are supported by the corresponding analytical records generated using the approved titration method |
| The registration letter for the product in country of origin has not been submitted. | Firm has submitted one page document which was valid till 25.2.2020 and it is not valid now |
| Impurity profiling by drug substance and drug product manufacturer as per BP. | Firm has stated that impurity is controlled during manufacturing however neither drug substance manufacturer nor drug product manufacturer has performed impurity profiling as per BP. |

**Decision**

**Deferred**

Registration Board deferred the case for the following:

1.Original legalised CoPP.

2. The registration letter for the product in country of origin has not been submitted.

| | | |
|---|---|---|
| | 3. Impurity profiling by drug substance and drug product manufacturer as per BP. | |
| 173 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UY8-N3R-EL5S, 2026-03-25) |
| | Detail of Fee Submitted | 75000,<br>2026-02-09, |
| | The proposed proprietary name / brand name | **Azacidine 200mg Tablet** |
| | Label Claim | Each film coated tablet contains: Azacitidine ..... 200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,14's-As per SRO,7's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | NIL |
| | Pharmacotherapeutic Group of (API) | Antineoplastic agent and a nucleoside metabolic inhibitor. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Accelerated Stability Study {0, 3 months (completed)}, Long term / Real time stability study{0,3) months (completed)} |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence and CDP has been provided, |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | The firm has withdrawn the instant application vide general request Tracking ID NE2-66J-LMNP. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as application withdrawn by the applicant | |
| 174 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UA9-X2R-44TY, 2026-03-10) |
| | Detail of Fee Submitted | 75000,<br>2026-02-06, |
| | The proposed proprietary name / brand name | **Elcasestran 345mg Tablet** |
| | Label Claim | Each film coated tablet contains: 400 mg elacestrant dihydrochloride ( approximately |

| | | |
|---|---|---|
| | | 345mg of elecastrant free base ) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,20's-As per SRO,30's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C in a cool and dry place. Protect from heat & light. |
| | For generic drugs (me-too Status) | Not applicable since this is a new drug. |
| | Pharmacotherapeutic Group of (API) | Selective Estrogen Receptor Degrader (SERD). |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Provided Accelerated Stability Study {0, 3 months(completed)}, Long term / Real time stability study{0, 3 months } |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence and Comparative Dissolution Profile Provided |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | Product Name: Orserdu Manufacturer: STEMLINE THERAP, New York, NY 10022 Reference Regulatory Authority: FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | Provided |
| | **Evaluation Remarks** | |
| | The firm has withdrawn the instant application vide general request Tracking ID NE2-66J-LMNP. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as application withdrawn by the applicant | |
| 175 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WXP-EZR-PP6Q, 2026-06-16) |
| | Detail of Fee Submitted | 38700,<br>2026-03-09, |
| | The proposed proprietary name / brand name | **Methotrex 2.5mg Tablet** |
| | Label Claim | Each Tablet Contains: Methotrexate ..... 2.5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-As per SRO,100's-As per SRO,12's-As per SRO,16's-As per SRO,20's-As per SRO,24's-As per SRO,28's-As per SRO,4's-As per SRO,50's-As per SRO,8's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 C |
| | For generic drugs (me-too Status) | ALLTREX (Methotrexate) 2.5mg Tablets |
| | Pharmacotherapeutic Group of (API) | Dihydrofolate Reductase Inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |

| | | |
|---|---|---|
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Accelerated 6 months, Long Term 6 months |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Provided |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided Accelerated 6 months, Long term 36 months. |
| | The status in reference regulatory authorities | Medicines and Healthcare products Regulatory Agency |
| | GMP status of the firm | Provided |
| | Evidence of approval of manufacturing facility | Provided |
| | **Evaluation Remarks** | |
| | The firm has withdrawn the instant application vide general request Tracking ID NE2-66J-LMNP. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as application withdrawn by the applicant | |
| 176 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5WP-6B3-XS3R, 2026-04-22) |
| | Detail of Fee Submitted | 75000,<br>2026-04-17, |
| | The proposed proprietary name / brand name | **Selinex 40mg Tablet** |
| | Label Claim | Each film coated tablet contains: Selinexor ..... 40mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 4's-As per SRO,8's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | Not applicable since it is a new product |
| | Pharmacotherapeutic Group of (API) | ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS (Nuclear export inhibitor) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Accelerated Stability Study {0 & 3 months}, Long term / Real time stability study{0 & 3) months } |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence and CDP has been provided, |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | Attached |

| | | |
|---|---|---|
| | **Evaluation Remarks** | |
| | The firm has withdrawn the instant application vide general request Tracking ID NE2-66J-LMNP. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as application withdrawn by the applicant | |
| 177 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BED-XQZ-UQZT, 2026-04-30) |
| | Detail of Fee Submitted | 75000,<br>2026-04-17, |
| | The proposed proprietary name / brand name | **Selinex Tablet 50mg** |
| | Label Claim | Each film coated tablet contains: Selinexor ..... 50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 8's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 C |
| | For generic drugs (me-too Status) | Not Applicable since this is a new product. |
| | Pharmacotherapeutic Group of (API) | ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS (Nuclear export inhibitor) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Accelerated 0, 3 months completed, Long Term 0, 3 months completed |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Provided |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided Accelerated 6 months, Long term 24 months. |
| | The status in reference regulatory authorities | Food and Drug Administration |
| | GMP status of the firm | Provided |
| | Evidence of approval of manufacturing facility | Provided |
| | **Evaluation Remarks** | |
| | The firm has withdrawn the instant application vide general request Tracking ID NE2-66J-LMNP. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as application withdrawn by the applicant | |
| 178 | Case Category | Routine (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U8S-2D8-PJU9, 2025-01-20) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-19, |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **Doiril 4mg** |
| | Label Claim | Each Capsule Contains: Thiocolchicoside .....4mg (Innovator Spec's) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | as per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C. |
| | For generic drugs (me-too Status) | Thicocid 4mg capsules Manufactured by Albert Pharma (pvt) Limited |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/S: Alkaliods Private Ltd. 834(P), Medchai Shamirpet Road, Medchai Mandal, Medchai, Malkajgiri District |
| | 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 | ANSM France Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The applicant has submitted same chromatograms in stability data as submitted by another firm in application TID: DVY-5U7-YL5E in 2024. | |
| | **Decision** | |
| | **Rejected** | |
| 179 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Indus Pharma (Pvt.) Ltd.** Plot No 26,27,63,64,65,66 & 67 Sector 27, Korangi Industrial Area, Karachi. **(000124)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LZN-2WQ-5EP4, 2025-01-14) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-09-10, 2024-09-16 |
| | The proposed proprietary name / brand name | **Recetril 30mg Sachet** |
| | Label Claim | Each sachet contains Racecadotril..... 30mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 16's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)store below 30°c |
| | For generic drugs (me-too Status) | Hidrasec 30mg Sachet |
| | Pharmacotherapeutic Group of (API) | A07XA04; Other antidiarrheals |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Name : Shandong Qidu Pharmaceutical Co., Ltd Address: No.17, Hongda Road, Linzi District, Zibo City, Shandong province, China. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |

| | | |
|---|---|---|
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted that API was FOC and attached invoice and Courier details |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Hidrasec 30mg Granules for Oral Suspension (SXE3024) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | HPRA, Ireland |
| | GMP status of the firm | GMP certificate dated 26 January 2024 |
| | Evidence of approval of manufacturing facility | Regularization of layout plan for DML No 000124 dated 21 July 2020 containing approval of Sachet Section (General) |
| | **Evaluation Remarks** | |
| | Under Export Facilitation | |
| | **Decision** | |
| | **Approved** | |
| 180 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)** |
| | Application Form Dy. No / Tracking ID & date of submission | (78B-72A-YB8A, 2025-02-07) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-28, |
| | The proposed proprietary name / brand name | **Sankast Chewable Tablet 5mg** |
| | Label Claim | Each chewable tablet contains Montelukast Sodium USP eq. to Montelukast 5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 14's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at (20°C-25°C). Excursion permitted between 15°C-30°C. Protect from light. |
| | For generic drugs (me-too Status) | Registration No: 034837. Montiget Chewable Tablet 5mg. Company: Getz Pharma (Pvt.) Limited (Karachi, Pakistan) |
| | Pharmacotherapeutic Group of (API) | R03DC03; Leukotriene receptor antagonists |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Singulair (Montelukast Sodium) Tablets Company: Merck Research Laboratories (USA) |
| | GMP status of the firm | GMP certificate dated 31 Jan 2024 |
| | Evidence of approval of manufacturing facility | Renewal of DML No. 000702 dated 21 September 2021 with approval of Capsule General Section |
| | **Evaluation Remarks** | |

| | | |
|---|---|---|
| | The firm did not perform CDP across all mediums and provided the following justification: Both test sample (SANTE (PVT) LTD) and reference samples (Montiget Tablet 5.0mg Chewable), produce Average results as 96.861% and 95.309%, declaring tablet as very rapidly dissolving drug. According to FDA and EMA guidance On dissolution testing for immediate-release solid oral dosage forms, when both test and reference products release 85% or more of the drug within 15 minutes, the dissolution profiles are considered very rapidly dissolving and are deemed similar without the need for mathematical comparison (e.g., $f_2$ testing). Under such circumstances, additional comparative testing in buffer media at pH 4.5 and pH 6.8 is not required for establishing similarity, provided that no formulation specific factors are expected to influence pH-dependent dissolution. Since both the test and reference products fulfill the compendial dissolution specification and meet the very rapid dissolution criterion in the monograph medium, it is scien&#xfffd;fically jus&#xfffd;fied to conclude that the products exhibit comparable dissolu&#xfffd;on behaviour. Therefore, addi&#xfffd;onal dissolu&#xfffd;on tes&#xfffd;ng at pH 4.5 and pH 6.8 is not warranted for the present compara&#xfffd;ve purpose. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of CDP data across all dissolution mediums as per WHO guidelines | |
| 181 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HUZ-ED6-6VQ5, 2025-02-13) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-28, |
| | The proposed proprietary name / brand name | **Sankast Tablet 10mg** |
| | Label Claim | Store at (20°C-25°C). Excursion permitted between 15°C-30°C |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 14's-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at (20°C-25°C). Excursion permitted between 15°C-30°C. Protect from light. |
| | For generic drugs (me-too Status) | Registration No: 034838, Montiget (10mg) Tablet, Company: Getz Pharma (Pvt.) Limited (Karachi, Pakistan) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Singulair (Montelukast Sodium) Tablets Company: Merck Research Laboratories (USA) |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

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| | The firm did not perform CDP across all mediums and submitted the following justification: Both test sample (SANTE (PVT) LTD) and reference samples (Montiget Tablet 10mg), produce Average results as 102.428% and 104.242%, declaring tablet as very rapidly dissolving drug. According to FDA and EMA guidance On dissolution testing for immediate-release solid oral dosage forms, when both test and reference products release 85% or more of the drug within 15 minutes, the dissolution profiles are considered very rapidly dissolving and are deemed similar without the need for mathematical comparison (e.g., $f_2$ testing). Under such circumstances, additional comparative testing in buffer media at pH 4.5 and pH 6.8 is not required for establishing similarity, provided that no formulation specific factors are expected to influence pH-dependent dissolution. Since both the test and reference products fulfill the compendial dissolution specification and meet the very rapid dissolution criterion in the monograph medium, it is scientifically justified to conclude that the products exhibit comparable dissolution behaviour. Therefore, additional dissolution testing at pH 4.5 and pH 6.8 is not warranted for the present comparative purpose. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of CDP data across all the dissolution medium as per WHO guidelines | |
| 182 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R92-XBG-16BD, 2025-09-25) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-09, |
| | The proposed proprietary name / brand name | **Mirolin 10mg Tablet** |
| | Label Claim | Each film coated tablet contains: Mirogabalin as besylate .....10mg (Innovator Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x 10's-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store below 30C and 65%RH |
| | For generic drugs (me-too Status) | Miro 10mg Tablet |
| | Pharmacotherapeutic Group of (API) | Gabapentinoids |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Neutan Pharma (Anhui) Co.,Ltd |
| | Detail of stability batches of drug product | Data of three batches of 5000 tablets at accelerated and long term conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance dated 08.04.2025, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at accelerated and long term conditions |
| | The status in reference regulatory authorities | PMDA(Japan) |
| | GMP status of the firm | GMP dated 05.05.2025 |
| | Evidence of approval of manufacturing facility | DML 000454 renewal dated 07.07.2021 |
| | **Evaluation Remarks** | |
| | Under export facilitation. API Clearance certificate is dated 08 April 2025 whereas stability batches were manufactured in Nov 2024. The firm replied At the time of import, the Release Order (RO) was required to be filed along with the Goods Declaration. However, due to an inadvertent omission by our nominated clearing agent, the Release Order entry was not submitted. Consequently, the consignment was cleared against Form-6 instead. | |

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| | **Decision** | |
| | **Approved**<br><br>Subject to verification of API consumption | |
| 183 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PH6-U3D-U4YW, 2025-10-01) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-09, |
| | The proposed proprietary name / brand name | **Mirolin 5mg Tablet** |
| | Label Claim | Each film coated tablet contains: Mirogabalin as besylate .....5mg (Innovator Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x 10's-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store below 30C and 65%RH |
| | For generic drugs (me-too Status) | Miro 5mg Tablet |
| | Pharmacotherapeutic Group of (API) | Gabapentinoids |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Neutan Pharma (Anhui) Co.,Ltd |
| | Detail of stability batches of drug product | Data of three batches of 5000 tablets at accelerated and long term conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance dated 08.04.2025, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at accelerated and long term conditions |
| | The status in reference regulatory authorities | PMDA(Japan) |
| | GMP status of the firm | GMP dated 05.05.2025 |
| | Evidence of approval of manufacturing facility | DML 000454 renewal dated 07.07.2021 |
| | **Evaluation Remarks** | |
| | Under export facilitation. API Clearance certificate is dated 08 April 2025 whereas stability batches were manufactured in Nov 2024. The firm replied At the time of import, the Release Order (RO) was required to be filed along with the Goods Declaration. However, due to an inadvertent omission by our nominated clearing agent, the Release Order entry was not submitted. Consequently, the consignment was cleared against Form-6 instead. | |
| | **Decision** | |
| | **Approved**<br><br>Subject to verification of API consumption | |
| 184 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B37-1RB-RUE3, 2025-10-02) |

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| | Detail of Fee Submitted | 37000.0,<br>2025-07-03, |
| | The proposed proprietary name / brand name | **Mirolin 2.5mg Tablets** |
| | Label Claim | Each film coated tablet contains: Mirogablin as besylate .....2.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x10-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Accelerated time: 40°C ± 2°C / 75% ± 5%RH , Real time: 30°C ± 2°C / 65% ± 5%RH |
| | For generic drugs (me-too Status) | Available |
| | Pharmacotherapeutic Group of (API) | Gabapentinoids |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | NEUTAN PHARMA?ANHUI?CO., LTD. |
| | Detail of stability batches of drug product | Data of three batches at accelerated and long term conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | ADC Clearance Certificate, Computerized No: E-11136802286172 Clearance dated 08.04.2025, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at accelerated and long term conditions |
| | The status in reference regulatory authorities | PMDA Japan |
| | GMP status of the firm | GMP dated 05.05.2025 |
| | Evidence of approval of manufacturing facility | DML 000454 renewal dated 07.07.2021 |
| | **Evaluation Remarks** | |
| | Under export facilitaiton API Clearance certificate is dated 08 April 2025 whereas stability batches were manufactured in Nov 2024. The firm replied At the time of import, the Release Order (RO) was required to be filed along with the Goods Declaration. However, due to an inadvertent omission by our nominated clearing agent, the Release Order entry was not submitted. Consequently, the consignment was cleared against Form-6 instead. | |
| | **Decision** | |
| | **Approved**<br><br>Subject to verification of API consumption | |
| 185 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4X5-VYT-YDH1, 2025-12-12) |
| | Detail of Fee Submitted | 38700,<br>2025-09-11, |
| | The proposed proprietary name / brand name | **Azila Tablet 80mg** |
| | Label Claim | Each tablet contains: Azilsartan Medoxomil Potassium Equivalent to Azilsartan Medoxomil .....80mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,12's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De- |

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| | | Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled,8's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 30oC. |
| | For generic drugs (me-too Status) | Myazil Tablet 80mg Kaizen Pharmaceuticals (Pvt) Ltd. |
| | Pharmacotherapeutic Group of (API) | ATC C09CA09 (Angiotensin II receptor blockers) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | METROCHEM API PRIVATE LIMITED |
| | Detail of stability batches of drug product | AZIC-T1-25 (1000 tablets), AZIC-T2-25 (1000 tablets), AZIC-T3-25 (1000 tablets) |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | RO-B715A4 dated 28.01.2025 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Azilsartan Medoxomil Tablet 80mg B# AZIC-T1-25 , Edarbi 80mg Tablets Batch # 356249 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | AZP/50031216, AZP/50041216, AZP/50051216 |
| | The status in reference regulatory authorities | Edarbi Tablet 80mg, Takeda Pharma. (EMA) |
| | GMP status of the firm | GMP certificated dated 27.03.2025 |
| | Evidence of approval of manufacturing facility | Renewal of DML No 000052 dated 08.06.2021 |
| | **Evaluation Remarks** | |
| | New section | |
| | **Decision** | |
| | **Approved** | |
| 186 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QDL-ANQ-UZ58, 2025-12-12) |
| | Detail of Fee Submitted | 38700,<br>2025-09-11, |
| | The proposed proprietary name / brand name | **Azila Tablet 40mg** |
| | Label Claim | Each tablet contains: Azilsartan Medoxomil Potassium Equivalent to Azilsartan Medoxomil .....40mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,12's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled,8's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 30oC. |
| | For generic drugs (me-too Status) | Myazil Tablet 40mg Kaizen Pharmaceuticals (Pvt) Ltd. |
| | Pharmacotherapeutic Group of (API) | ATC C09CA09 (Angiotensin II receptor blockers) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | METROCHEM API PRIVATE LIMITED |

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| | Detail of stability batches of drug product | AZIB-T1-25 (1000 tablets), AZIB-T2-25 (1000 tablets), AZIB-T3-25 (1000 tablets) |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | RO-B715A4 dated 28.01.2025 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Azilsartan Medoxomil Tablet 40mg B# AZIB-T1-25 , Edarbi 40mg Tablets Batch # 456265 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | AZP/50031216, AZP/50041216, AZP/50051216 |
| | The status in reference regulatory authorities | Edarbi Tablet 40mg, Takeda Pharma. (EMA) |
| | GMP status of the firm | GMP certificated dated 27.03.2025 |
| | Evidence of approval of manufacturing facility | Renewal of DML No 000052 dated 08.06.2021 |
| | **Evaluation Remarks** | |
| | New section | |
| | **Decision** | |
| | **Approved** | |
| 187 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **CCL Pharmaceuticals (Pvt.) Ltd.** 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat **(000052)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UBW-SZE-YV8H, 2025-12-12) |
| | Detail of Fee Submitted | 38700,<br>2025-09-11, |
| | The proposed proprietary name / brand name | **Azila Tablet 20mg** |
| | Label Claim | Each tablet contains: Azilsartan Medoxomil Potassium Equivalent to Azilsartan Medoxomil .....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled,10's-De-Controlled,100's-De-Controlled,12's-De-Controlled,14's-De-Controlled,2's-De-Controlled,20's-De-Controlled,28's-De-Controlled,3's-De-Controlled,30's-De-Controlled,4's-De-Controlled,40's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled,8's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 30oC. |
| | For generic drugs (me-too Status) | Myazil Tablet 20mg Kaizen Pharmaceuticals (Pvt) Ltd. |
| | Pharmacotherapeutic Group of (API) | ATC C09CA09 (Angiotensin II receptor blockers) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | METROCHEM API PRIVATE LIMITED |
| | Detail of stability batches of drug product | AZIA-T2-25 (1000 tablets), AZIA-T3-25 (1000 tablets), AZIA-T4-25 (1000 tablets) |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | RO-B715A4 dated 28.01.2025 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Azilsartan Medoxomil Tablet 20mg B# AZIA-T2-25 , Edarbi 20mg Tablets Batch # 0050624 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | AZP/50031216, AZP/50041216, AZP/50051216 |
| | The status in reference regulatory authorities | Edarbi Tablet 20mg, Takeda Pharma. (EMA) |

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| | GMP status of the firm | GMP certificated dated 27.03.2025 |
| | Evidence of approval of manufacturing facility | Renewal of DML No 000052 dated 08.06.2021 |
| | **Evaluation Remarks** | |
| | New Section | |
| | **Decision** | |
| | **Approved** | |
| 188 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7B5-TGQ-M1QV, 2026-02-04) |
| | Detail of Fee Submitted | 75000,<br>2025-12-29, |
| | The proposed proprietary name / brand name | **Delzof Lyophilized Injection 300mg** |
| | Label Claim | Each vial contains: Delafloxacin Meglumine 433 mg eq. to Delafloxacin.....300mg (Innovator's specs.) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | Packed in single dose vial pack of 1's,7's, 10's, 14's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Stored below 30°C |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Fluoroquinolones, Anti-bacterials for systemic use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Chongqing Kangle Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | Submitted stability study data of 3 batches of drug product at both accelerated as well as long time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The long time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 36 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Submitted copy of commercial invoice dated 23-02-2022 with Goods Declaration Certificate, specifying quantity 750 gm of Delafloxacin Meglumine Injectable grade. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted PE of their product against the product Baxdela 300mg Injection of Hikma Pharmaceutical LLC, Jordan. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted stability study data of 3 batches of drug substance at both accelerated as well as long time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months. The long time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 24 months. |
| | The status in reference regulatory authorities | FDA APPROVED |
| | GMP status of the firm | GMP certificate dated 3-06-2025 based on inspection conducted on 27-05-2025. |
| | Evidence of approval of manufacturing facility | Renewal of DML No 000105 dated 01.08.2025 |
| | **Evaluation Remarks** | |
| | Under export facilitation Innovator's Risk Management Plan | |
| | **Decision** | |

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| | **Approved**<br><br>Approved subject to submission of innovator's Risk Management Plan | |
| 189 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2DX-31H-5ER9, 2025-08-06) |
| | Detail of Fee Submitted | 93000.0,<br>2025-06-12, |
| | The proposed proprietary name / brand name | **D-Vel 5mg/ml** |
| | Label Claim | Each 1 ml ampoule contains: Colecalciferol BP....5mg (Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's and 5's-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below at 30°C |
| | For generic drugs (me-too Status) | Trick-D Injection |
| | Pharmacotherapeutic Group of (API) | A11CC05; Vitamin D and analogues |
| | Name, address of Manufacturing site: | M/s. Surge laboratories (Pvt.) Ltd.-10th Km, Faisal Abad road, Bikhi, District, Sheikhupura- |
| | Name & address of API manufacturer | Sichuan Province Yuxin Pharmaceutical Co.,Ltd |
| | Detail of stability batches of drug product | Submitted stability study data of 2 batches at both accelerated as well as real time conditions. The accelerated stability data is conducted at 40°C ± 2°C / 75% ± 5% RH for 6 months and the real time stability data is conducted at 30°C ± 2°C / 65% ± 5% RH for 18 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Submitted copy of commercial invoice with Clearance Certificate dated 06-11-2023 issued by AD, DRAP, Lahore Specifying quantity 5 Kg of Vitamin D3 BP |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted pharmaceutical equivalence of our product against the product VYDEE Injection 5mg/ml by Hudson Pharma (Pvt) Ltd. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted stability study data of 3 batches of Colecalciferol (Drug substance) at both accelerated as well as real time conditions. The accelerated stability data is conducted at 25°C ± 2°C / 60% ± 5% RH for 6 months. The real time stability data is conducted at 5°C ± 3°C / for 36 months. |
| | The status in reference regulatory authorities | ANSM France Approved |
| | GMP status of the firm | GMP certificate dated 29.10.2024 |
| | Evidence of approval of manufacturing facility | DML renewal dated 11.01.2022 |
| | **Evaluation Remarks** | |
| | Under export facilitation The formulation contains Butylated Hydroxyanisole (BHA) and the US FDA has initiated an assessment of BHA as per FDA statement released on 1st Feb 2026 with the following comments “BHA has remained in the food supply for decades despite being identified by the National Toxicology Program as ‘reasonably anticipated to be a human carcinogen’ based on animal studies.” The firm has provided archived GRAS assessment of the year 2017. | |
| | **Decision** | |
| | **Deferred** | |

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| | Deferred for confirmation of latest GRAS status of Butylated Hydroxyanisole (BHA) in RRAs | |
| 190 | Case Category | Routine (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Shazeb Pharmaceutical Industries Limited** Hazara Trunk road Sarai Gadaee District Haripur KPK Pakistan **(000380)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E59-YAA-9TYD, 2026-04-30) |
| | Detail of Fee Submitted | 30000.0, 7000.0<br>2024-08-30, 2024-11-29 |
| | The proposed proprietary name / brand name | **Zeesol 25% IV Infusion** |
| | Label Claim | Each 100ml contains: Dextrose Anhydrous ..... 25gm |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1x1000ml-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30oC |
| | For generic drugs (me-too Status) | Medisol 25% IV Infusion (Medipak) |
| | Pharmacotherapeutic Group of (API) | V06DC01; Nutrient, Carbohydrates |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of 3 batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate 27 Nov 2023 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches |
| | The status in reference regulatory authorities | USFDA |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Fee for pre-registration variation | |
| | **Decision** | |
| | **Approved**<br><br>Subject to submission of pre-registration variation fee | |
| 191 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7J9-U7H-XAN9, 2025-10-07) |
| | Detail of Fee Submitted | 37000.0,<br>2025-04-18, |
| | The proposed proprietary name / brand name | **Hair Max 2.5mg Tablet** |
| | Label Claim | Each tablet contains: Minoxidil USP 2.5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-De-Controlled,20's-De-Controlled,30's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at (20°C-25°C). Excursion permitted between 15°C-30°C. |

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| | For generic drugs (me-too Status) | Capileo 2.5mg Tablet, Registration No: 117399, Company Name: Schazoo Zaka (Pvt) Ltd., Company Address: 20 Km Lahore-Jaranwala Road Distt: Sheikhupura. |
| | Pharmacotherapeutic Group of (API) | Antihypertensives |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches of 13333 tablets at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 has been provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Minoxidil WATSON LABS USFDA Approved |
| | GMP status of the firm | GMP Certificate No. 17/2024-DRAP(K) Valid till 24th Jan 2027 |
| | Evidence of approval of manufacturing facility | Approved Section Letter No. F.2-12/2006-Lic (Vol-III) Dated 20th Sep 2021 is attached |
| | **Evaluation Remarks** | |
| | Under export facilitation | |
| | **Decision** | |
| | **Approved** | |
| 192 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1L8-3XL-E687, 2025-12-12) |
| | Detail of Fee Submitted | 38700, 2025-09-24, |
| | The proposed proprietary name / brand name | **SERCONA** |
| | Label Claim | Each gram contains: Sertaconazole Nitrate BP .... 20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10g-De-Controlled,20g-De-Controlled,60g-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at (20°C - 25 °C). Excursions permitted to 15 °- 30°C. |
| | For generic drugs (me-too Status) | SERTAZOL 2%, Hudson Pharma |
| | Pharmacotherapeutic Group of (API) | Anti-fungal Dermatological |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Optimus Drugs Private Limited |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE |

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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | ERTACZO 2% Cream, LACER PHARMA, USFDA Approved |
| | GMP status of the firm | Certificate No.17/2024-DRAP (K) Valid till 24th Jan 2027 |
| | Evidence of approval of manufacturing facility | Approved Section Letter No.No. F. 2-12/2006-Lic (Vol-III) Dated 20th September 2021 is attached |
| | **Evaluation Remarks** | |
| | Under export facilitation | |
| | **Decision** | |
| | **Approved** | |
| 193 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)** |
| | Application Form Dy. No / Tracking ID & date of submission | (54Q-4VE-ZQEV, 2026-03-30) |
| | Detail of Fee Submitted | 38700,<br>2025-12-26, |
| | The proposed proprietary name / brand name | **NETARSU 0.02% OPHTHALMIC SOLUTION** |
| | Label Claim | Each ml contains: Netarsudil Dimesylate eq. to Netarsudil 0.2mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2.5ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store between 2°C to 8°C |
| | For generic drugs (me-too Status) | Netsudil 0.02% Ophthalmic Solution |
| | Pharmacotherapeutic Group of (API) | ANTIGLAUCOMA PREPARATIONS AND MIOTICS |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Yibin Hongguang Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | RHOPRESSA OPHTHALMIC SOLUTION, ALCON LABS INC (USA) |
| | GMP status of the firm | Certificate No.17/2024-DRAP (K) Valid till 24th Jan 2027 |
| | Evidence of approval of manufacturing facility | Approved Section Letter No. F. 2-12/2006-Lic (Vol-III) Dated 20th September 2021 is attached |
| | **Evaluation Remarks** | |
| | Under export facilitation | |
| | **Decision** | |
| | **Approved** | |

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| 194 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Genome Pharmaceuticals (Pvt.) Ltd,** Plot No. 16/1, Phase-IV, Industrial Estate Hattar Dist: Haripur (KPK)-PAKISTAN. **(000454)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M6U-6LU-LJ3X, 2026-04-13) |
| | Detail of Fee Submitted | 38700,<br>2026-02-02, |
| | The proposed proprietary name / brand name | **Tzolid 200mg Tablet** |
| | Label Claim | Each film-coated tablet contains: Tedizolid Phosphate .....200mg (Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store below 30ºC and 65 % ± 5% RH |
| | For generic drugs (me-too Status) | Tezlid 200mg Tablet |
| | Pharmacotherapeutic Group of (API) | Antibacterial drug (Oxazolidinone) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Chongqing Asincan Biotech Co., Ltd. |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed against Tedzild by Hiranis Pharmaceuticals |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | US-FDA Approved |
| | GMP status of the firm | GMP |
| | Evidence of approval of manufacturing facility | DML |
| | **Evaluation Remarks** | |
| | Under Export Facilitation | |
| | **Decision** | |
| | **Approved** | |
| 195 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Bloom Pharmaceuticals (Pvt) Ltd.** Plot No. 30, Phase I & II, Industrial Estate, Hattar **(000374)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1DG-2EE-8AU2, 2025-11-03) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-03, |
| | The proposed proprietary name / brand name | **DARCIN DRY SUSPENSION** |
| | Label Claim | Each 5ml Contains Azithromycin .....200MG |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Ambient |
| | For generic drugs (me-too Status) | Attached |
| | Pharmacotherapeutic Group of (API) | Attached |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Hebei Guolong Pharmaceutical Co., Ltd. |

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| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Aries Pharmaceuticals |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Attached |
| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | Grant of Additional Section (Dry Powder for Suspension General) vide letter dated 28.03.2025 |
| | **Evaluation Remarks** | |
| | Fee was submitted for consideration under New Section | |
| | **Decision** | |
| | **Approved** | |
| 196 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DP8-HTV-1G6Q, 2026-04-21) |
| | Detail of Fee Submitted | 38700,<br>2026-03-13, |
| | The proposed proprietary name / brand name | **Famorid Tablets 40mg** |
| | Label Claim | Each film-coated tablet contains: Famotidine .....40mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1X10's, -De-Controlled,2x10's, -De-Controlled,3x10's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children. |
| | For generic drugs (me-too Status) | Hiler 40mg tablets ; GETZ PHARMA |
| | Pharmacotherapeutic Group of (API) | H2 receptor antagonist |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | K-2186024263542 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Famotidine Tablets 40mg: TEVA PHARMACEUTICAL USA, Inc: https://assets.hpra.ie/products/Human/41925/Licen 392-002_31102025110122.pdf |
| | GMP status of the firm | GMP |
| | Evidence of approval of manufacturing facility | Dml no. 000136 |

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| | **Evaluation Remarks** | |
| | Export facilitation Applicant was asked to provide clearance certificate to which they replied: Please note that at the time Form 6 for Famotidine was issued (01-Aug-2023), DRAP had not yet begun issuing separate clearance certificates for import of API. DRAP only started issuing these certificates in late July 2024. Famotidine (API) was procured prior to this implementation. | |
| | **Decision** | |
| | **Approved** | |
| 197 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9MN-AS5-1XDZ, 2026-04-02) |
| | Detail of Fee Submitted | 38700,<br>2026-03-13, |
| | The proposed proprietary name / brand name | **Famorid Tablets 20mg** |
| | Label Claim | Each film-coated tablet contains: Famotidine .....20mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1X10's, -De-Controlled,2x10's, -De-Controlled,3x10's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30ºC. Protect from sunlight & moisture. Keep out of reach of children. |
| | For generic drugs (me-too Status) | Hiler 20mg tablets ; GETZ PHARMA |
| | Pharmacotherapeutic Group of (API) | H2-receptor antagonists |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | -- |
| | Detail of stability batches of drug product | Data of three batches at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | K-2186024263542 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Pepcid Tablets 20mg; Johnson & Johnson Consumer, Inc, Fort Washington, USA.: https://assets.hpra.ie/products/Human/22266/Licen 032-001_01072024122933.pdf |
| | GMP status of the firm | GMP |
| | Evidence of approval of manufacturing facility | Dml no. 000136 |
| | **Evaluation Remarks** | |
| | Export facilitation Applicant was asked to provide clearance certificate to which they replied: Please note that at the time Form 6 for Famotidine was issued (01-Aug-2023), DRAP had not yet begun issuing separate clearance certificates for import of API. DRAP only started issuing these certificates in late July 2024. Famotidine (API) was procured prior to this implementation. | |
| | **Decision** | |
| | **Approved** | |
| 198 | Case Category | New Molecule/Formulation (Incharge Evaluation Cell) |

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| Name, address of Applicant. | **Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)** |
| Application Form Dy. No / Tracking ID & date of submission | (H9N-PTD-PL55, 2026-02-27) |
| Detail of Fee Submitted | 75000,<br>2025-12-08, |
| The proposed proprietary name / brand name | **Rimepant OD Tablets 75mg** |
| Label Claim | Each Oro-dispersible tablet contains: Rimegepant Sulfate as Rimegepant.....75mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,7's-De-Controlled |
| Shelf Life (Unit) | 24 MonthDo not store above 30°C. Protect from sunlight and moisture. |
| For generic drugs (me-too Status) | N/A |
| Pharmacotherapeutic Group of (API) | Calcitonin gene-related peptide (CGRP) antagonists. |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | - |
| Detail of stability batches of drug product | Firm has submitted stability data of two batches of drug product on both real time and accelerated condition. |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted Form 6, Invoice, Airway Bill and GD as the evidence for documents of procurement. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Firm has submitted Pharmaceutical Equivalence Study and Comparative Dissolution Profile against comparator product Nurtec ODT Tablets 75mg by M/s Biohaven Pharmaceuticals Inc., USA |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability data of three batches of drug substance on both real time and accelerated condition. |
| The status in reference regulatory authorities | Nurtec ODT Tablets 75mg by M/s Biohaven Pharmaceuticals Inc., USA |
| GMP status of the firm | Valid GMP of FPP manufacturer is submitted. |
| Evidence of approval of manufacturing facility | Firm has submitted Valid Drug Manufacturing License (License No.: 000284) as the evidence of manufacturing facility. |
| **Evaluation Remarks** | |
| Deferred in 358 for reference of using conventional formulation in DRAP's approved RRAs The firm has now submitted that: This is in reference to DRAP CTD Guidance Document for Submission of Application on Form 5-F (CTD) for Registration of Pharmaceutical Drug Products for Human Use which states “Compatibility studies of the Drug Substance(s) with excipients shall be provided if the qualitative composition of the formulation is not similar to innovator / reference product”. We are hereby enclosing Drug-Excipients compatibility study performed by Getz Pharma on Rimepant OD (Rimegepant) Tablets 75mg for your review. We have also performed Pharmaceutical Equivalence Study and Comparative Dissolution Profile Study on our product vs. innovator product which confirms that both products are Pharmaceutically Equivalent.<br>Furthermore, 06 months accelerated and real time stability studies of Rimepant OD (Rimegepant) Tablets 75mg has been completed and no significant changes in physical & chemical characteristics were observed and results of all the physical and chemical tests are within the specifications. Hence, it indicates that the drug product is stable with the used excipients. Our | |

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| | approach is consistent with international regulatory frameworks such as ICH Q8 and ICH Q12, which encourages flexible, science-based lifecycle and change management of pharmaceutical products. Therefore, the use of a conventional method for the manufacture of Rimegepant OD Tablets 75mg is justified based on Drug-Excipients compatibility study, comparative PE study / CDP study and Stability Studies. Please also note that technology used by innovator is complex and expensive, which is available with only few manufacturers worldwide. Alternatively, Getz Pharma has used conventional method for the manufacturing of Rimepant OD (Rimegepant) Tablets 75mg. | |
| | **Decision** | |
| | **Deferred**<br><br>For following method of manufacturing of Innovator Product. | |
| 199 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SGV-ZMU-286R, 2026-04-08) |
| | Detail of Fee Submitted | 38700,<br>2026-03-30, |
| | The proposed proprietary name / brand name | **Trigaba 75mg Capsule** |
| | Label Claim | Each Capsule Contains: Pregabalin....75mg (BP Specs.) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 2x7's-As per SRO |
| | Shelf Life (Unit) | 2 Yearstore below 30°C |
| | For generic drugs (me-too Status) | Lyrica Capsules 75mg (AGP Limited) |
| | Pharmacotherapeutic Group of (API) | Almelo Pvt.Ltd, India |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Available; Attached |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Available; Attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Available; Attached |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Available; Attached |
| | The status in reference regulatory authorities | Pregablin Tillomed Capsule 75mg (MHRA Approved) |
| | GMP status of the firm | Available; Attached |
| | Evidence of approval of manufacturing facility | Available; Attached |
| | **Evaluation Remarks** | |
| | The loan request is dated 18.06.2025 and the stability was initiated on 18.08.2025. However, the intimation of loan to DRAP was given on 03.09.2025. Product development was done on borrowed API. However, DRAP's notification No.14-1/2022-PEC dated 01.08.2025 permits the borrowing of APIs on a loan basis which was exclusively permitted only to holders of new Drug Manufacturing Licenses (DMLs). | |
| | **Decision** | |
| | **Approved** | |
| 200 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Trigon Pharmaceuticals (Private) Ltd** 8-k.m thokar raiwind road Lahore **(000342)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (NNJ-NNN-VBWG, 2026-04-08) |
| | Detail of Fee Submitted | 38700,<br>2026-03-30, |
| | The proposed proprietary name / brand name | **Trigaba 300mg Capsule** |
| | Label Claim | Each Capsule Contains: Pregabalin....300mg (BP Specs.) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 14's -As per SRO |
| | Shelf Life (Unit) | 2 Yearstore below 30°C |
| | For generic drugs (me-too Status) | Gablin capsule 300mg (CCL Pharmaceuticals Pvt. Ltd.)icals |
| | Pharmacotherapeutic Group of (API) | Almelo Pvt.Ltd, India |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Available; Attached |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Available; Attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Available; Attached |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Available; Attached |
| | The status in reference regulatory authorities | Pregablin Tillomed Capsule 300mg (MHRA Approved) |
| | GMP status of the firm | Available; Attached |
| | Evidence of approval of manufacturing facility | Available; Attached |
| | **Evaluation Remarks** | |
| | The loan request is dated 18.06.2025 and the stability was initiated on 18.08.2025. However, the intimation of loan to DRAP was given on 03.09.2025. Product development was done on borrowed API. However, DRAP's notification No.14-1/2022-PEC dated 01.08.2025 permits the borrowing of APIs on a loan basis which was exclusively permitted only to holders of new Drug Manufacturing Licenses (DMLs). | |
| | **Decision** | |
| | **Approved** | |
| 201 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) **(000837)** |
| | Application Form Dy. No / Tracking ID & date of submission | (953-74Z-LWQ7, 2025-11-11) |
| | Detail of Fee Submitted | 75000.0,<br>2025-06-23, |
| | The proposed proprietary name / brand name | **Aprocit 12.5mg Tablet** |
| | Label Claim | Each film coated tablet contains:<br>Aprocitentan.....12.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x10's-As per SRO,1x15s (15s)-As per SRO,2x15's-As per SRO,3x10's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 25°C. Excursions permitted between 15°C and 30°C. |
| | For generic drugs (me-too Status) | N/A |

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| | Pharmacotherapeutic Group of (API) | Endothelin Receptor Antagonist |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches having batch size of 5500 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Firm has submitted copy of Form 6 issued dated 12-11-2024 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted stability study data of 3 batches of drug substance |
| | The status in reference regulatory authorities | TRYVIO 12.5MG TABLETS By IDORSIA Pharmaceutical Ltd. USFDA Approved. |
| | GMP status of the firm | Submitted copy of cGMP certificate of the firm based on inspection dated 21st Jan 2025 |
| | Evidence of approval of manufacturing facility | Submitted copy of letter of renewal of DML dated 01-06-2021 specifying Tablet (General) section. |
| | **Evaluation Remarks** | |
| | Under export facilitation | |
| | **Decision** | |
| | **Approved** | |
| 202 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi **(000718)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YEP-PWU-8TX7, 2026-04-08) |
| | Detail of Fee Submitted | 38700, 2026-04-04, |
| | The proposed proprietary name / brand name | **Momit Ointment** |
| | Label Claim | Each gram contains: Mometasone Furoate .....1mg (0.1% w/w) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)15c-30C |
| | For generic drugs (me-too Status) | Mometaderm 1mg Ointment (0.1% w/w) |
| | Pharmacotherapeutic Group of (API) | Other antibiotics for topical use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches of 250 tubes at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API on loan from Medera Pharmaceuticals |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of three batches at long term and accelerated conditions |
| | The status in reference regulatory authorities | Mometasone Furoate 0.1% w/w Ointment by Generics [UK] Limited |

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| | GMP status of the firm | GMP required |
| | Evidence of approval of manufacturing facility | DML No. 000718 dated 17.01.2024 having cream ointment general section |
| | **Evaluation Remarks** | |
| | GMP | |
| | **Decision** | |
| | **Approved**<br><br>Subject to provision of latest GMP certificate/ report of the applicant | |
| 203 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi **(000718)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SHQ-U1W-NN8A, 2026-04-08) |
| | Detail of Fee Submitted | 38700,<br>2026-04-04, |
| | The proposed proprietary name / brand name | **Momit Cream** |
| | Label Claim | Each gram contains: Mometasone Furoate .....1mg (0.1% w/w) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 15gram-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)15c-30C |
| | For generic drugs (me-too Status) | Mometaderm 1mg Cream (0.1% w/w) by danas pharma |
| | Pharmacotherapeutic Group of (API) | Other antibiotics for topical use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of three batches of 250 tubes at long term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API on loan from Medera Pharmaceuticals |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | DML No. 000718 dated 17.01.2024 having cream ointment general section |
| | The status in reference regulatory authorities | Mometasone Furoate by Glenmark Pharmaceuticals UK |
| | GMP status of the firm | GMP required |
| | Evidence of approval of manufacturing facility | attached |
| | **Evaluation Remarks** | |
| | API loan verification | |
| | **Decision** | |
| | **Approved**<br><br>Subject to provision of latest GMP certificate/ report of the applicant and API loan verification | |
| 204 | Case Category | New Section (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (XNH-Z3P-8JPP, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-05, |
| | The proposed proprietary name / brand name | **Nizonide Oral Suspension 100mg/5ml** |
| | Label Claim | Each 5ml contains 100mg of Nitazoxanide after reconstitution. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 60ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool dry place, stored at room temperature below 30°C. |
| | For generic drugs (me-too Status) | Izato Oral Suspension 100mg/5ml by SAMI Pharmaceuticals Pvt.Ltd |
| | Pharmacotherapeutic Group of (API) | Anti-Protozoal |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Synthimed Labs Pvt.Ltd |
| | Detail of stability batches of drug product | Stability study conditions: Long term: 30°C ± 2°C/ 75% ± 5% RH for 3 months & Accelerated: 40°C ± 2°C / 75% ± 5% RH for 3 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Documents for Import of API |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP have been done against Izato Oral Suspension 100mg/5ml |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability study conditions: Long term: 30°C ± 2°C/ 75% ± 5% RH, for 60 months, Accelerated: 40°C ± 2°C / 75% ± 5% RH for 6 months. |
| | The status in reference regulatory authorities | Alinia 100mg/5ml Oral Suspension -US(FDA Approved) |
| | GMP status of the firm | GMP certificate valid till 14 October, 2028 |
| | Evidence of approval of manufacturing facility | DML |
| | **Evaluation Remarks** | |
| | New Section | |
| | **Decision** | |
| | **Approved** | |
| 205 | Case Category | Export Facilitation (Incharge Evaluation Cell) |
| | Name, address of Applicant. | **AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AE7-DLA-252R, 2026-06-01) |
| | Detail of Fee Submitted | 75000,<br>2025-12-30, |
| | The proposed proprietary name / brand name | **Goofie Tablet 5mg** |
| | Label Claim | Each film coated tablet contains: 5mg of Elobixibat. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14's(2 x 7's)-De-Controlled, 28's (4 x 7's)-De-Controlled,10's (1 x 10's)-De-Controlled,20's (2 x 10's)-De-Controlled,30's (3 x 10's)-De-Controlled,40's (4 x 10's)-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 ºC in a dry place, away from direct heat or sunlight and moisture. |

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| | For generic drugs (me-too Status) | Locally available with the brand name Laxocare by Martin Dow Marker (formerly Merck)Pvt. Ltd |
| | Pharmacotherapeutic Group of (API) | Elobixibat: Ileal bile acid transporter (IBAT) inhibitors. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | GANSU HAOTIAN PHARMATECH CO., LTD |
| | Detail of stability batches of drug product | Stability data conducted on 3 batches(234DS01, 234DS02, 234DS03) (3 Month Accelerated 40C + 2C and 75% RH + 5% and 3 Month Long Term 30C + 2C and 75% RH + 5% ) |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Ptrovided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP have been conducted against GOOFICE 5mg Tablet manufactured by EA Pharma Co.Ltd., Japan |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Long Term:24 Months, Accelerated_6 Months. HT200220606ELO,HT200220611ELO,HT20022( |
| | The status in reference regulatory authorities | PMDA Approved detailed provided in Module 1 Section 1.5.9 |
| | GMP status of the firm | The certificate is valid till 14/10/2028 |
| | Evidence of approval of manufacturing facility | Drug Manufacturing License dated 06.02.2025 |
| | **Evaluation Remarks** | |
| | Under export facilitation | |
| | **Decision** | |
| | **Approved** | |
| 206 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (682-TH5-216V, 2025-11-07) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-07-02, 2025-10-08 |
| | The proposed proprietary name / brand name | **INTONING (IBRUTINIB) 140MG CAPSULE** |
| | Label Claim | Each Capsule Contains: Ibrutinib ..... 140mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 120's-As per SRO,90's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30°C in a cool and dry place |
| | For generic drugs (me-too Status) | Ibrutix Capsule 140mg manufactured by: Himmel Pharmaceuticals (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Protein kinase inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Anhui Haikang Pharmaceutical., Co.,Ltd ADDRESS:N0.21 HUANCHENG WEST ROAD, DAGUAN DISTRICT, ANQING CITY, ANHUI PROVINCE, 246000 CHINA |
| | Detail of stability batches of drug product | Accelerated stability performed for 6 months, Long term stability performed for 6 months |
| | Documents for the procurement of API with approval from DRAP | Provided |

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| | (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Provided |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | Provided |
| | **Evaluation Remarks** | |
| | Applicant has requested for withdrawal of Ibrutinib Capsules 70mg, 140mg and 560mg. Following deficiencies were communicated to the applicant: GMP certificate and DML of API manufacturer. The active substance specification doesn't include heavy metals test by (ICP-MS) and crystal form (DSC). The specifications to be updated as per COA. Chiral purity, polymorphic form,PSD , residue on ignition not performed by DP manufacturer on API. A forced degradation study and photolysis not performed. Clarification is required. Water content to be made part of DP specifications at release. Water content, chiral impurity, crystal form to be made part of stability specifications of DP. Provide dissolution of each unit independently instead of providing mean. Provide source of gelatin.For animal source, provide valid TSE CEP from the suppliers of the gelatine used in the manufacture is provided. Justify your dissolution specification with CDP .As specification mentions "The percentage dissolution is not less than 85% (Q+5=85%) of the label claim in 45 minutes" whereas, in CDP the release is less then 51 % even after 60 minutes. The innovator has performed dry granulation whereas, you have performed wet granulation. Moreover, it is moisture sensitive product. Clarification is required. The assay of API is 99.4% whereas, your assay in potency adjustment is 99.6%. Justify. Attach Audit trail. Verify the attached chromatograms from audit trail and share evidence.(correct file attached) 70 mg 140 mg Tablet 280 mg 420 mg 560 mg 140mgFurthermore, you have imported 1.3 Kg API and manufactured following products(3 batches (500) of each strength) with same API: Capsule 140 mg That makes total of 2.415 kg. Clarification is required. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as withdrawn by applicant. | |
| 207 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7YM-Q53-W7V4, 2025-10-06) |
| | Detail of Fee Submitted | 75000,<br>2025-07-02, |
| | The proposed proprietary name / brand name | **Intoning 560mg Tablet** |
| | Label Claim | Each Film coated Tablet Contains: Ibrutinib ..... 560mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 28's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | NIL |
| | Pharmacotherapeutic Group of (API) | Protein kinase inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Anhui Haikang Pharmaceutical., Co.,Ltd & ADDRESS:N0.21 HUANCHENG WEST ROAD, DAGUAN DISTRICT, ANQING CITY, ANHUI PROVINCE, 246000 CHINA |

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| | Detail of stability batches of drug product | Accelerated Stability Study {0, 3, 6 months (completed)}, Long term / Real time stability study{0,3, 6) months (completed)} |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Provided |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence and CDP has been provided, |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | Medicines and Healthcare products Regulatory Agency (MHRA) |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | Applicant has requested for withdrawal of this application via tracking ID 3NQ-2L4-PBJR. Application was evaluated and found deficient for the following: GMP certificate and DML of API manufacturer. The manufacturing of ibrutinib uses diisopropylethylamine (DIPEA) base but is has not been determined in testing of API by API manufacturer. Clarification is required.(refererence Auspar) Qty of enantiomer not provided. Clarification is required. (refererence Auspar) The active substance specification doesn't include heavy metals test by (ICP-MS) and crystal form (DSC). The specifications to be updated as per COA. Chiral purity, polymorphic form,PSD , residue on ignition not performed by DP manufacturer on API. A forced degradation study and photolysis not performed. Clarification is required. Water content to be made part of DP specifications at release. Assay in PE is 91 %. Clarify. Justify QTy and role of excipients in the tabet. Provide tablet weight of innovator product used in PE> Water content, chiral impurity, crystal form to be made part of stability specifications of DP. Provide dissolution of each unit independently instead of providing mean. Clarification is required for dissolution specification of 45 minutes. Justify your dissolution specification with CDP .As specification mentions "The percentage dissolution is not less than 85% (Q+5=85%) of the label claim in 45 minutes" whereas, in CDP the release is less then 51 % even after 60 minutes. The innovator has performed dry granulation whereas, you have performed wet granulation. Moreover, it is moisture sensitive product. Clarification is required. Attach Audit trail. Provide evidence of audit trail of 3 months and 6 months standard chromatograms. Justify the qty of API(1.3 kg) used in 4 tablet strengths and 2 capsules strength. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as withdrawn by applicant. | |
| 208 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B6E-QTH-1S83, 2025-10-06) |
| | Detail of Fee Submitted | 75000,<br>2025-07-02, |
| | The proposed proprietary name / brand name | **Intoning 70mg Capsule** |
| | Label Claim | Each Capsule Contains: Ibrutinib ..... 70mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 28's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | Nil |
| | Pharmacotherapeutic Group of (API) | Protein kinase inhibitors |

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| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | API Manufacturer's Name:Anhui Haikang Pharmaceutical., Co.,Ltd,API Manufacturer's Address:ADDRESS:N0.21 HUANCHENG WEST ROAD, DAGUAN DISTRICT, ANQING CITY, ANHUI PROVINCE, 246000 CHINA |
| | Detail of stability batches of drug product | Accelerated Stability Study {0, 3, 6 months (completed)}, Long term / Real time stability study{0,3, 6) months (completed)} |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | - |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence has been provided. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | Food and Drug Administration |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | attached |
| | **Evaluation Remarks** | |
| | Applicant has requested for withdrawal of this application via tracking ID 3NQ-2L4-PBJR Application was evaluated and found deficient for the following: GMP certificate and DML of API manufacturer. The manufacturing of ibrutinib uses diisopropylethylamine (DIPEA) base but is has not been determined in testing of API by API manufacturer. Clarification is required.(refererence Auspar) Qty of enantiomer not provided. Clarification is required. (refererence Auspar) The active substance specification doesn't include heavy metals test by (ICP-MS) and crystal form (DSC). The specifications to be updated as per COA. Chiral purity, polymorphic form,PSD , residue on ignition not performed by DP manufacturer on API. A forced degradation study and photolysis not performed. Clarification is required. Water content to be made part of DP specifications at release. Assay in PE is 91 %. Clarify. Justify QTy and role of excipients in the tabet. Provide tablet weight of innovator product used in PE> Water content, chiral impurity, crystal form to be made part of stability specifications of DP. Provide dissolution of each unit independently instead of providing mean. Clarification is required for dissolution specification of 45 minutes. Justify your dissolution specification with CDP .As specification mentions "The percentage dissolution is not less than 85% (Q+5=85%) of the label claim in 45 minutes" whereas, in CDP the release is less then 51 % even after 60 minutes. The innovator has performed dry granulation whereas, you have performed wet granulation. Moreover, it is moisture sensitive product. Clarification is required. Attach Audit trail. Provide evidence of audit trail of 3 months and 6 months standard chromatograms. Justify the qty of API(1.3 kg) used in 4 tablet strengths and 2 capsules strength. | |
| | **Decision** | |
| | **Rejected**<br><br>Rejected as withdrawn by applicant. | |
| 209 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XNV-ZLX-81Y2, 2026-03-19) |
| | Detail of Fee Submitted | 38700,<br>2026-02-23, |
| | The proposed proprietary name / brand name | **Azocel 250mg Tablet** |
| | Label Claim | Each film Coated Tablet Contains: -<br>Azithromycin Dihydrate Eq to Azithromycin 250mg |

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|---|---|
| Reference to Finished product specifications | United States Pharmacopeia |
| Proposed Pack Size | As per SRO-As per SRO |
| Shelf Life (Unit) | 2 Year(s)Below 30 Degree Celsius |
| For generic drugs (me-too Status) | Zetro Tablet 250mg Getz Pharmaceuticals (Pvt) Ltd. REG 066913 |
| Pharmacotherapeutic Group of (API) | Macrolide |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Ningxia Taiyicin Biotech Co., Ltd. Pacific Road No.1, Nuanquan Economic Zone, Helan County, Yinchuan, Ningxia, China |
| Detail of stability batches of drug product | T-001, T-002, T-003 1500 tablets |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Loan from M/s Winthrox. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE attached with Brand Leader ( Zetro 250 mg Tablet) and CDP is of Capsule 250mg. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVA. |
| The status in reference regulatory authorities | MHRA Aprroved |
| GMP status of the firm | Additional Section Tablet General Feb 2025 |
| Evidence of approval of manufacturing facility | Additional Section Tablet General |

**Evaluation Remarks**

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| The peak area values observed in the 500 mg chromatograms appear to be almost identical to those of the 250 mg chromatograms, with the only apparent difference being the removal of the second digit from the peak area values. |
| Same injection time e.g. T003. for both strengths: 2:13 PM 2:21 PM 2:29 PM |

Other shortcomings: Valid DML/GMP certificate of the API manufacturer. Section 1.5.2 is missing. Complete characterization studies under section 3.2.S.3. COA of API submitted by the drug product manufacturer pertains to Tranexamic Acid. Submitted COA of API is not legible/readable. Section 3.2.S.5 (Reference Standard) is required. Clarify to which reference product the applied product is qualitatively similar. CDP submitted pertains to capsule dosage form. Very high level of Calcium Hydrogen Phosphate (31.43%) used in formulation; justification required. Sodium Lauryl Sulfate has been labeled as glidant; justification required. Justify the use of three fillers in the formulation, i.e., Lactose + DCP + Starch. Process validation protocol for commercial batches is required. As per BP, the content of Azithromycin (C38H72N2O12) should be 95.0% to 105.0% of the stated amount, whereas your proposed limit is 90.0% to 110.0%; justify. Test method is not in accordance with BP, whereas BP specifications have been claimed in sections 3.2.P.5.1 and 3.2.P.5.6 (Justification of Specifications). Section 3.2.P.5.4: Batch analysis for each batch in the form of COA is required. Section 3.2.P.6: Reference Standards or Materials are required. Identification test by FTIR should be performed. DT test should be included in specifications. System suitability has not been performed for dissolution. System suitability is not part of specifications. Submit batch analysis under section 3.2.P.5.4. Section 3.2.P.6: Reference Standards or Materials are required. Drug substance specifications are based on USP, whereas drug product specifications are based on BP; justify in light of applicable reference guidelines. Drug substance verification studies by the drug product manufacturer are required. Chromatograms, retention times, and number of peaks for assay and dissolution are identical for capsule and tablet, whereas capsule method is BP and tablet method is USP; clarification required. Method ID is also the same; justify. Commercial invoice submitted is not legible/readable. Quantity of API shown as taken on loan from M/s Winthrox. Original loan agreement is required. Submit documents regarding procurement/import approval of API from DRAP. API has been shown as locally purchased from M/s City Pharmaceuticals; clarification required. In dissolution test method, 500 mg tablet has been mentioned; clarify. Supporting data for method verification, including specificity, is required. System suitability data for tailing factor and RSD calculations to be provided. Conversion factor (0.001 mg / 1 µg) has not been included in assay calculation. Dissolution and assay formulae are not in accordance with USP. Intimation letter was

not submitted within 15 days. At serial number 484 dated 11-07-2025 in digital data logger, humidity recorded as 44% RH instead of 65% RH; justify. At serial number 1541 dated 01-08-2025 in digital data logger, humidity recorded as 98.2% RH instead of 65% RH; justify. At serial number 1624, humidity again found out of limit at 41.7% RH; justify. Chromatograms for method verification are required. Dissolution chromatograms are unclear; chromatographic conditions are not visible, numerous peaks seen in dissolution chromatograms, and raw data sheets are not legible. Dissolution results of each unit should be provided separately with % release. The calculation sheets mention absorbance. Justify. Attach audit trail of dissolution and assay. Sample information is not appearing on dissolution and assay chromatograms. Clarify which pharmacopoeia method (USP/BP) has been applied for stability testing. Same time mentioned on chromatograms for both strengths of tablet.eg batch T003 it is not practically possible. Attach BMR of all three strengths.

**Decision**

**Rejected**

The Registration Board rejected the application due to concerns regarding the integrity of the submitted stability data, based on the following observations:

- The peak area values observed in the 500 mg chromatograms appear to be almost identical to those of the 250 mg chromatograms, with the only apparent difference being the removal of the second digit from the peak area values.
- The chromatograms for both the 250 mg and 500 mg strengths show identical injection times (e.g., T003), specifically:
    - 2:13 PM
    - 2:21 PM
    - 2:29 PM

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| 210 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Medwell Pharmaceuticals** 1 km, terbella road, lawrencepur, faqirabad Attock **(000699)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TLL-7ME-A2DP, 2026-03-19) |
| | Detail of Fee Submitted | 38700,<br>2026-02-23, |
| | The proposed proprietary name / brand name | **Azocel 500mg Tablet** |
| | Label Claim | Each film Coated Tablet Contains: -<br>Azithromycin Dihydrate Eq to Azithromycin 500mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30 degree Celsius |
| | For generic drugs (me-too Status) | ZETRO Tablet 500mg GETZ Pharmaceuticals Reg 053120 |
| | Pharmacotherapeutic Group of (API) | Macrolide |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Ningxia Taiyicin Biotech Co., Ltd. Pacific Road No.1, Nuanquan Economic Zone, Helan County, Yinchuan, Ningxia, China |
| | Detail of stability batches of drug product | T001 T002 T003 1500 Tablet |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan from M/s Winthrox |

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| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP Zetro 500 mg Tablet |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IV a condition. |
| The status in reference regulatory authorities | MHRA Approved |
| GMP status of the firm | Additional Section Approval |
| Evidence of approval of manufacturing facility | Additional Section Tablet Approval |

**Evaluation Remarks**

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| The area values in the 500 mg report appear to be almost exactly the same numbers as the 250 mg report with the second digit removed. |
| Same injection time e.g. T003. for both strengths: 2:13 PM 2:21 PM 2:29 PM |

Other shortcomings: Valid DML/GMP certificate of the API manufacturer. Section 1.5.2 is missing. Complete characterization studies under section 3.2.S.3. Submitted COA of API is not legible/readable. Section 3.2.S.5 (Reference Standard) is required. Clarify to which reference product the applied product is qualitatively similar. Very high level of Calcium Hydrogen Phosphate used in formulation; justification required. Sodium Lauryl Sulfate has been labeled as glidant; justification required. Justify the use of three fillers in the formulation, i.e., Lactose + DCP + Starch. Process validation protocol for commercial batches is required. As per BP, the content of Azithromycin (C38H72N2O12) should be 95.0% to 105.0% of the stated amount, whereas your proposed limit is 90.0% to 110.0%; justify. Test method is not in accordance with BP, whereas BP specifications have been claimed in sections 3.2.P.5.1 and 3.2.P.5.6 (Justification of Specifications). Section 3.2.P.5.4: Batch analysis for each batch in the form of COA is required. Section 3.2.P.6: Reference Standards or Materials are required. Identification test by FTIR should be performed. DT test should be included in specifications. System suitability has not been performed for dissolution. System suitability is not part of specifications. Submit batch analysis under section 3.2.P.5.4. Section 3.2.P.6: Reference Standards or Materials are required. Drug substance specifications are based on USP, whereas drug product specifications are based on BP; justify in light of applicable reference guidelines. Drug substance verification studies by the drug product manufacturer are required. Chromatograms, retention times, and number of peaks for assay and dissolution are identical for capsule and tablet, whereas capsule method is BP and tablet method is USP; clarification required. Method ID is also the same; justify. Commercial invoice submitted is not legible/readable. Quantity of API shown as taken on loan from M/s Winthrox. Original loan agreement is required. Submit documents regarding procurement/import approval of API from DRAP. API has been shown as locally purchased from M/s City Pharmaceuticals; clarification required. In dissolution test method, 500 mg tablet has been mentioned; clarify. Supporting data for method verification, including specificity, is required. System suitability data for tailing factor and RSD calculations to be provided. Conversion factor (0.001 mg / 1 µg) has not been included in assay calculation. Dissolution and assay formulae are not in accordance with USP. Intimation letter was not submitted within 15 days. At serial number 484 dated 11-07-2025 in digital data logger, humidity recorded as 44% RH instead of 65% RH; justify. At serial number 1541 dated 01-08-2025 in digital data logger, humidity recorded as 98.2% RH instead of 65% RH; justify. At serial number 1624, humidity again found out of limit at 41.7% RH; justify. Chromatograms for method verification are required. Dissolution chromatograms are unclear; chromatographic conditions are not visible, numerous peaks seen in dissolution chromatograms, and raw data sheets are not legible. Dissolution results of each unit should be provided separately with % release. The calculation sheets mention absorbance. Justify. Attach audit trail of dissolution and assay. Sample information is not appearing on dissolution and assay chromatograms. Clarify which pharmacopoeia method (USP/BP) has been applied for stability testing. Same time mentioned on chromatograms for both strengths of tablet.eg batch T003 it is not practically possible. Attach BMR of all three strengths. The CDP results of 250mg capsule and 500mg tablet are same. The method verification report is same only 250mg has been converted to 500mg. Time is same for chromatograms for 250 mg and 500mg. In dissolution testing T003RL peak area of 250mg capsule and that of 500 mg tablet is same.

**Decision**

**Rejected**

| | | |
|---|---|---|
| | The Registration Board rejected the application due to concerns regarding the integrity of the submitted stability data, based on the following observations:<br>• The peak area values observed in the 500 mg chromatograms appear to be almost identical to those of the 250 mg chromatograms, with the only apparent difference being the removal of the second digit from the peak area values.<br>• The chromatograms for both the 250 mg and 500 mg strengths show identical injection times (e.g., T003), specifically:<br>◦ 2:13 PM<br>◦ 2:21 PM<br>◦ 2:29 PM | |
| 211 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)** |
| | Application Form Dy. No / Tracking ID & date of submission | (48Q-G86-PX3S, 2024-10-31) |
| | Detail of Fee Submitted | 75000.0, 18000.0<br>2024-06-27, 2024-09-12 |
| | The proposed proprietary name / brand name | **Racadot 100mg Capsule** |
| | Label Claim | Each Capsule Contains:<br>Racecadotril.....100MG (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Yearstore below 30 degree centigrade |
| | For generic drugs (me-too Status) | Hidrasec Capsule 100mg (Abbott Laboratories Pakistan) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Welcome Pakistan Trading Pharma (Pvt) Ltd.-Chakri Interchange, Gangawala, Rawalpindi- |
| | The status in reference regulatory authorities | UK MHRA RACECADOTRIL 100MG Capsule (SOPHARTEX 21 rue de Pressoir , 28500 Vernouillet France) |
| | Detail of previous approval | M-336 |
| | **Evaluation Remarks** | |
| | Data already approved in M-336 and applicant has also submitted pre-registration fee for change in data already approved from NO to Yes in eApp. | |
| | **Decision** | |
| | **Approved** | |
| 212 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VPU-R5D-P72Q, 2024-08-23) |
| | Detail of Fee Submitted | 30000.0,<br>2024-08-16, |
| | The proposed proprietary name / brand name | **Fluconazole 150mg Capsule** |

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|---|---|
| Label Claim | Each Capsule Contains Fluconazole ..... 150mg |
| Reference to Finished product specifications | British Pharmacopeia |
| Proposed Pack Size | 1 x 1's -As per SRO |
| Shelf Life (Unit) | 2 Year(s)Store below 25°C , protect from light |
| For generic drugs (me-too Status) | Fungone 150mg Capsule |
| Pharmacotherapeutic Group of (API) | Triazole and tetrazole derivatives |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | HEMA PHARMACEUTICAL (PVT) LTD. |
| Detail of stability batches of drug product | CTR083, CTR084, CTR085 |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate attached |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per zone IV a. |
| The status in reference regulatory authorities | FDA, MHRA, EMC |
| GMP status of the firm | Not provided. |
| Evidence of approval of manufacturing facility | Capsule general |

**Evaluation Remarks**

| Observation | Response |
|---|---|
| Several chromatograms in AMV were acquired in November 2023 but processed in February 2023. For example: Page 1: Data acquired on 18-Nov-2023, whereas processing date is 18-Feb-2023. Page 2: Acquired on 18-Nov-2023 and processed on 18-Feb-2023. Chromatograms were printed before running the injections, which is impossible. | |
| Provide the polymorphic form of fluconazole. Characterization technique for polymorphism should be XRPD (X-ray Powder Diffraction). How many polymorphic forms exist for fluconazole as DS manufacturer has mentioned 3. Clarify and provide evidence of 3 forms. Provide details of reference standard used in DS identification/assay. Justify the specifications of DS part during release and stability like identification by UV and assay by potentiometer. Update the specifications as per latest pharmacopoeia of DS by DS manufacturer. | With due respect, we would like to submit that the Active Pharmaceutical Ingredient (API) used in our drug product is sourced from a manufacturer located in India. Following the escalation of tensions between Pakistan and India in May 2025 and the subsequent restrictions on bilateral trade and business communications, we have been facing significant difficulties in establishing contact with the API manufacturer and obtaining the requested technical and regulatory data. Despite our efforts, the prevailing circumstances have limited our ability to secure additional information regarding polymorphic forms, XRPD characterization data, reference standards, justification of specifications, and updated pharmacopeial specifications from the manufacturer within the required timeframe. In |

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| | | view of these exceptional circumstances, we humbly request the Registration Board/Authority to kindly consider granting relaxation or additional time for submission of the requested documents. We assure you that the required information will be furnished as soon as communication and access to the manufacturer become feasible. Your kind consideration and support in this matter will be highly appreciated. |

**Decision**

**Rejected**

The Registration Board rejected the application due to serious data integrity deficiencies in the submitted analytical method validation chromatograms. Several chromatograms were reported to have been acquired in November 2023, whereas the corresponding processing dates were recorded as February 2023, indicating that the chromatograms were printed several months before the injections were run, which is scientifically impossible.

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| 213 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RQE-PRE-75XS, 2026-02-03) |
| | Detail of Fee Submitted | 75000,<br>2025-10-16, |
| | The proposed proprietary name / brand name | **Veneclax 50mg tablet** |
| | Label Claim | Each Film coated Tablet Contains: Venetoclax ..... 50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO,30's-As per SRO,7's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | NIL |

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| | Pharmacotherapeutic Group of (API) | Antineoplastic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Nantong Chanyoo Pharmatech Co.,Ltd |
| | Detail of stability batches of drug product | TF-01, TF-02, TF-03 500 tablets |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Final clearance certificate attached. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence and CDP has been provided, |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per zone IV a. |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | Cytoxic Tablet new section. |
| | Evidence of approval of manufacturing facility | Cytoxic Tablet new section. |
| | **Evaluation Remarks** | |
| | Chromatograms in the stability data for 10 mg tablet and 50 mg with only change in date, see attached. Other Discrepencies License of Drug Substance Manufacturer from the Regulatory Authority of the country of origin for domestic market as attached DML is for export only for venetoclax The submitted data in PE reveals that standards 1-5 were run from 12 to 1 Am with last standard specifically on 1.47 AM. However, the standards were run after a difference of approx 30 minutes around 1.48 and 1.59 respectively. Please justify the difference between run times for analysis of one sample? The dissolution procedure specified in CDP protocol is different from the dissolution procedure mentioned in the CDP report. Please provide pictorial and data evidence that correct dissolution procedure was used for performing CDP. The DS is manufactured by Nantong Chanvoo Pharmatech Co.,Ltd, as per your application. However, you have used Reference standard from Changzhou Pharmaceutical Factory.It is subsidiary but still different pharmaceutical unit. The innovator has used crystalline form, your's is amorphous, how qualitative composition can be same. | |
| | **Decision** | |
| | **Rejected**<br><br>The Registration Board rejected the application based on the following observations:<br><br>1. During the evaluation of the 50 mg strength, it was observed that the chromatograms submitted in the stability data for the 10 mg and 50 mg tablets were identical, with only change in dates.<br>2. Evidence of any reference product utilizing the amorphous form of the API.<br>3. Scientific justification for the claim of qualitative similarity with the innovator product, whereas the innovator product contains the crystalline form of the API. | |
| 214 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U3E-LBA-HR1P, 2025-11-07) |
| | Detail of Fee Submitted | 75000,<br>2025-10-16, |
| | The proposed proprietary name / brand name | **Veneclax 10mg tablet** |
| | Label Claim | Each Film coated Tablet Contains: Venetoclax ..... 10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 14's-As per SRO,2's-As per SRO,30's-As per SRO |

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| Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place. Below 30°C |
| For generic drugs (me-too Status) | NIL |
| Pharmacotherapeutic Group of (API) | antineoplastic agents |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | NANTONG CHANYOO PHARMATECH CO., LTD NO.2 TONGHAI SI ROAD, YANGKOU CHEMICAL INDUSTRIAL PARK, RUDONG COASTAL ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU PROVINCE 226407 |
| Detail of stability batches of drug product | Accelerated Stability: 40□2°C, RH 75□5% Long-term Stability: 30□2°C; RH 65□5% 24 months |
| Documents for the procurement of API with approval from DRAP (in case of Import) | FINAL CLEARANCE CERTIFICATE Computerized No: RO-A49769 Date of Issue: 25-02-2025 VENETOCLAX 000755 VCL□702-240701 0.3000 Kilogram 05- 07- 2024 05- 07- 2027 NANTONG CHANYOO PHARMATECH CO., LTD NO.2 TONGHAI SI ROAD, YANGKOU CHEMICAL INDUSTRIAL PARK, RUDONG COASTAL ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU PROVINCE 226407, P.R.CHINA China |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence and CDP has been provided against Abbvie Healthcare India Batch No 127672 |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| GMP status of the firm | New section Dated May 2024 |
| Evidence of approval of manufacturing facility | New Section Tablet Cytotoxic Dated May 2024 |
| **Evaluation Remarks** | |
| During the evaluation of 50mg of applied molecule it has been observed that Chromatograms in the stability data for 10 mg tablet and 50 mg are same with only change in date. The Registration Board in M-358, deferred the case pending submission of the following documents: Evidence of any reference product using the amorphous form of the API. Clarification regarding the claim of qualitative similarity with the innovator product, whereas the innovator product contains the crystalline form of the API. Performance and submission of test results for solution clarity, color, microbiological quality, and water content, along with a revised Certificate of Analysis. Snapshot of the innovator product clearly indicating the manufacturer's information/batch No. Scientific justification for the repeated post-run reprocessing of integration and calibration parameters. | |
| **Decision** | |

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| | **Rejected**<br><br>The Registration Board rejected the application based on the following observations:<br><br>1. During the evaluation of the 50 mg strength, it was observed that the chromatograms submitted in the stability data for the 10 mg and 50 mg tablets were identical, with only change in dates.<br>2. Evidence of any reference product utilizing the amorphous form of the API.<br>3. Scientific justification for the claim of qualitative similarity with the innovator product, whereas the innovator product contains the crystalline form of the API. | |
| 215 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4JA-D8T-GVTD, 2025-08-22) |
| | Detail of Fee Submitted | 75000.0,<br>2025-07-18, |
| | The proposed proprietary name / brand name | **Netano Ophthalmic Solution 2.5ml** |
| | Label Claim | Each ml of solution contains 50 micrograms latanoprost and 200 micrograms netarsudil (as mesylate). |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 2°C to 8°C (36°F to 46°F) until opened |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Netarsudil Dimesylate: Netarsudil Dimesylate is a rho kinase inhibitor used to reduce intraocular pressure in patients with open angle glaucoma or ocular hypertension.Latanoprost: Latanoprost is an isopropyl ester prodrug used to treat increased intraocular pressure. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Cayman Pharma s.r.o.,Flax Laboratories Pvt. Ltd. |
| | Detail of stability batches of drug product | NLD-001, NLD-002 Each of 700 packs |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | commercial invoice attached for latanoprost and license to import for netarsudil. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed with Rocklatan Ophthalmic Solution 0.02%+0.005% |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Both Accelerated and real time stability studies performed for both APIs |
| | The status in reference regulatory authorities | US FDA |
| | GMP status of the firm | w.e.f 16-08-2022 applied for renewal 21-12-2023 |
| | Evidence of approval of manufacturing facility | DML# 000856 |
| | **Evaluation Remarks** | |
| | Commercial invoice of Netarsudil is required and fee for typographical error. | |
| | Query | Response |
| | Methanesulfonates in batch no NET/19/009 and NET/19/010 and is Out of specifications at 6 months at 2-8C accelerated stability i.e. 0.2 % limit is 0.1%. | With reference to the stability data submitted for Batch No. NET/19/009 and NET/19/010, it has come to our attention that an inadvertent typographical/documentation error (missed the |

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| | | typing of digit 0 in results) occurred in the stability summary regarding the reporting of Methanesulfonates results at accelerated stability conditions (2-8°C, 6 months).The previously submitted statement indicated that Methanesulfonates were Out of Specification (OOS) with a reported value of 0.2% against a specification limit of 0.1%. Upon review and verification of the original analytical records, it was confirmed that the information was entered incorrectly in the submitted document.Therefore, we are hereby submitting the updated and corrected stability data for Batch No. NET/19/009 and NET/19/010. The revised data accurately reflects the analytical results as recorded in the source documents.We confirm that the discrepancy was limited to a documentation/transcription error and does not affect the quality, safety, or efficacy assessment of the product.Kindly replace the previously submitted data with the antached updated version and consider the corrected information for regulatory evaluation. |
| | **Decision** | |
| | **Approved**<br><br>Approved. Registration letter to be issued upon submission of fee for typographical error in stability data of API. | |
| 216 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (V7Q-8RT-EUMX, 2025-10-01) |
| | Detail of Fee Submitted | 38700,<br>2025-09-09, |
| | The proposed proprietary name / brand name | **Cabozanib 20mg Capsule** |
| | Label Claim | Each Capsule Contains: Cabozantinib (s) malate equivalent to Cabozantinib ..... 20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 112's-As per SRO,56's-As per SRO,84's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30°C in a cool and dry place |
| | For generic drugs (me-too Status) | Cabozanix 20mg Capsule, Manufactured by HIMMEL PHARMACEUTICALS (PVT.) LTD |
| | Pharmacotherapeutic Group of (API) | L01EX07 protein kinase inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | NO. 11, CHONGQING ROAD, SMALL AND MEDIUM-SIZED ENTERPRISE BUSINESS BASE BAIYIN GANSU P. R. CHINA |
| | Detail of stability batches of drug product | Accelerated stability performed for 6 months, Long term stability performed for 6 months TF-01, TF-02, TF-03 Batch size 1500 capsules. |

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| | Documents for the procurement of API with approval from DRAP (in case of Import) | Commercial Invoice and license to import submitted. BATCH NO: 20240829CAB MFG. DATE: 2024.08.29 EXP. DATE: 2026.08.28 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP performed with Cometriq Capsule. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | r accelerated test condition (40±2°C/ RH75±5%) for 6 months and long term test condition (30±2°C/RH65±5%) for 24 months |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | New section Cytotoxic Capsule Dated May 2024 |
| | Evidence of approval of manufacturing facility | New section Cytotoxic Capsule Dated May 2024 |
| | **Evaluation Remarks** | |
| | Query | Response |
| | The innovator product "COMETRIQ capsules are supplied in 140 mg daily-dose cartons, each containing four blister cards, and each blister card contains seven 80 mg capsules and twenty-one 20 mg capsules. Clarify in which packaging material your product will be supplied. Evidence of co blistering machine is required. | We would like to inform you that the product will be supplied in Alu–Alu blister packaging.During commercial-scale manufacturing, suitable blister tooling andforming plates will be employed to accommodate both strengths (20 mgand 80 mg capsules) within a single blister configuration, in accordancewith the innovator approved pack design. |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of product development data including stability studies aligned with the innovator's packaging configuration, along with documentary evidence of procurement of the co-blistering machine. | |
| 217 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QBT-GH2-VQUD, 2025-10-03) |
| | Detail of Fee Submitted | 75000,<br>2025-09-09, |
| | The proposed proprietary name / brand name | **Cabozanib 80mg Capsule** |
| | Label Claim | Each Capsule Contains: Cabozantinib (s) malate equivalent to Cabozantinib ..... 80mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 112 capsules-As per SRO,56 capsules-As per SRO,84 Capsules-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30°C in a cool and dry place |
| | For generic drugs (me-too Status) | Not applicable since this is a new drug product |
| | Pharmacotherapeutic Group of (API) | protein kinase inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Gansu Haotian Pharma / Address: No.11 Chongqing Road,Baiyin District, Baiyin City, Gansu Province |
| | Detail of stability batches of drug product | Accelerated stability performed for 6 months, Long term stability performed for 6 months TF-01, TF-02, TF-03 with batch size 1500 capsule each. |

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| | Documents for the procurement of API with approval from DRAP (in case of Import) | Commercial invoice and License to import submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP done with Cometriq Capsule 80mg |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Storing condition: 40°C±2°C/RH75%±5% Test period: 6 months Test intervals: 0th, 1st, 2nd, 3rd and 6th months Storing condition: 30°C ±2°C/RH65%±10% Test period: 24 months Test times: 0th, 3th, 6th, 9th,12th, 18th, 24th months |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | New Section Capsule Cytotoxic |
| | Evidence of approval of manufacturing facility | New Section Capsule Cytotoxic |
| | **Evaluation Remarks** | |
| | Query | Response |
| | The innovator product "COMETRIQ capsules are supplied in 140 mg daily-dose cartons, each containing four blister cards, and each blister card contains seven 80 mg capsules and twenty-one 20 mg capsules. Clarify in which packaging material your product will be supplied. Evidence of co blistering machine is required. | We would like to inform you that the product will be supplied in Alu–Alu blister packaging.During commercial-scale manufacturing, suitable blister tooling andforming plates will be employed to accommodate both strengths (20 mgand 80 mg capsules) within a single blister configuration, in accordancewith the innovator approved pack design.For clarification of the layout design, a graphical representation ofthe proposed blister configuration—consisting of three 20 mgcapsules and one 80 mg capsule per daily dose—is attached forreference |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of product development data including stability studies aligned with the innovator's packaging configuration, along with documentary evidence of procurement of the co-blistering machine. | |
| 218 | Case Category | New Section (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8DZ-8S2-E8RE, 2026-02-03) |
| | Detail of Fee Submitted | 75000,<br>2025-10-16, |
| | The proposed proprietary name / brand name | **Veneclax 100mg tablet** |
| | Label Claim | Each Film coated Tablet Contains: Venetoclax ..... 100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO,120's-As per SRO,14's-As per SRO,180's-As per SRO,30's-As per SRO,7's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place. Below 30°C |
| | For generic drugs (me-too Status) | NIL |
| | Pharmacotherapeutic Group of (API) | Antineoplastic agent. |
| | Name, address of Manufacturing site: | Self Manufacturing |

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| | Name & address of API manufacturer | Nantong Chanvoo Pharmatech Co.,Ltd, 2 tonghai si ROad yangkou ChenmicaI IndustriaI Park Rudong Coastal Econonic DeveIopment z0ne,Nantong jiangsu Province 226407, 'P.R China |
| | Detail of stability batches of drug product | Accelerated Stability Study {0, 3, 6 months (completed)}, Long term / Real time stability study{0,3, 6) months (completed)} |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Final clearance certificate. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Venclexta 100mg Tablet by AbbVie Healthcare india Pvt Ltd. batch number 127677 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data as per Zone IV a condition. |
| | The status in reference regulatory authorities | FOOD & DRUG ADMINISTRATION (FDA) |
| | GMP status of the firm | Grant of Additional Sections (Tablet Cytotoxic) approval dated 10.05.2024 |
| | Evidence of approval of manufacturing facility | DML 000755 dated 24.09.2022; Grant of Additional Sections (Tablet Cytotoxic) approval dated 10.05.2024 |
| | **Evaluation Remarks** | |
| | Evidence of any reference product using the amorphous form of the API, as innovator has used crystalline form of API. Clarification regarding the claim of qualitative similarity with the innovator product, whereas the innovator product contains the crystalline form of the API. Performance and submission of test results for solution clarity, color, microbiological quality, and water content, along with a revised Certificate of Analysis. Snapshot of the innovator product clearly indicating the manufacturer's information/batch No. Scientific justification for the repeated post-run reprocessing of integration and calibration parameters. | |
| | **Decision** | |
| | **Rejected**<br><br>The Registration Board rejected the application based on the following observations:<br><br>1. The applicant did not provide evidence of any reference product utilizing the amorphous form of the API, whereas the innovator product contains the crystalline form of the API.<br>2. The applicant also did not provide an adequate scientific justification for claiming qualitative similarity with the innovator product despite the difference in the solid-state form of the API, with the applied product containing the amorphous form and the innovator product containing the crystalline form. | |
| 219 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DZB-7Q4-ERNP, 2024-08-09) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-09, |
| | The proposed proprietary name / brand name | **Vorcaz Tablet 100mg** |
| | Label Claim | Each Film Coated Tablet Contains: Voriconazole ..... 100mg |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 7's, 10's, 14's, 20'-As per SRO |

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| | Shelf Life (Unit) | 2 Year(s)Store below 30 Protect from Light and Moisture |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | ANTIMYCOTICS FOR SYSTEMIC USE |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zhejiang Huahai Pharmaceutical Co., Ltd. (Xunqiao site) Manufacturing Site: Xunqiao, Linhai, Zhejiang 317024, C |
| | Detail of stability batches of drug product | 23SB-704-01 :1500 Tablet 23SB-705-02:150 Tablet 23SB-706-03 Tablet |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | CLEARANCE CERTIFICATE Computerized No: E-6729880624537 Date of issue: 21-Sep-2023 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP performed against Aristo 100mg Batch no 284569 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa. |
| | The status in reference regulatory authorities | Aristo Pharma GmbH (Germany) |
| | GMP status of the firm | Valid GMP certificate is required. GMP certificate Validity: 06-06-2025 |
| | Evidence of approval of manufacturing facility | Section letter attached. |
| | **Evaluation Remarks** | |
| | Now, the applicant has submitted CERTIFICATE OF STRUCTURAL INTEGRITY and sequence record. | |
| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the case for the submission of the following documents:<br><br>• 21 CFR Part 11 compliance certificate. | |
| 220 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **Bio-Labs(Pvt) Ltd** Plot 145, Industrial Triangle, Kahuta Road **(000296)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UND-8Y2-TJ6Y, 2024-08-26) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-26, |
| | The proposed proprietary name / brand name | **Posacone tablet 100mg** |
| | Label Claim | Each enteric coated Tablet Contains: |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2x10's, 3x10's ,4x10-As per SRO |
| | Shelf Life (Unit) | 2 YearStore Below 30 |
| | For generic drugs (me-too Status) | Noxafil Gastro-resistant Tablets 100mg. |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | BrightGene Bio-Medical technology Co., Ltd. |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |

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| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| The status in reference regulatory authorities | USFDA Approved |
| GMP status of the firm | |
| Evidence of approval of manufacturing facility | |

**Evaluation Remarks**

The application was evaluated on 17 March 2026, following which deficiency observations were communicated to the applicant. Subsequently, two reminder letters were issued on 11 May 2026 and 17 June 2026. Despite the lapse of sufficient time and repeated reminders, no response has been received from the applicant. The following deficiencies were communicated to the applicant: Documents for the procurement of API with approval from DRAP (in case of import). Attach valid GMP and DML of API. Provide your product is qualitatively similar to which innovator/reference product. The innovator/reference has prepared amorphous molecular dispersion by HME (Hot-melt extrusion) which is necessary to produce similar dissolution profiles and to stabilise the composition with regard to impurities.WHich method you have used. Justify. The polymorphic conversion was confirmed by PXRD analysis how you have ensured whether conversion has taken place or not during manufacturing of DP. No antioxidant has been used justify. The reference product posaconazole in phosphate buffer solution pH 6.8 is significantly low when compared to the solubility in presence of Polysorbate. Hence, phosphate buffer pH 6.8 containing polysorbate was selected as the buffer medium for the dissolution. Justify your dissolution method. As per reference PAR the polymorphic form of the API is considered to be a critical process parameter; it was demonstrated that the QC dissolution method is able to detect the presence of crystalline material.Justify how you have ensured that. Multimedia dissolution studies on the test and reference product biobatches were also conducted acetate buffer pH 4.5. Submit your CDP at pH 4.5. The reference product more than 85% of drug was released within 15 min in pH 6.8 buffer stage.Justify your specs. The finished product release specifications include appropriate tests for this kind of dosage form:,, water (KF),dissolution-acid stage (HPLC), uniformity of dosage units by content uniformity for posaconazole (Ph. Eur.), , related substances (HPLC) and microbial quality (TAMC, TYMC and E. coli) (Ph. Eur.). Make these tests part of specifications. CDP to be performed on 12 units whereas, you have used 6 units. The complete stability data(chromatograms) will be evaluated on submission of above manufacturing method justifications. The medium for posaconazole is not as per USFDA, comply with it.

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| Posaconazole | Tablet (Delayed Release) | II (Paddle) | 75 | Acid Stage: 0.01 N HCl: Buffer Stage: 50 mM phosphate buffer, pH 6.8 with 0.37 % Polysorbate 80 (after 120 minutes, to the acid stage, add 250 mL of 0.2M Phosphate Buffer, 1.46% Polysorbate 80) | Acid Stage: 750 mL; Buffer Stage 1000 mL | Acid Stage: 120; Buffer Stage: 10, 15, 20, 30 |

**Decision**

**Deferred**

The Registration Board deferred the case for the submission of the following documents:

- Documents for the procurement of API with approval from DRAP (in case of import).
- Attach valid GMP and DML of API.
- Provide your product is qualitatively similar to which innovator/reference product.
- The innovator/reference has prepared amorphous molecular dispersion by HME (Hot-melt extrusion) which is necessary to produce similar dissolution profiles and to stabilise the composition with regard to impurities.WHich method you have used. Justify.
- The polymorphic conversion was confirmed by PXRD analysis how you have ensured whether conversion has taken place or not during manufacturing of DP.
- No antioxidant has been used justify.
- The reference product posaconazole in phosphate buffer solution pH 6.8 is significantly low when compared to the solubility in presence of Polysorbate. Hence, phosphate buffer pH 6.8 containing polysorbate was selected as the buffer medium for the dissolution. Justify your dissolution method.
- As per reference PAR the polymorphic form of the API is considered to be a critical process parameter; it was demonstrated that the QC dissolution method is able to detect the presence of crystalline material.Justify how you have ensured that.
- Multimedia dissolution studies on the test and reference product biobatches were also conducted acetate buffer pH 4.5. Submit your CDP at pH 4.5.
- The reference product more than 85% of drug was released within 15 min in pH 6.8 buffer stage.Justify your specs.
- The finished product release specifications include appropriate tests for this kind of dosage form:,, water (KF),dissolution-acid stage (HPLC), uniformity of dosage units by content uniformity for posaconazole (Ph. Eur.), , related substances (HPLC) and microbial quality (TAMC, TYMC and E. coli) (Ph. Eur.). Make these tests part of specifications.
- CDP to be performed on 12 units whereas, you have used 6 units.
- The complete stability data(chromatograms) will be evaluated on submission of above manufacturing method justifications.
- The medium for posaconazole is not as per USFDA, comply with it.

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| Posaconazole | Tablet (Delayed Release) | II (Paddle) | 75 | Acid Stage: 0.01 N HCl: Buffer Stage: 50 mM phosphate buffer, pH 6.8 with 0.37 % Polysorbate 80 (after 120 minutes, to the acid stage, add 250 mL of 0.2M Phosphate Buffer, 1.46% Polysorbate 80) | Acid Stage: 750 mL; Buffer Stage 1000 mL | Acid Stage: 120; Buffer Stage: 10, 15, 20, 30 |

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| 221 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **M/s. Genix Pharma (Pvt) Ltd.** Plot No 44-45-B, Korangi Creek Road, Karachi **(000351)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XUD-VYG-V5HA, 2024-10-16) |

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| Detail of Fee Submitted | 75000.0,<br>2024-10-03, |
| The proposed proprietary name / brand name | **PASCOZL Gastro-resistant Tablet 100mg** |
| Label Claim | Each Gastro-resistant tablet contains:<br>Posaconazole.....100mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 7s, 10s, 14s, 20s, 2-As per SRO |
| Shelf Life (Unit) | 2 YearStore below 30°C, protect from heat light and moisture |
| For generic drugs (me-too Status) | Not Applicable |
| Pharmacotherapeutic Group of (API) | |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Bright Gene Pharmaceutical Co., Ltd,.No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, China |
| Detail of stability batches of drug product | |
| Documents for the procurement of API with approval from DRAP<br>(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 | Noxafil gastro-resistant Tablet 100mg by Merck Sharp & Dohme B.V Netherlands |
| GMP status of the firm | |
| Evidence of approval of manufacturing facility | |

**Evaluation Remarks**

The application was initially evaluated on 17 March 2026, and the applicant submitted a response on 31 March 2026. Upon evaluation of the submitted response, the application was found to remain deficient. Consequently, further deficiency letters were issued on 16 April 2026, 11 May 2026, and 4 June 2026. Despite repeated communications, no response has been received from the applicant.
The following deficiencies remain outstanding: Submit clearance certificate/ADC attested commercial invoice of batch No SPO-I-211003(crystalline I).The attached commercial invoice is of posaconazole injectable grade. Submit your applied formulation is qualitatively similar to which reference product, provide the name of that reference product with official link. Evidence of any reference product of posaconazole that has been manufactured with polymer-assisted thermal conversion process. Moreover, which polymer you have used. Elaborate how your submitted method is polymer-assisted thermal conversion process. Evidence of thermal equipment is required. Stability studies show no significant recrystallization or impurity increase. Clarify how you have ensured that no significant recrystallization has taken place and impurity increase. As no degradation product has been studies in DP. PXRD analysis data will be submitted as soon as we received data from outsourcing party. Mention the outsourcing party and submit results. The applied formulation is qualitatively similar to the reference with respect to excipient composition you have mentioned earlier but not used antioxidant. No significant increase in oxidative degradation impurities under accelerated and long-term storage condition whereas, you have not performed impurities. Dissolution should be on (HPLC) as per innovator.CDP should include 12 units and sampling time should be 120 minutes for pH 4.5. The study was conducted in compliance with the innovator's specification; in accordance with the FDA PAR for "Noxafil DR Tablet 100 mg", dissolution testing was performed at the 20-minute time point, Attach reference of FDA PAR. Annex V does not include Dissolution by HPLC.

**Decision**

**Deferred**

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| | The Registration Board deferred the case for the submission of the following shortcomings:<br>• Submit clearance certificate/ADC attested commercial invoice of batch No SPO-I-211003(crystalline I).<br>• The attached commercial invoice is of posaconazole injectable grade.<br>• Submit your applied formulation is qualitatively similar to which reference product, provide the name of that reference product with official link.<br>• Evidence of any reference product of posaconazole that has been manufactured with polymer-assisted thermal conversion process. Moreover, which polymer you have used.<br>• Elaborate how your submitted method is polymer-assisted thermal conversion process.<br>• Evidence of thermal equipment is required.<br>• Stability studies show no significant recrystallization or impurity increase. Clarify how you have ensured that no significant recrystallization has taken place and impurity increase. As no degradation product has been studies in DP.<br>• PXRD analysis data will be submitted as soon as we received data from outsourcing party. Mention the outsourcing party and submit results.<br>• The applied formulation is qualitatively similar to the reference with respect to excipient composition you have mentioned earlier but not used antioxidant.<br>• No significant increase in oxidative degradation impurities under accelerated and long-term storage condition whereas, you have not performed impurities.<br>• Dissolution should be on (HPLC) as per innovator.CDP should include 12 units and sampling time should be 120 minutes for pH 4.5.<br>• The study was conducted in compliance with the innovator's specification; in accordance with the FDA PAR for "Noxafil DR Tablet 100 mg", dissolution testing was performed at the 20-minute time point, Attach reference of FDA PAR.<br>• Annex V does not include Dissolution by HPLC. | |
| 222 | Case Category | Contract Manufacturing (Iqra Aftab) |
| | Name, address of Applicant. | **M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3U8-AAV-NE8S, 2024-11-13) |
| | Detail of Fee Submitted | 93000.0,<br>2024-10-09, |
| | The proposed proprietary name / brand name | **Pozolin Gastro-resistant Tablet** |
| | Label Claim | Each Gastro-resistant tablet contains:<br>Posaconazole.....100mg OR Each delayed release tablet contains:<br>Posaconazole.....100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7s, 10s, 14s, 20s, 2-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C, protect from heat light and moisture |
| | For generic drugs (me-too Status) | Not Applicable |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Genix Pharma (Pvt) Limited-Plot No.44-45 B, Korangi Creek Road, Karachi - |
| | Name & address of API manufacturer | Bright Gene Pharmaceutical Co., Ltd,.No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215123, China |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | |

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| Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| The status in reference regulatory authorities | Noxafil gastro-resistant Tablet 100mg by Merck Sharp & Dohme B.V Netherlands |
| GMP status of the firm | |
| Evidence of approval of manufacturing facility | |

**Evaluation Remarks**

The application was initially evaluated on 17 March 2026, and the applicant submitted a response on April 1st, 2026. Upon evaluation of the submitted response, the application was found to remain deficient. Consequently, further deficiency letters were issued on 16 April 2026, 11 May 2026,17 June 2026 and 30 June 2026. Despite repeated communications, no response has been received from the applicant. The following deficiencies remain outstanding: Submit clearance certificate/ADC attested commercial invoice of batch No SPO-I-211003(crystalline I).The attached commercial invoice is of posaconazole injectable grade. Submit your applied formulation is qualitatively similar to which reference product, provide the name of that reference product with official link. Evidence of any reference product of posaconazole that has been manufactured with polymer-assisted thermal conversion process. Moreover, which polymer you have used. Elaborate how your submitted method is polymer-assisted thermal conversion process. Evidence of thermal equipment is required. Stability studies show no significant recrystallization or impurity increase. Clarify how you have ensured that no significant recrystallization has taken place and impurity increase. As no degradation product has been studies in DP. PXRD analysis data will be submitted as soon as we received data from outsourcing party. Mention the outsourcing party and submit results. The applied formulation is qualitatively similar to the reference with respect to excipient composition you have mentioned earlier but not used antioxidant. No significant increase in oxidative degradation impurities under accelerated and long-term storage condition whereas, you have not performed impurities. Dissolution should be on (HPLC) as per innovator.CDP should include 12 units and sampling time should be 120 minutes for pH 4.5. The study was conducted in compliance with the innovator's specification; in accordance with the FDA PAR for "Noxafil DR Tablet 100 mg", dissolution testing was performed at the 20-minute time point, Attach reference of FDA PAR. Annex V does not include Dissolution by HPLC.

**Decision**

**Deferred**

The Registration Board deferred the case for the submission of the following documents:

- Submit clearance certificate/ADC attested commercial invoice of batch No SPO-I-211003(crystalline I).The attached commercial invoice is of posaconazole injectable grade.
- Submit your applied formulation is qualitatively similar to which reference product, provide the name of that reference product with official link.
- Evidence of any reference product of posaconazole that has been manufactured with polymer-assisted thermal conversion process. Moreover, which polymer you have used.
- Elaborate how your submitted method is polymer-assisted thermal conversion process.
- Evidence of thermal equipment is required.
- Stability studies show no significant recrystallization or impurity increase. Clarify how you have ensured that no significant recrystallization has taken place and impurity increase. As no degradation product has been studies in DP.
- PXRD analysis data will be submitted as soon as we received data from outsourcing party. Mention the outsourcing party and submit results.
- The applied formulation is qualitatively similar to the reference with respect to excipient composition you have mentioned earlier but not used antioxidant.
- No significant increase in oxidative degradation impurities under accelerated and long-term storage condition whereas, you have not performed impurities.
- Dissolution should be on (HPLC) as per innovator.CDP should include 12 units and sampling time should be 120 minutes for pH 4.5.

- The study was conducted in compliance with the innovator's specification; in accordance with the FDA PAR for "Noxafil DR Tablet 100 mg", dissolution testing was performed at the 20-minute time point, Attach reference of FDA PAR.
- Annex V does not include Dissolution by HPLC.

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| 223 | Case Category | Contract Manufacturing (Iqra Aftab) |
| | Name, address of Applicant. | **Welwrd Pharmaceuticals** Plot # 3, Block A, Phase I-II, Industrial Estate, Hattar **(000574)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QU3-4NX-MJP8, 2024-10-31) |
| | Detail of Fee Submitted | 93000.0,<br>2024-10-30, |
| | The proposed proprietary name / brand name | **WZOLE 200mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains: Voriconazole (USP).....200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | Vorinaz 200mg Tablet by Atco Laboratories |
| | Pharmacotherapeutic Group of (API) | Triazoles, Antifungal |
| | Name, address of Manufacturing site: | M/s Wezen Pharmaceuticals-Plot # 23 & 24, S-1, RCCI, Industrial Estate, Rawat.- |
| | Name & address of API manufacturer | Bajaj Healthcare Limited. (Unit-2), Block No. 588, Savli Karachia Road, At & Post-Gothada, Tal-Salvi, Gothada=391776, Dist Vadodara, India. |
| | Detail of stability batches of drug product | T-01,T-02,T-03 with batch size 1200 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan from M/s Wnsfield. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Wzole 200mg tabs VORIOLE 200mg tabs B. No: PD200TAB B. No. EJ006 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa. |
| | The status in reference regulatory authorities | MHRA approved |
| | GMP status of the firm | M/w Wezen has been granted additional Tablet General Section on December 2020 |
| | Evidence of approval of manufacturing facility | Not provided. |
| | **Evaluation Remarks** | |
| | The application was evaluated on 12 March 2026, following which deficiency observations were communicated to the applicant. Subsequently, two reminder letters were issued on 05 May 2026 and 04 June 2026. Despite the lapse of sufficient time and repeated reminders, no response has been received from the applicant. The following deficiencies were communicated to the applicant: Valid DML of DP manufacturer. Provide polymorphic form of API. The COA mentions Voriconazole BP But 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.5,3.2.S.5.1 mentions USP. Justify. Clarify you have performed method verification against USP or BP. Stability summary data sheets of API attached are not readable. The applied formulation is qualitatively similar which innovator/reference product. The reference of specs is as per innovator product whereas, the product is pharmacopeial. Therefore, comply with pharmacopoeia and submit studies as per it. 3.2.P.6 Reference Standards or Materials is required. Submit valid GMP and DML of API manufacturer. | |
| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the case for the submission of the following documents: | |

- Valid DML of DP manufacturer.
- Provide polymorphic form of API.
- The COA mentions Voriconazole BP But 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.5,3.2.S.5.1 mentions USP. Justify.
- Clarify you have performed method verification against USP or BP.
- Stability summary data sheets of API attached are not readable.
- The applied formulation is qualitatively similar which innovator/reference product.
- The reference of specs is as per innovator product whereas, the product is pharmacopeial. Therefore, comply with pharmacopoeia and submit studies as per it.
- 3.2.P.6 Reference Standards or Materials is required.
- Submit valid GMP and DML of API manufacturer.

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| 224 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PDX-HQ3-T7LA, 2024-10-29) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-29, |
| | The proposed proprietary name / brand name | **W-Zole 200mg Tablet** |
| | Label Claim | Each Film Coated Tablet Contains: Voriconazole (USP).....200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)storage below 25°c |
| | For generic drugs (me-too Status) | Vorinaz 200mg Tablet By Atco Laboratories |
| | Pharmacotherapeutic Group of (API) | Triazoles, Antifungal |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Bajaj Healthcare Limited. (Unit-2), Block No. 588, Savli Karachia Road, At & Post-Gothada, Tal-Salvi, Gothada=391776, Dist Vadodara, India. |
| | Detail of stability batches of drug product | T-01, T02, T-03, Batch size 1200 tablets. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan agreement with M/s Wnsfeild |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Wzole 200mg tabs VORIOLE 200mg tabs B. No: PD200TAB B. No. EJ006 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | AS per zone IVa. |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Not provided |
| | Evidence of approval of manufacturing facility | Grant of Tablet General section |
| | **Evaluation Remarks** | |
| | The application was evaluated on 12 March 2026, following which deficiency observations were communicated to the applicant. Subsequently, two reminder letters were issued on 5 May 2026 and 4 June 2026. Despite the lapse of sufficient time and repeated reminders, no response has been received from the applicant. The following deficiencies were communicated to the applicant: Valid DML of DP manufacturer. Provide polymorphic form of API. The COA mentions Voriconazole BP But 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.5,3.2.S.5.1 mentions USP. Justify. Clarify you have performed method verification against USP or BP. Stability summary data sheets of API attached are not readable. The applied formulation is qualitatively similar which innovator/reference product. The reference of specs is as per innovator product whereas, the product is pharmacopeial. Therefore, comply with pharmacopoeia and submit studies as per it. 3.2.P.6 Reference Standards or Materials is required. Submit valid GMP and DML of API manufacturer. | |

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| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the case for the submission of the following documents:<br><br>• Valid DML of DP manufacturer.<br>• Provide polymorphic form of API.<br>• The COA mentions **Voriconazole BP** But 3.2.S.4.1, 3.2.S.4.2, 3.2.S.4.3, 3.2.S.4.5,3.2.S.5.1 mentions USP. Justify.<br>• Clarify you have performed method verification against USP or BP.<br>• Stability summary data sheets of API attached are not readable.<br>• The applied formulation is qualitatively similar which innovator/reference product.<br>• The reference of specs is as per innovator product whereas, the product is pharmacopeial. Therefore, comply with pharmacopoeia and submit studies as per it.<br>• 3.2.P.6 Reference Standards or Materials is required.<br>• Submit valid GMP and DML of API manufacturer. | |
| 225 | Case Category | Contract Manufacturing (Iqra Aftab) |
| | Name, address of Applicant. | **Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6SS-9LZ-8JNL, 2024-10-29) |
| | Detail of Fee Submitted | 93000.0,<br>2024-10-29, |
| | The proposed proprietary name / brand name | **W-Zole 200mg Infusion** |
| | Label Claim | Each Vial (20mL) Contains: Voriconazole (JP).....200Mg (Product complies JP Specs) |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)storage below 25°c |
| | For generic drugs (me-too Status) | Vivid 200mg INJECTION by SG & J |
| | Pharmacotherapeutic Group of (API) | Antifungal |
| | Name, address of Manufacturing site: | Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK- |
| | Name & address of API manufacturer | Bajaj Healthcare Limited. (Unit-2), Block No. 588, Savli Karachia Road, At & Post-Gothada, Tal-Salvi, Gothada=391776, Dist Vadodara, India. |
| | Detail of stability batches of drug product | W-01,W-02,W-03 Batch size 250 Vials |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | CLEARANCE CERTIFICATE Computerized No: E-7192760487153 Imported by (000610) Wnsfeild Pharmaceuticals Plot No. 122, Phase-V, Block-A, |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Fungal 200mg Infusion Vfend 200mg Infusion B. No: PD200INFUSION B. No. VF8764 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IV a,. |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Not provided. |
| | Evidence of approval of manufacturing facility | Not provided. |
| | **Evaluation Remarks** | |
| | The application was evaluated on 16 March 2026, following which deficiency observations were communicated to the applicant. Subsequently, three reminder letters were issued on 5 May 2026, 4 June 2026 and 1 July 2026. Despite the lapse of sufficient time and repeated reminders, no response | |

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| | has been received from the applicant. The following deficiency was communicated to the applicant: Evidence of lyophilized section is required for further evaluation of your application. | |
| | **Decision** | |
| | **Deferred**<br><br>The Registration Board deferred the case for evidence of lyophilized section for further evaluation of application. | |
| 226 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L1P-EQL-BQEJ, 2024-08-22) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-24, |
| | The proposed proprietary name / brand name | **Rofair 0.3% Cream** |
| | Label Claim | Each gram contains: Roflumilast.....3mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 60'g-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place below 30°C |
| | For generic drugs (me-too Status) | Nil |
| | Pharmacotherapeutic Group of (API) | Other antipsoriatics for topical use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Glenmark Life Sciences LTD.Address :Plot No Z-103/I, Dahej Sez, Phase-II, City- Dahej, Dist-Bharuch Gujarat State, India |
| | Detail of stability batches of drug product | TF-01,TF-02,TF-03 16 tubes. batch size |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | No ADC attested commercial invoice /Clearance certificate. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | - |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per zone IVa. |
| | The status in reference regulatory authorities | Food and Drug Administration - USFDA |
| | GMP status of the firm | Valid GMP certificate required. |
| | Evidence of approval of manufacturing facility | Cream section approved. |
| | **Evaluation Remarks** | |
| | The batch size of 16 tubes is not scientifically justified for development and stability studies. The submitted stability plan does not mention samples required for initial release testing and retention samples. Accordingly, the proposed batch size is considered insufficient to support the planned studies and desired testing. Applicant has stated they have kept 2 tubes for testing at each time point 3,6,9,12,18,24(Long term) and 3,6 (accelerated)=16 tubes. | |
| | The audit trail shows that the 3-month assay sequence was created by modifying the Initial assay sequence instead of creating new sequence. Batch table changing from 8 rows to 18 rows during preparation of the 3-month assay sequence. Product name (Azelnidipine) is appearing in a Roflumilast sequence. | |
| | Other Shortcomings Complete characterization studies of API. DML of API manufacturer | |
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| | **Decision** | |
| | **Rejected** | |

The Registration Board rejected the application, based on the following observations:

- The proposed development and stability batch size of 16 tubes is not scientifically justified. The submitted justification does not include for samples required for initial release testing, retention samples, repeat analyses or any additional testing that may be required during the study.
- Review of the chromatographic audit trail revealed that the 3-month assay sequence was created by modifying the Initial assay sequence instead of generating an independent analytical sequence.
- The audit trail also demonstrated that the product name "Azelnidipine" appeared within a chromatographic sequence intended for Roflumilast.

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| 227 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZYD-H2V-QA1Q, 2024-08-20) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-23, |
| | The proposed proprietary name / brand name | **Rofair** |
| | Label Claim | Each gram contains Roflumilast ..... 1.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 60'g-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place below 30°C |
| | For generic drugs (me-too Status) | Nil |
| | Pharmacotherapeutic Group of (API) | Other antipsoriatics for topical use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Glenmark Life Sciences LTD.Address :Plot No Z-103/I, Dahej Sez, Phase-II, City- Dahej, Dist-Bharuch Gujarat State, India |
| | Detail of stability batches of drug product | TF-01,TF-02,TF-03 |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Final clearance certificate attached. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE with Zoryve Cream |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per Zone IVa. |
| | The status in reference regulatory authorities | Food and Drug Administration - USFDA |
| | GMP status of the firm | GMP certificate valid till 2025 |
| | Evidence of approval of manufacturing facility | Cream section present. |
| | **Evaluation Remarks** | |
| | The batch size of 16 tubes is not scientifically justified for development and stability studies. The submitted stability plan does not mention samples required for initial release testing and retention samples. Accordingly, the proposed batch size is considered insufficient to support the planned studies and desired testing. Applicant has stated they have kept 2 tubes for testing at each time point 3,6,9,12,18,24(Long term) and 3,6 (accelerated)=16 tubes. | |
| | Other Shortcomings Complete characterization studies of API. DML of API manufacturer | |

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| | **Decision** |
| | **Rejected**<br><br>The Registration Board rejected the application, based on the following observations:<br><br>• The proposed development and stability batch size of 16 tubes is not scientifically justified. The submitted justification does not include for samples required for initial release testing, retention samples, repeat analyses or any additional testing that may be required during the study.<br>• Review of the chromatographic audit trail revealed that the 3-month assay sequence was created by modifying the Initial assay sequence instead of generating an independent analytical sequence.<br>• The audit trail also demonstrated that the product name "Azelnidipine" appeared within a chromatographic sequence intended for Roflumilast. |

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| 228 | Case Category | Export Facilitation (Iqra Aftab) |
| | Name, address of Applicant. | **Remington Pharmaceutical Industries (Pvt) Ltd** 18 Km Multan Road Lahore, 53800, Pakistan **(000061)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y52-Z2W-TTL7, 2025-10-01) |
| | Detail of Fee Submitted | 37000.0,<br>2025-05-15, |
| | The proposed proprietary name / brand name | **Zolopat OD Eye Drops** |
| | Label Claim | Each ml contains: Olopatadine HCl 7.76mg equivalent to Olopatadine 7mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 ml-As per SRO,15 ml-As per SRO,2.5 ml-As per SRO,5 ml-As per SRO,7.5 ml-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store between 2°C-25°C. |
| | For generic drugs (me-too Status) | Winolop Forte Ophthalmic Solution (Atco Pharma) |
| | Pharmacotherapeutic Group of (API) | Decongestant and antiallergics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Medigraph Pharmaceuticals Pvt. Ltd |
| | Detail of stability batches of drug product | 3 batches manufactured each having 3 Liters batch size. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate dated 26-Apr-2024 specifies 1Kg import of Olopatadine HCl has been imported. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE study is conducted against Pataday 0.7% Once Daily Relief Eye Drops (Batch No.:124TP, EXP Date:07/2025) of ALCON LABORATORIES, INC |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 3 batches of API as per Zone IV-A |
| | The status in reference regulatory authorities | USFDA |

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| | GMP status of the firm | GMP Inspection Date: 30.01.2025 & Satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Letter for issuance of DML dated 13.06.2023 specifies Eye/Ear/Nose Drop solution/ suspension section (General & Steroids) |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 229 | Case Category | Routine (Iqra Aftab) |
| | Name, address of Applicant. | **Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W5N-8RU-Z7ML, 2024-07-30) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-05, |
| | The proposed proprietary name / brand name | **FLUCAS 50mcg Nasal Spray** |
| | Label Claim | Each Spray Contains:Fluticasone Propionate .....50mcg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C. |
| | For generic drugs (me-too Status) | Ticovate Nasal Spray 50mcg |
| | Pharmacotherapeutic Group of (API) | Glucocorticoids |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | VAMSI LABS LTD. A-14/15, MIDC AREA, CHINCHOLI, SOLAPUR-413255. MAHARASHTRA, INDIA |
| | Detail of stability batches of drug product | T-01,T-02,T-03 |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form 6 attached and commercial invoice. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE conducted with TIcovate Nasal Spray. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability is as per Zone IV a condition. |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Not provided. |
| | Evidence of approval of manufacturing facility | Nasal Drop is present. Nasal Spray facility could not be confirmed. |
| | **Evaluation Remarks** | |
| | This is self -manufacturing application and data is already approved in M-359 on contract manufacturing. i. A declaration from applicant that they will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. ii. In case of any post-registration variation, same shall be immediately applied for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website. Following deficiencies were communicated to the applicant: Valid GMP certificate and DML of drug substance manufacturer. Valid GMP certificate of M/s. Winbrains. Valid DML of the applicant. Justification for developing an aerosol(liquid) inhaler in dry Powder Inhaler section/Nasal Drops. Is it possible for a drug substance to comply with the European Pharmacopoeia (EP) while the corresponding drug product complies with the United | |

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| | States Pharmacopeia (USP)? Please provide a justification Import documents like Clearance certificate or DRAP attested invoice. Aerodynamic Particle Size Distribution (APSD) is not performed by Manufacturer. Number of Actuations per Canister are not part of specifications of drug product. Upload COA of imported lot of API/drug substance. Audit trail of 21 CFR compliant system. Evidence of segregated dispensing booths for steroids, cleaning validation and controls studies for processes and adequate system to minimize the potential risk of cross contamination. BMR | |
| | **Decision** | |
| | **Approved**<br><br>Approved. Applicant will submit following documents before issuance of Registration Letter.<br><br>1. A declaration from applicant that they will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board in M-359 for the same formulation at the same manufacturing site.<br>2. In case of any post-registration variation by the manufacturer, same shall be immediately applied for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website. | |
| 230 | Case Category | Contract Manufacturing (Iqra Aftab) |
| | Name, address of Applicant. | **Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA **(000751)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3A2-7J6-TBW8, 2024-08-29) |
| | Detail of Fee Submitted | 75000.0,<br>2024-06-26, |
| | The proposed proprietary name / brand name | **Flutas 50mcg Nasal Spray** |
| | Label Claim | Each Spray Contains: Fluticasone Propionate (USP).....50mcg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30°c |
| | For generic drugs (me-too Status) | Flexosone Nasal Spray by Schazoo Laboratories |
| | Pharmacotherapeutic Group of (API) | Data already approved in M-359. |
| | Name, address of Manufacturing site: | Winbrains Research Laboratories-Plot No.69/1 Block B, Phase I-II, Industrial Estate, Hattar Pakistan- |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data already approved in M-359. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Data already approved in M-359. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Data already approved in M-359. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data already approved in M-359. |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | Data already approved in M-359. |
| | Evidence of approval of manufacturing facility | Data already approved in M-359. |
| | **Evaluation Remarks** | |
| | Data already approved in M-359. As per DRAP's Notification F.No.1-2/2022-DMC dated 13-06-2023 on the subject, "Applications for contract manufacturing,": i. A declaration from | |

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| | applicant that they will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. ii. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website. 2. Fee Rs. 9400/- as applicable on cross referred products on contract manufacturing. Following deficiencies were communicated to the applicant: Valid GMP certificate and DML of drug substance manufacturer. Valid GMP certificate of M/s. Winbrains. Valid DML of the applicant. Justification for developing an aerosol(liquid) inhaler in dry Powder Inhaler section/Nasal Drops. Is it possible for a drug substance to comply with the European Pharmacopoeia (EP) while the corresponding drug product complies with the United States Pharmacopeia (USP)? Please provide a justification Import documents like Clearance certificate or DRAP attested invoice. Aerodynamic Particle Size Distribution (APSD) is not performed by Manufacturer. Number of Actuations per Canister are not part of specifications of drug product. Upload COA of imported lot of API/drug substance. Audit trail of 21 CFR compliant system. Evidence of segregated dispensing booths for steroids, cleaning validation and controls studies for processes and adequate system to minimize the potential risk of cross contamination. BMR | |
| | **Decision** | |
| | **Approved**<br><br>Approved. Registration letter will be issued on submission of the following documents:<br><br>• A declaration from applicant that they will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site.<br>• In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website.<br>• Fee Rs. 9400/- as applicable on cross referred products on contract manufacturing. | |
| 231 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **DDF PAKISTAN** Office No.7, 4th Floor, Plot 63-C, Bukhari Commercial Lane 5, Phase 6, DHA **(0126)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7EX-564-JPZG, 2025-01-10) |
| | Detail of Fee Submitted | 75000.0,<br>2025-01-09, |
| | The proposed proprietary name / brand name | **Limoxin-200 LA** |
| | Label Claim | Each ml contains: Oxytetracycline (as dihydrate) .....200mg |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 3 Year(s)Store dark at room temperature. Shelf-life after first opening is 28 days. |
| | For generic drugs (me-too Status) | OXYTRON LA INJECTION (112253) by M/s Kayans Pharmaceuticals. |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | Interchemie werken "De Adelaar" BV-5804 CG Venray, The Netherlands -Netherlands |

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| | Name, address of Marketing Authorization Holder: | DDF PAKISTAN, Suite #8, Plot 63-C, Bukhari Commerical Lane, Phase VI, DHA, Karachi, 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 has provided scanned copies of CoPP, GMP, Agency Agreement. As per online vet data base from official website of EMA applied product is confirmed. | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. | |
| 232 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1VL-H1N-Z315, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Norflex-20 Oral Liquid** |
| | Label Claim | Each 100 ml contains: Norfloxacin.....20 grm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature (25-30°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 233 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (288-L6W-8JZS, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Doxytos-30 Oral Powder** |
| | Label Claim | Each 100gm contains: Tylosin Tartrate.....10g Doxycycline Hcl.....20g |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,50 gm- |

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|---|---|---|
| | | De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 234 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2AU-PHJ-53RB, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Feniflor-20** |
| | Label Claim | Each 100ml contains<br>Florfenicol.....20gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 235 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2X3-WS1-789N, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Amprol CP 70 Oral Powder** |
| | Label Claim | Each gm Contains Amprolium<br>HCL.....700mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |

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| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 236 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Kohinoor Industries** 159-160/B Small Industrial Estate, Sahiwal **(000197)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HQ5-2L3-34GY, 2025-01-21) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-30, |
| | The proposed proprietary name / brand name | **VITANOOR PLUS ORAL W/S Powder** |
| | Label Claim | Each KG powder contains (Kohinoor Spec.) Vitamin A.....0.8gm, Vitamine D3....0.16gm, Vitamin E....0.38gm, Vitamin B1....1gm, Vitamin B2....1.25gm, Vitamin B12....0.001gm, Vitamin B3....6.25gm, Copper Sulphate....0.25gm, Magnesium Sulphate....25gm, Calcium Chloride....0.023gm, Zinc Sulphate.....2.17gm, Manganese Sulphate....10gm, Potassium Iodide....0.5gm, Sodium Selenite....0.01gm, D.C.P(Phosphorous)....150gm, Sodium Chloride.....120gm, Vitamin B6....4gm |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 20gm,50gm,100gm,250g-De-Controlled |
| | Shelf Life (Unit) | 2 YearBelow 30 CG |
| | For generic drugs (me-too Status) | White Gold Powder (058842) Leads Pharama |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 237 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (482-BUB-SBZU, 2025-01-16) |
| | Detail of Fee Submitted | 37000.0,<br>2024-12-18, |
| | The proposed proprietary name / brand name | **AR Med Gold Oral Powder** |
| | Label Claim | Each Kg Contains: Vitamin A ..... 0.8gm(equal to 8,00,000IU) Vitamin D3 ..... .0.16gm(equal to 80,000IU) Vitamin E ..... .....0.38gm(equal to 380IU) Vitamin B1 .....1.0gm |

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| | | Vitamin B2 ..... .....1.25gm Vitamin B12..... .....0.001gm Vitamin B3 (Nicotinamide) ..... 6.25gm Vitamin B6 ..... .....4gm Copper Sulhpate (Cu) ..... 0.25gm Magnesium Sulphate ..... .....25gm Calcium Choride (Ca) .....0.023gm Zinc Sulphate(Zn) ..... .....2.17gm Manganese Sulphate ..... 120gm Potassium Iodine (I2) ..... 0.5gm Sodium Selenite (Se) ..... ...0.01gm D.C.P (Phosphorous) ..... 150gm Sodium Chloride ..... .....120gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1kg, 5kg as Per SRO -De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature below 30 |
| | For generic drugs (me-too Status) | White Gold Powder of M/s Leads Pharma |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel approved the plant for GMP Injection |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm has revised composition as per generic : Label Claim:Each Kg Contains:Vitamin A ..... 0.8gm(equal to 8,00,000IU)Vitamin D3 ..... 0.16gm(equal to 80,000IU)Vitamin E ..... ……. 0.38gm(equal to 380IU)Vitamin B1 ..... 1.0gmVitamin B2 ..... …….. 1.25gmVitamin B12..... ….. 0.001gmVitamin B3 (Nicotinamide) ..... 6.25gmCopper Sulhpate (Cu) ..... 0.25gmMagnesium Sulphate ..... …..25gmCalcium ChLoride (Ca) .....0.023gmZinc Sulphate(Zn) ..... …..2.17gmManganese Sulphate ..... 10gmPotassium Iodine (I2) ..... 0.5gmSodium Selenite (Se) ..... ...0.01gmD.C.P (Phosphorous) ..... 150gmSodium Chloride ..... …….120gmVitamin B6 ..... ……..4gm | |
| | **Decision** | |
| | **Approved**<br><br>Firm will submit pre-registration variation fee for revised composition. | |
| 238 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (34D-A4W-E649, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Spectramox Forte Oral Powder** |
| | Label Claim | Each 100 gm contains: Amoxicillin Trihydrate ..... 20g Lincomycin HCl ..... 8.8g Spectinomycin HCl 8.8g |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |

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| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 239 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4H9-VYA-TDEU, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Metafos-T Oral Powder** |
| | Label Claim | Each 100gm contains: Fosfomycin Calcium.....20.gm Tylosin as Tartrate.....5.grm Fructose.....18.gm Sodium Phosphate.....15.gm Magnesium Sulphate.....10.gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm will submit fee for revised composition Each 100gm contains: Fosfomycin Calcium……..…..20.gm Tylosin as Tartrate……5.grm Fructose……18.gm Sodium Phosphate……..15.gm Magnesium Sulphate……..10.gm Sodium chloride qs...100gm | |
| | **Decision** | |
| | **Approved**<br><br>Firm will submit fee for revised composition | |
| 240 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4J3-SWV-QSNS, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Lincomid Plus Oral Powder** |
| | Label Claim | Each 100gm contains Lincomycin HCl Monohydrate ...44gm |
| | Reference to Finished product specifications | United States Pharmacopeia |

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| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C). Protect from sunlight |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 241 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6P5-QTN-A89W, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Amoxico 50 Oral Powder** |
| | Label Claim | Each 100 gm Contain: - Amoxicillin base ..... 50gm Colistin Sulphate ..... 50MIU Dextrose Anhydrous.....100g |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | composition corrected as per form 5, firm shall submit pre-registration fee. | |
| | **Decision** | |
| | **Approved**<br><br>composition corrected as per form 5, firm shall submit pre-registration fee. | |
| 242 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6SH-YTB-WPZY, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Amprol CP 60 Oral Powder** |

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|---|---|---|
| | Label Claim | Each gm Contains Amprolium HCL.....600mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 243 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7MG-B8P-ZSXZ, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Coliflox-C Oral liquid** |
| | Label Claim | Each 100ml contains Enrofloxacin.....10gm Colistin Sulphate.....48MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 244 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7NN-DT5-ZHDP, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Lincomid Oral Powder** |
| | Label Claim | Each 100gm contains Lincomycin HCl Monohydrate ...4.4gm |

| | | |
|---|---|---|
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C). Protect from sunlight |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 245 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8JZ-7G8-Q1AX, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Neotron-60 Oral Powder** |
| | Label Claim | Each 1000 gm contains: Neomycin Sulphate.....600.gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg -De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 246 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (91P-YHL-JRB8, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **T-Vilo-Sen-50 Oral Powder** |
| | Label Claim | Each gm Contains Acetyl Isovalery Tylosin Tartrate....50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |

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| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 247 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (A4D-T51-RXY6, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Lincomid-Forte Oral Powder** |
| | Label Claim | Each 100gm contains Lincomycin HCl Monohydrate ...40gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C). Protect from sunlight |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 248 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (A91-YG9-LZWD, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Amoxico 23 Oral Powder** |
| | Label Claim | Each 100g contains: Amoxicillin Trihydrate.....23g Colistin Sulphate 100MIU |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |

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| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 249 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BDS-L14-8ZYM, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Metafos-T Plus Oral Powder** |
| | Label Claim | Each 100gm contains: Fosfomycin Calcium.....20.gm Tylosine Tartate.....10.gm Fructose.....18.gm sodium phosphate .....15.gm Magnesium sulphate.....10.gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 250 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BXN-5UG-MY9N, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Norvex-Plus Oral Liquid** |
| | Label Claim | Each 100 ml contains: Norfloxacin.....20g Aminophylin.....8g Guaiphenein..... 20g |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De- |

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|---|---|---|
| | | Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature (25-30°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 251 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EYL-4QL-Y1L8, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Tilcolide Plus Oral Liquid** |
| | Label Claim | Each 100ml contains Tilmicosin(as Phosphate) .....30gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 252 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GXT-YQD-ZP92, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Neoside Oral Powder** |
| | Label Claim | Each 1000gm contains: Neomycine Sulphate (BP)...70gm Colistin Sulphate (BP).....4gm Chlortetracycline HCL (BP)....80gm |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |

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| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 253 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GYH-5SL-LGR7, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Amprol CP 90 Oral Powder** |
| | Label Claim | Each gm Contains Amprolium HCL.....900mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg -De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 254 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (H23-71G-5TB5, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Feniflor-25 Oral Liquid** |
| | Label Claim | Each 100ml contains Florfenicol .....25gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |

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| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 255 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (H8J-UPQ-GH6A, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Omox 50 Oral Powder** |
| | Label Claim | Each 100 gm contains: Amoxicillin Trihydrate ..... 50g equivalent to Amoxicillin base |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 256 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HDM-E66-ENLE, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Lincomid-C Oral Powder** |
| | Label Claim | Each 100gm contains: Lincomycin HCl Monohydrate ...11gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100 gm-De-Controlled,1000 gm-De-Controlled,10kg-De-Controlled,25 kg-De-Controlled,500 gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C). Protect from sunlight |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |

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| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 257 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HGB-2EV-R2S9, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Cinflor-23 Oral Liquid** |
| | Label Claim | Each 100ml contains: Florfenicol .....23g Colistin Sulphate ..... 50MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature (25-30°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 258 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J98-HSB-7PQG, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Neotron-70 Oral Powder** |
| | Label Claim | Each 1000 gm contains: Neomycin Sulphate.....700.gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

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| | **Decision** | |
| | **Approved** | |
| 259 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JM3-ZTN-X2UQ, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Super-C Oral Powder** |
| | Label Claim | Each 100 gm Contains:<br>Paracetamol.....2gm Vit C.....20gm Calcium Carbonate.....4.5gm Magnesium Sulphate.....3.5gm Potassium Chloride.....4.0gm |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 260 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JV2-M64-5HHM, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Omox 20 Oral Powder** |
| | Label Claim | Each 100 gm contains: Amoxicillin Trihydrate ..... 20g equivalent to Amoxicillin base |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

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|---|---|---|
| | Firm shall submit fee for Label claim corrected as per fomr 5. Each 100gm contains amoxicillin trihydrate eq. to amoxicillin ---------20gm | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit fee for Label claim corrected as per fomr 5. | |
| 261 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LED-JGQ-3Y5V, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Coliflox-10 Oral liquid** |
| | Label Claim | Each 100ml contains Enrofloxacin ..... 10gm Colistin Sulphate.....50MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 262 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LZX-4QA-RRBG, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Amoxico Oral Powder** |
| | Label Claim | Each 100 gm contains: Amoxicillin as Trihydrate ..... 15g Colistin Sulphate.....50MIU |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |

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| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 263 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M52-QLJ-LEYX, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Coliflox-20 Oral liquid** |
| | Label Claim | Each 100ml contains Enrofloxacin ..... ...20gm Colistin Sulphate 20MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 264 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MDJ-BBJ-LUTM, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Amoxico Pro Oral Powder** |
| | Label Claim | Each 100 gm contains: Amoxicillin... ..... 20g Colistin Sulphate.....50MIU |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |

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| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm shall submit fee for label claim correction as per form 5 Each 100g contains: Amoxicillin Trihydrate ……20gm Colistin Sulfate…….50 MIU | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit fee for label claim correction as per form 5 | |
| 265 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MHE-VMU-8E58, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Spectramox Oral Powder** |
| | Label Claim | Each 100 gm contains: Amoxicillin Trihydrate ..... 10g Lincomycin HCl ..... 5g Spectinomycin HCl 5g |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 266 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N77-MQW-4W97, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Levopoint-30 Oral Powder** |
| | Label Claim | Each 100gm contains Levamisole HCl..... 30gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |

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| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 267 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N9H-W51-U7MV, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Neotron-50 Oral Powder** |
| | Label Claim | Each 1000 gm contains: Neomycin Sulphate.....500.gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 268 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NGP-Z4B-7GSB, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Levopoint-75 Oral Powder** |
| | Label Claim | Each 100gm contains Levamisole HCl..... 75gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg -De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |

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| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 269 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NQL-A6L-6ML7, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Neotron-72 Oral Powder** |
| | Label Claim | Each 1000 grm contains: Neomycin Sulphate.....720.gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg -De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 270 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NY3-MZ9-XJSP, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Tilcolide-25 Oral Liquid** |
| | Label Claim | Each 100ml contains Tilmicosin(as Phosphate) .....25gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |

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| | **Approved** | |
| 271 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (P5W-R88-8TB8, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Doxitocin-C Forte Oral Powder** |
| | Label Claim | Each 100gm contains: Tylosine Tartate ....20gm Doxycycline HCl ...40gm Colistin Sulphate ....10gm Bromhexine HCL.....2gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 272 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PH4-RW1-69QB, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Sultyprim Oral Liquid** |
| | Label Claim | Each 100ml contains Tylosin Tartrate ..... 5gm Sulphamethoxypyridazine.... 5gm Trimethoprim ..... 4gm Bromhexine HCL ..... 0.5gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C). Protect from sunlight |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

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| | **Decision** | |
| | **Approved** | |
| 273 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R5D-64N-XE26, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Amprol CP 50** |
| | Label Claim | Each gm Contains Amprolium HCL.....500mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 274 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RLN-1Y8-WU9S, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Coliflox-Forte Oral liquid** |
| | Label Claim | Each 100ml contains Enrofloxacin.....20gm Colistin Sulphate 50MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |

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| | **Approved** | |
| 275 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SB5-XXL-8V3X, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Feniflor-Plus Oral Liquid** |
| | Label Claim | Each 100ml contains Florfenicol .....23gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 276 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SQE-61N-RVLZ, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **T-Vilo-Sen-85 Oral Powder** |
| | Label Claim | Each gm Contains Acetyl Isovalery Tylosin Tartrate.....850mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 277 | Case Category | New License (Muhammad Sarfraz Nawaz) |

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| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T9W-JT1-EST9, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Neotetra-Plus Oral Powder** |
| | Label Claim | Each gram contains: Neomycin Sulphate.....150mg Florfenicol.....100mg Oxytetracycline HCL.....300mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 278 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U31-BYB-LRTT, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Neoside-Forte Oral Powder** |
| | Label Claim | Each 1000gm contains Neomycine Sulphate (BP).....140gm Colistin Sulphate (BP).....8gm Chlortetracycline HCL (BP)....160gm |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 279 | Case Category | New License (Muhammad Sarfraz Nawaz) |

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| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ULJ-QGG-EZLP, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Doxitocin-T Oral Powder** |
| | Label Claim | Each 1000gm contains: Tylosin Tartrate.....170gm Doxycycline Hcl.....130gm Bromhexine HCl.....5gm Colistin Sulphate.....30gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 280 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (V51-HQ5-Y8AL, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Levopoint-50 Oral Powder** |
| | Label Claim | Each 100gm contains Levamisole HCl..... 50gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 281 | Case Category | New License (Muhammad Sarfraz Nawaz) |

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| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VRN-59S-YRZZ, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **X-Mox Plus Oral Powder** |
| | Label Claim | Each 100gm contains: Amoxicillin Trihydrate.....10g Colistin Sulphate.....50MIU Spectinomycin as HCL.....5g Bromhexine HCL .....0.5g |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Composition corrected as per generic firm shall submit fee as per SRO in pre-registration variation: Each 100gm contains: Amoxicillin as Trihydrate……10g Colistin Sulphate…… 50MIU Spectinomycin as HCL……...5g Bromhexine HCL ..... ….0.5g | |
| | **Decision** | |
| | **Approved**<br><br>Composition corrected as per generic firm shall submit fee as per SRO in pre-registration variation | |
| 282 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VVY-X51-EL77, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Amprol CP 98 Oral Powder** |
| | Label Claim | Each gm Contains Amprolium HCL.....980mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

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| | **Decision** | |
| | **Approved** | |
| 283 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W4B-4GD-5T3U, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Nortadin Oral Liquid** |
| | Label Claim | Each Liter contains: Norfloxacin .....<br>.....100g Trimethoprim ..... 30g<br>Sulphamethoxypyridazine.....150g |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature (25-30°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 284 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WDZ-URX-AA2E, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Cinflor-Plus Oral Liquid** |
| | Label Claim | Each 100ml contains Florfenicol<br>..... 25gm Colistin Sulphate<br>..... 50MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature (25-30°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |

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| | **Approved** | |
| 285 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WPV-AA8-3W3V, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Novamox-B Oral Powder** |
| | Label Claim | Each 100gm contains: Amoxicillin Trihydrate.....16g Clavulanic Acid .....4g Bromhexine HCl.....0.5g (As per Innovator's specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Label claim shall be corrected as per form 5 and firm shall submit fee for correction Each 100g contains: Amoxicillin trihydrate eq. to Amoxicillin ..... 16 g Clavulanic Acid as Potassium Clavunate ..... 4 g Bromhexine HCl ..... 0.5 g | |
| | **Decision** | |
| | **Approved**<br><br>Label claim shall be corrected as per form 5 and firm shall submit fee for correction | |
| 286 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (X9X-5R2-GNEQ, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Tococillin-E Oral Powder** |
| | Label Claim | Each 1gm contains: Amoxicillin Trihydrate.....200mg Lincomycin (HCl).....88mg Spectinomycin Dihydrochloride...88mg Pentahydrate eq. to Spectinomycin Vitamin E.....30mg |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |

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| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 287 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XAX-9SA-7P1H, 2026-05-16) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Coliflox-25 Oral liquid** |
| | Label Claim | Each 100ml contains Enrofloxacin.....25gm Colistin Sulphate 50MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 L-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,15 L-De-Controlled,5 L-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 288 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YMB-198-5HVP, 2026-05-15) |
| | Detail of Fee Submitted | 38700,<br>2026-05-14, |
| | The proposed proprietary name / brand name | **Doxytos-40 Oral Powder** |
| | Label Claim | Each 100gm contains: Tylosin Tartrate.....20g Doxycycline Hcl.....20g |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,5 kg-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in Cool & Dry Place (15-25°C) |
| | For generic drugs (me-too Status) | Yes |

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|---|---|---|
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 289 | Case Category | New License (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crosspoint Pharmaceuticals** 36-KM Koont Stop, Mandra Chakwal Road, **(001024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z88-PTE-A884, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-05-18, |
| | The proposed proprietary name / brand name | **Moxacid-C Oral Powder** |
| | Label Claim | Each 100gm contains: Amoxicillin Trihydrate.....20g Clavulanic Acid ..... ...4g Colistin Sulphate ..... ...4g (As per Innovator's specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10 kg-De-Controlled,100 g-De-Controlled,1000 g-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled,500 g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore in a tightly sealed container at controlled temperature (20-25°C) |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | NA |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>Approved. | |
| 290 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Brand Station** 69 Wocland Villas Lahore Near Raiwind Road **(05-352-0065-042264D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (D1Q-U78-B9VS, 2025-05-28) |
| | Detail of Fee Submitted | 300000.0,<br>2025-05-26, |
| | The proposed proprietary name / brand name | **Tylo F-Bs** |
| | Label Claim | Contain per 1000g: Fosfomycin Calcium.....200g Tylosin Tartrate.....100g Fructose+Electrolytes.....100g |
| | Reference to Finished product specifications | Manufacturers Specification |
| | Proposed Pack Size | 1 Kg-De-Controlled |

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|---|---|---|
| | Shelf Life (Unit) | 36 MonthStore in shade and dry place, temperature below 25°C. |
| | For generic drugs (me-too Status) | Ty Fos Water Soluble Powder, Mfg: Inshal Pharmaceutical Industries, Address: Islamabad |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s Inner Mongolia Huatian Pharmaceutical Co., Ltd-Economic Development & Experiment Zone Economical Transformation of Resource Dependent City, ChiFeng, Inner Mongolia, P.R. China-China |
| | Name, address of Marketing Authorization Holder: | M/s Brand Station, 69 Wocland Villas, Near Raiwind Road, Near Valenica Town, Opposite Alfatah Store, Lahore, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | generic is not confirmed firm has submitted generic as per composition (Per 100g contains) Fosfomycin Calcium ..... 20 g Tylosin Tartrate ..... 10 g Fructose ..... 18 g Sodium Phosphate..…….. 15 g Magnesium Sulphate……. 10 g | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. Firm shall submit pre-registration variation fee before issuance the letter. | |
| 291 | Case Category | New Section (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Sunshine Pharmaceuticals** Emanabad,G.T Road **(000662)** |
| | Application Form Dy. No / Tracking ID & date of submission | (44V-UUR-DV1W, 2025-04-21) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-22, |
| | The proposed proprietary name / brand name | **Avast 10mg** |
| | Label Claim | Each Film Coated tablet Contains: Atorvastatin as Calcium Trihydrate ..... 10mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1x10's-As per SRO |
| | Shelf Life (Unit) | 2 Year15$^{o}$c-30$^{o}$c |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | HMG-CoA reductase inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | NA |
| | Detail of stability batches of drug product | Attached |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached |
| | The status in reference regulatory authorities | FDA Approved |

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|---|---|---|
| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 292 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |
| | Application Form Dy. No / Tracking ID & date of submission | (X5V-E7Y-W5UL, 2026-06-04) |
| | Detail of Fee Submitted | 38700,<br>2026-04-07, |
| | The proposed proprietary name / brand name | **Apiquis Tablet 5mg** |
| | Label Claim | Each film-coated tablet contains:<br>Apixaban.....5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 3x10's-As per SRO,1x10's-As per SRO,1x7's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,4x7's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C. Protect from moisture and sunlight |
| | For generic drugs (me-too Status) | Apiban 5mg Tablet by Highnoon Laboratories Limited (Reg. No, 104682) |
| | Pharmacotherapeutic Group of (API) | Antithrombotic, Direct Factor Xa Inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # NPD063, NPD0664, NPD065, Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 %. Data submitted for 3 months with commitment to complete the studies till the assigned shelf life. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Drug import license attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Apiban 5mg Tablet by Highnoon Laboratories Limited |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of 3 batches (AP-707-220901, AP-707-221001 & AP-707-221002) submitted both accelerated (6M) and real time (24M) |
| | The status in reference regulatory authorities | ELIQUIS 5mg Tablet by US FDA |
| | GMP status of the firm | GMP Certified. valid up to: 18-Sep-2026 |
| | Evidence of approval of manufacturing facility | Tablet Section approved |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 293 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (WTB-RYU-6WSD, 2026-06-04) |
| | Detail of Fee Submitted | 97200,<br>2026-05-05, |
| | The proposed proprietary name / brand name | **Bitrilva 97mg/103mg Tablets** |
| | Label Claim | Each film coated tablet contains: Sacubitril ..... 97mg Valsartan ..... 103mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x10's-As per SRO,1x14's-As per SRO,2x10's-As per SRO,2x14's-As per SRO,3x10's-As per SRO |
| | Shelf Life (Unit) | 2 YearDo not store above 30°C. |
| | For generic drugs (me-too Status) | Ubetril Tablets 97mg/103mg by FEROZSONS Laboratories Limited (Reg. No. 097070) |
| | Pharmacotherapeutic Group of (API) | Angiotensin II receptor blockers (ARBs) |
| | Name, address of Manufacturing site: | M/s. Ferozsons Laboratories Limited-P.O. Ferozsons Nowshera, Pakistan- |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # 230551 and 231156 Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 %. Data submitted with 6 months with commitment to complete the studies till the assigned shelf life. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Invoices, clearance certificate attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Entresto 97/103mg Tablets by Novartis Singapore pharmaceutical, Manufacturing Pte, Ltd., 637461 Singapore |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of 3 batches (RD-LCZ696-202012181, RD-LCZ696- 202012271 & RD-LCZ696- 202101101) submitted both accelerated (6M) and real time (36M) |
| | The status in reference regulatory authorities | ENTRESTO 97mg/103mg tablets by EMA-UK |
| | GMP status of the firm | GMP Certified. valid up to: 09-Aug-2027 |
| | Evidence of approval of manufacturing facility | Tablet Section approved |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 294 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NQV-4W4-MQ1D, 2026-06-04) |
| | Detail of Fee Submitted | 97200,<br>2026-05-05, |
| | The proposed proprietary name / brand name | **Bitrilva 49mg/51mg Tablets** |
| | Label Claim | Each film coated tablet contains: Sacubitril ..... 49mg Valsartan ..... 51mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x10's-As per SRO,1x14's-As per SRO,2x10's-As per SRO,2x14's-As per SRO,3x10's-As per SRO |
| | Shelf Life (Unit) | 2 YearDo not store above 30°C. |

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| | For generic drugs (me-too Status) | Ubetril Tablets 49mg/51mg by FEROZSONS Laboratories Limited (Reg. No. 097078) |
| | Pharmacotherapeutic Group of (API) | Angiotensin II receptor blockers (ARBs) |
| | Name, address of Manufacturing site: | M/s. Ferozsons Laboratories Limited-P.O. Ferozsons Nowshera, Pakistan- |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # 2H132 and 2J178 Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 %. Data submitted with 6 months with commitment to complete the studies till the assigned shelf life. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Invoices, clearance certificate attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Entresto 49/51mg Tablets by Novartis Singapore pharmaceutical, Manufacturing Pte, Ltd., 637461 Singapore |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of 3 batches (RD-LCZ696-202012181, RD-LCZ696- 202012271 & RD-LCZ696- 202101101) submitted both accelerated (6M) and real time (36M) |
| | The status in reference regulatory authorities | ENTRESTO 49mg/51mg tablets by EMA-UK |
| | GMP status of the firm | GMP Certified. valid up to: 09-Aug-2027 |
| | Evidence of approval of manufacturing facility | Tablet Section approved |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 295 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1SZ-J1B-L9BN, 2026-04-20) |
| | Detail of Fee Submitted | 38700,<br>2026-04-07, |
| | The proposed proprietary name / brand name | **Apiquis Tablet 2.5mg** |
| | Label Claim | Each film-coated tablet contains:<br>Apixaban.....2.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 3x10's-As per SRO,1x10's-As per SRO,1x7's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,4X7's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C. Protect from moisture and sunlight |
| | For generic drugs (me-too Status) | Apiban 2.5mg Tablet by Highnoon Laboratories Limited (Reg. No, 104681) |
| | Pharmacotherapeutic Group of (API) | Antithrombotic, Direct Factor Xa Inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # NPD066, NPD0667, NPD068, Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 %. Data submitted for 3 months |

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| | | with commitment to complete the studies till the assigned shelf life. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Drug import license attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Apiban 2.5mg Tablet by Highnoon Laboratories Limited |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of 3 batches (AP-707-220901, AP-707-221001 & AP-707-221002) submitted both accelerated (6M) and real time (24M) |
| | The status in reference regulatory authorities | ELIQUIS 2.5mg Tablet by US FDA |
| | GMP status of the firm | GMP Certified. valid up to: 18-Sep-2026 |
| | Evidence of approval of manufacturing facility | Tablet Section approved |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 296 | Case Category | Routine (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Al Habib Pharmaceuticals.** Plot 81 SMCHS BLOCK B **(0414)** |
| | Application Form Dy. No / Tracking ID & date of submission | (P55-TQR-QNQY, 2026-02-03) |
| | Detail of Fee Submitted | 313500,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **DACA-AHP 200mg Lyophilized powder for Injection** |
| | Label Claim | Each Lyophilized vial contains: Dacarbazine (Ph.Eur).....200 mg Water for Injection (W.F.I).....5ml |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1s, 5s, 10s, 15s,-As per SRO |
| | Shelf Life (Unit) | 3 YearStore Below 30 c |
| | For generic drugs (me-too Status) | Manufacturer name: Lab Diagnostic Systems (SMC) Pvt. Ltd. Brand name: Dacarbazine for Injection 200mg Strength: 200 mg Composition: Each vial contains Dacarbazine 200 mg inj Registration number: 11054 |
| | Pharmacotherapeutic Group of (API) | MAC-CHEM Product India Pvt Ltd |
| | Name, address of Manufacturing site: | SP ACCURE LABS PVT LTD-Plot No.12, Biotech Park, Phase-II. Lalgadi Malakpet, Shamirpet, Medchal-Malkajgiri District, Telangana State-500101, India.-India |
| | Name & address of API manufacturer | Mac Chem Products (India) Pvt. Ltd. ADDRESS: N-211/2/10, M.I.D.C. Boisar, Dist. Thane-401 506, Palghar, Maharashtra, India Telephone: + 91– 7770016606/7770016607 |
| | Detail of stability batches of drug product | Provided |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | GMP API Attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Provided |

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|---|---|---|
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided in Module 3 |
| | The status in reference regulatory authorities | REFERENCE AUTHORITY: US-FDA Company: FRESENIUS KABI USA (ANDA): 075371 Brand name: DACARBAZINE Strength: 200 mg Dosage form / Route: INJECTABLE ; INJECTION Marketing Status: Prescription RLD: NO E-LINK: https://www.accessdata.fda.gov/scripts/cder/daf/index.event=overview.process&ApplNo=075371 |
| | GMP status of the firm | Provided |
| | Evidence of approval of manufacturing facility | DML ATTACHED |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. | |
| 297 | Case Category | Export Facilitation (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YGU-RNN-PX8T, 2025-10-03) |
| | Detail of Fee Submitted | 75000.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **APROVECST TABLETS 300mg+5mg (Irbesartan + Amlodipine)** |
| | Label Claim | Each Film-coated tablet contains:<br>Irbesartan.....300mg + Amlodipine Besylate eq. to Amlodipine.....5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,14's-As per SRO,28's-As per SRO,30's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 C |
| | For generic drugs (me-too Status) | Not applicable |
| | Pharmacotherapeutic Group of (API) | Antihypertensive |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # NPD009, NPD010, NPD011, Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 % for 6 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 7 & Invoice documents attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability data of 3 batches (AAMB-II21002, AAMB- |

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|---|---|---|
| | | II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M) |
| | The status in reference regulatory authorities | APREXEVO 300mg/5mg by M/s Sanofi, France |
| | GMP status of the firm | GMP Certified. valid up to: 18-Sep-2026 |
| | Evidence of approval of manufacturing facility | Tablet Section approved |
| | **Evaluation Remarks** | |
| | the application is complete as per codal formalities for consideration by the Registration Board | |
| | **Decision** | |
| | **Approved** | |
| 298 | Case Category | Export Facilitation (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XTP-YLH-SJNY, 2025-10-03) |
| | Detail of Fee Submitted | 75000.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **Aprovecst Tablets 300mg+10mg** |
| | Label Claim | Each Film-coated tablet contains:<br>Irbesartan.....300mg + Amlodipine Besylate eq. to Amlodipine.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,14's-As per SRO,28's-As per SRO,30's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30ºC. Protect from light |
| | For generic drugs (me-too Status) | Not Applicable |
| | Pharmacotherapeutic Group of (API) | Antihypertensive |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # NPD012, NPD013, NPD014, Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 % for 6 months |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 7 & Invoice documents attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability data of 3 batches (AAMB-II21002, AAMB-II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M) |
| | The status in reference regulatory authorities | APREXEVO 300mg/10mg by M/s Sanofi, France |
| | GMP status of the firm | GMP Certified. valid up to: 18-Sep-2026 |
| | Evidence of approval of manufacturing facility | Liquid Injectable (SVP) Section approved |
| | **Evaluation Remarks** | |
| | the application is complete as per codal formalities for consideration by the Registration Board | |
| | **Decision** | |

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| | **Approved** | |
| 299 | Case Category | Export Facilitation (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SNB-DU4-VTM3, 2025-09-30) |
| | Detail of Fee Submitted | 75000.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **APROVECST TABLETS 150mg+10mg (Irbesartan + Amlodipine)** |
| | Label Claim | Each Film-coated tablet contains:<br>Irbesartan.....150mg + Amlodipine Besylate eq. to Amlodipine.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,14's-As per SRO,28's-As per SRO,30's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 C |
| | For generic drugs (me-too Status) | Not applicable |
| | Pharmacotherapeutic Group of (API) | Antihypertensive |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # NPD004, NPD005, NPD006, Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 % for 6 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 7 & Invoice documents attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability data of 3 batches (AAMB-II21002, AAMB-II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M) |
| | The status in reference regulatory authorities | APREXEVO 150mg/10mg by M/s Sanofi, France |
| | GMP status of the firm | GMP Certified. valid up to: 18-Sep-2026 |
| | Evidence of approval of manufacturing facility | Tablet Section approved |
| | **Evaluation Remarks** | |
| | the application is complete as per codal formalities for consideration by the Registration Board | |
| | **Decision** | |
| | **Approved** | |
| 300 | Case Category | Export Facilitation (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EVE-1JA-3YWM, 2025-10-30) |

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| | Detail of Fee Submitted | 75000.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **Aprovecst Tablets 150mg+5mg** |
| | Label Claim | Each Film-coated Tablet Contains:<br>Irbesartan.....150mg + Amlodipine Besylate eq. to Amlodipine ..... 5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's-As per SRO,14's-As per SRO,28's-As per SRO,30's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30ºC. Protect from light |
| | For generic drugs (me-too Status) | Not Applicable |
| | Pharmacotherapeutic Group of (API) | Antihypertensive |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Batch # NPD003, NPD006, NPD007, Accelerated Stability Studies = 40 ± 2 ºC & RH 75 ± 5 % & Real Time Stability Studies = 30 ± 2 ºC & RH 65 ± 5 % for 6 months |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 7 & Invoice documents attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical equivalence & CDP for the quality test are submitted against the innovator drug Aprovasc Tablet by M/s Sanofi. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Irbesartan: Stability data of 3 batches (L0102320230301M, L0102320230401M & L0102320230402M) submitted both accelerated (6M) and real time (24M) Amlodipine: Stability data of 3 batches (AAMB-II21002, AAMB-II21003 & AAMB-II21004) submitted both accelerated (6M) and real time (36M) |
| | The status in reference regulatory authorities | APREXEVO 150mg/5mg by M/s Sanofi, France |
| | GMP status of the firm | GMP Certified. valid up to: 18-Sep-2026 |
| | Evidence of approval of manufacturing facility | Liquid Injectable (SVP) Section approved |
| | **Evaluation Remarks** | |
| | the application is complete as per codal formalities for consideration by the Registration Board | |
| | **Decision** | |
| | **Approved** | |
| 301 | Case Category | Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Crown Pharmaceuticals Pvt Ltd** Office # 73/16 Swiss Cottages Block-4 Clifton **(163)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SDL-8U9-ZYHN, 2024-11-04) |
| | Detail of Fee Submitted | 300000.0,<br>2024-09-27, |
| | The proposed proprietary name / brand name | **IBUTIGEN 140mg CAPSULE** |
| | Label Claim | Each capsule contains: Ibrutinib INN 140 mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 120's-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store below 30°C |

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| | For generic drugs (me-too Status) | Luvica 140mg Capsule M/s: Lab Diagnostic Systems (SMC) Pvt. Ltd Pakistan |
| | Pharmacotherapeutic Group of (API) | L01EL Bruton's tyrosine kinase (BTK) inhibitors |
| | Name, address of Manufacturing site: | GENERAL Pharmaceuticals Ltd. (Unit-l)-Telirchala, Mouchak, Kaliakair , Gazipur, Bangladesh -Bangladesh |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Not submitted |
| | Name, address of Marketing Authorization Holder: | GENERAL Pharmaceuticals Ltd, Sara Aftab Tower, 29 Ring Road (Holding 6/1/A) Shyamoli, Adabor, Dhaka-1207 Bangladesh , Bangladesh |
| | Details of Certificates (CoPP/FSC/cGMP): | confirmed |
| | Details of Authorization Letter : | N/A |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | submitted |
| | The status in reference regulatory authorities | Imbruvica 140mg Capsules By M/s Johnson & Johnson Innovative Medicine, USA |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. | |
| 302 | Case Category | Priority As Per 257-M of RB (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Hakimsons (Pvt)., Ltd.** A-58/B , SITE Karachi **(055)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1MB-V5G-ETN1, 2024-03-13) |
| | Detail of Fee Submitted | 300000.0,<br>2024-01-05, |
| | The proposed proprietary name / brand name | **DECINJET Injection 50mg** |
| | Label Claim | Each Vial Contains : Decitabine .....50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's or As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store below 30C |
| | For generic drugs (me-too Status) | -- |
| | Pharmacotherapeutic Group of (API) | Anticancer |
| | Name, address of Manufacturing site: | M/s Eugia Pharma Specialities Limited,-Survey No. 550, 551 & 552, Kolthur Village, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana, India, Pin- 500078 -India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Name, address of Marketing Authorization Holder: | M/s Hakimsons (Private)., Limited., A-58/B, S.I.T.E., Manghopir Road - Karachi., Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | Submitted |
| | Details of Authorization Letter : | N/A |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | The status in reference regulatory authorities | DACOGEN Injection 50mg by MGI Pharma, Inc. as approved by USFDA |

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| | **Evaluation Remarks** | |
| | Regarding the applied product, we have reviewed the submitted documents and noted the following deficiencies that need to be addressed: i. Letter of Authorization (LOA): Submit a valid Letter of Authorization from the product's license holder abroad. ii. Certificate of Pharmaceutical Product (COPP) Compliance: As per the submitted COPP, the product is not currently available in the market of the exporting country. Kindly provide clarification and justification for this status. iii. Real-Time Stability Data: The required real-time stability data has not been submitted. Submit complete and updated real-time stability studies to support the product's shelf-life and storage conditions. Firm has submitted requisite data | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. | |
| 303 | Case Category | Export Facilitation (Muhammad Sarfraz Nawaz) |
| | Name, address of Applicant. | **Haleon Pakistan Limited** Petaro Road, Jamshoro **(000010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E67-1LJ-E67E, 2025-12-18) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-08, |
| | The proposed proprietary name / brand name | **Panadol Migraine** |
| | Label Claim | Each caplet contains: |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 20's-De-Controlled,24's-De-Controlled |
| | Shelf Life (Unit) | 2 Yearstore below 30°C |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | ATC Code: N02B E51 Paracetamol Combinations |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Lianyungang Kangle Pharmaceutical Co., Ltd. No. 2, Huanan Road, Ganyu Economic Development Zone, Lianyungang,NOVACYL1 Usine de St-Fons Rue Prosper Monnet F- 69190 St-FONS, FRANCE DUNS N°: 38-366-1402 GPS Coordinates of site entrance: N 45.706824° E 4.848589°,Siegfried PharmaChemikalien Minden GmbH Karlstraße 15–39, 42–44 32423 Minden,THE ANDHRA SUGARS LIMITED, Venkatarayapuram, West Godavari District, Tanuku - 534 215, ANDHRA PRADESH |
| | Detail of stability batches of drug product | AV5P, AV5R, AV5S |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | DRAP NOCs are provided in Module 3 with 6-point stability data |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE & CDP performed and provide in Module 3 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability of each API is conducted at zone IV condition |
| | The status in reference regulatory authorities | Panadol Migraine Caplet Manufactured by GSK Consumer Health care USA approved by USFDA |
| | GMP status of the firm | GMP certificate is valid till 05 March 2027 |
| | Evidence of approval of manufacturing facility | Drug Manufacturing License is provided in Module 1 |

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| | **Evaluation Remarks** | |
| | the application is complete as per codal formalities for consideration by the Registration Board | |
| | **Decision** | |
| | **Approved** | |
| 304 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y4G-1R3-RG5X, 2024-08-23) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-20, |
| | The proposed proprietary name / brand name | **Adfen 800mg/8ml** |
| | Label Claim | Each 8ml Contains: Ibuprofen .....800mg (As per Innovator's specs.) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store at controlled room temperature 20 °C to 25 °C (68 °F to 77 °F). |
| | For generic drugs (me-too Status) | UBROF 800mg/8ml Injection IV |
| | Pharmacotherapeutic Group of (API) | NSAID |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | ZENITH CHEMICAL INDUSTRIES (PVT.) LTD 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore – Pakistan |
| | Detail of stability batches of drug product | 2 batches of 2000 ampoules each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Local purchase form M/s Zenith Chemical Industries |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Ubrof injection of M/s Sami |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | as per zone IV-A conditions |
| | The status in reference regulatory authorities | Registered drug by US FDA as (CALDOLOR 800mg/8ml injection). |
| | GMP status of the firm | GMP certificate based on the inspection conducted on 16-08-2022 |
| | Evidence of approval of manufacturing facility | Liquid ampoule confirmed from the submitted GMP certificate |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit valid GMP certificate of the applicant before issuance of registration letter. | |
| 305 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8RW-TMZ-NEQY, 2024-08-23) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-14, |

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| | The proposed proprietary name / brand name | **Adfen 400mg/4ml** |
| | Label Claim | Each 4mL ampoule contains:<br>Ibuprofen.....400 mg (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store at controlled room temperature 20 °C to 25 °C (68 °F to 77 °F). |
| | For generic drugs (me-too Status) | Xaleve 400mg/4ml injection IV of Ms Hudson Pharma |
| | Pharmacotherapeutic Group of (API) | NSAID |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | ZENITH CHEMICAL INDUSTRIES (PVT.) LTD 16 Kilometer off Ferozepur-Road, Behind Wapda Grid station,1 kilometer of Chandrai Road Lahore – Pakistan |
| | Detail of stability batches of drug product | 2 batches of 2000 ampoules each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | N/A |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Xaleve 400mg/4ml injection IV of Ms Hudson Pharma |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | submitted as per zone IV-A conditions |
| | The status in reference regulatory authorities | Registered drug by US FDA as (CALDOLOR 400mg/4ml injection). |
| | GMP status of the firm | GMP certificate based on evaluation conducted on 16-08-2022 |
| | Evidence of approval of manufacturing facility | Liquid ampoule section approval letter submitted |
| | **Evaluation Remarks** | |
| | The firm shall submit valid GMP certificate of the applicant before issuance of registration letter. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit valid GMP certificate of the applicant before issuance of registration letter. | |
| 306 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **OPTIMUS LABORATORIES (PVT.) LTD.**<br>259 F1 Block Wapda Town **(001010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (31U-2J6-71XB, 2026-04-09) |
| | Detail of Fee Submitted | 38700,<br>2025-12-04, |
| | The proposed proprietary name / brand name | **ECONOPRED 1% Ophthalmic Suspension** |
| | Label Claim | Each ml of Ophthalmic Suspension Contains:<br>Prednisolone Acetate..... 10mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 5 ml-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store Below 25°C |
| | For generic drugs (me-too Status) | Econopred Eye Drops by Winthrox Laboratories Pvt. Ltd |
| | Pharmacotherapeutic Group of (API) | Corticosteroid / Glucocorticoid. |
| | Name, address of Manufacturing site: | Self Manufacturing |

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|---|---|---|
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Submitted in Module 3 |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan API from Ms Winthrox |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Econopred Eye Drops by Winthrox Laboratories Pvt. Ltd |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | MHRA |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section Approval Letter Attached in Module 1 & 3 |
| | **Evaluation Remarks** | |
| | Registration letter shall be issued after verification of loan letter. | |
| | **Decision** | |
| | **Approved**<br><br>Registration letter shall be issued after verification of loan letter. | |
| 307 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (P9Q-B76-TAV4, 2026-04-09) |
| | Detail of Fee Submitted | 38700,<br>2025-12-16, |
| | The proposed proprietary name / brand name | **ECONODEX 0.1% Eye Drops** |
| | Label Claim | Each ml of Solution contains : Dexamethasone sodium Phosphate equivalent to dexamethasone phosphate.....1mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 ml-As per SRO,5ml-As per SRO |
| | Shelf Life (Unit) | 2 YearStore Below 25°C |
| | For generic drugs (me-too Status) | Methadex Eye Drops by JAENS PHARMACEUTICAL PVT LTD |
| | Pharmacotherapeutic Group of (API) | Corticosteroid / Glucocorticoid. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Submitted in Module 3 |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | R& I Copy of Loan Letter Of API attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Methadex Eye Drops by JAENS PHARMACEUTICAL PVT LTD |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted |
| | The status in reference regulatory authorities | USFDA |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section Approval Letter Attached in Module 1 & 3 |
| | **Evaluation Remarks** | |

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| | Registration letter shall be issued after verification of loan letter. | |
| | **Decision** | |
| | **Approved**<br><br>Registration letter shall be issued after verification of loan letter. | |
| 308 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LRU-4H8-E5U9, 2026-03-19) |
| | Detail of Fee Submitted | 38700,<br>2026-01-16, |
| | The proposed proprietary name / brand name | **LOTINOL 0.5% Ophthalmic Ointment** |
| | Label Claim | Each gram contains: Loteprednol Etabonate ..... 5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 3.5 gm-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30 degree |
| | For generic drugs (me-too Status) | Lotenol Forte ophthalmic Ointment By Remington Pharmaceuticals Lahore (Approved in DRB 347th ) |
| | Pharmacotherapeutic Group of (API) | Corticosteroid / Glucocorticoid |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Submitted in Module 3 |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API loan from Ms Winthrox; clearance certificate submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Lotemax Ophthalmic Ointment by Bausch & Lomb |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted in Module 3 |
| | The status in reference regulatory authorities | USFDA |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section Approval Letter Attached in Module 1 |
| | **Evaluation Remarks** | |
| | Registration letter shall be issued after verification of loan letter. | |
| | **Decision** | |
| | **Deferred**<br><br>for review of manufacturing process of applied product in comparison to that of innovator's product. | |
| 309 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)** |
| | Application Form Dy. No / Tracking ID & date of submission | (22M-3Q1-5P8G, 2024-11-01) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-27, |
| | The proposed proprietary name / brand name | **Megamine Injection 50 mL** |

| | | |
|---|---|---|
| | Label Claim | Each ml contains: Flunixin as Meglumine.....83mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50 ml-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Store Cool and Dry place below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | (Reg. No. 117364) FUMIN 8.3% INJECTION of M/S. FARM AID GROUP, HARIPUR. |
| | Pharmacotherapeutic Group of (API) | Anti-inflammatory |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Approved |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 310 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B1Q-B8B-ER2E, 2024-11-27) |
| | Detail of Fee Submitted | 30000.0, 37000.0<br>2022-06-22, 2025-07-11 |
| | The proposed proprietary name / brand name | **LEVANEL 3% DRENCH** |
| | Label Claim | Each ml contains: Levamisole HCl ..... 3% |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25 °C. Protect from light |
| | For generic drugs (me-too Status) | LEVAROLD 3% oral suspension REG. # 109078 HAAROLDS PHARMACEUTICALS (PVT.)LTD BHIMBER AJ & K |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | cGMP certificate based on inspection conducted on 27-05-2025 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit proposed pack sizes before issuance of registration letter. | |
| 311 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W4G-919-U985, 2024-08-28) |
| | Detail of Fee Submitted | 30000.0, 9400<br>2023-02-13, 2025-12-16 |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **LINCO SPIRA INJECTION(10ml)** |
| | Label Claim | Each ml contains:- Spiramycin adipate..... 125mg. Lincomycin HCL ..... 75mg. (As per Innovator‟s Specs.) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25 °C. Protect from light |
| | For generic drugs (me-too Status) | LINCOSPIRA INJECTION REG. #046570 ( SELMORE PHARMACEUTICALS (PVT) LTD., LAHORE) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | cGMP compliance (Satisfactory) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 312 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Eterna Pharma Pvt Ltd** plot no 99,100,101 & 198-c sector D1, Old industrial Estate,Mirpur, Aj&K **(000923)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YJZ-3QB-D6B3, 2024-11-27) |
| | Detail of Fee Submitted | 37000.0, 9400<br>2024-11-26, 2026-04-17 |
| | The proposed proprietary name / brand name | **Y-Gent 11 Injection (50ml)** |
| | Label Claim | Each ml contains: Gentamycin Sulphate ..... 110mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25 °C. Protect from light |
| | For generic drugs (me-too Status) | GENT ROLD 11 INJECTION REG. # 108985 (HAAROLDS PHARMACEUTICALS (PVT.)LTD BHIMBER AJ &K) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | cGMP compliance (Satisfactory) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 313 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2LL-R8V-LRWP, 2024-08-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-31, |
| | The proposed proprietary name / brand name | **Duasol Injection** |

| | | |
|---|---|---|
| | Label Claim | Each mL Contains:-Oxytetracycline (as Dihydrate)...300mg) Flunixin (as Meglumine).....20mg) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30C |
| | For generic drugs (me-too Status) | 122813 ETER OXY 2/30 INJECTION of M/S. ETERNA PHARMA (PVT) LTD., MIRPUR, |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 report for DML renewal recommends renewal of DML. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 314 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (34T-G2Q-GHY2, 2024-08-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-31, |
| | The proposed proprietary name / brand name | **Duasol Injection** |
| | Label Claim | Each mL Contains:-Oxytetracycine (as Dihydrate).....300mgFlunixin (As Meglumine ).....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30C |
| | For generic drugs (me-too Status) | 122813 ETER OXY 2/30 INJECTION M/S. ETERNA PHARMA (PVT) LTD., MIRPUR, AJK. |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 recommended DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 315 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **ACE PHARMACEUTICALS** PLOT NO 23, STREET NO SS-2, RCCI INDUSTRIAL ESTATE RAWAT **(001025)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3GM-L28-ABT8, 2026-05-03) |
| | Detail of Fee Submitted | 38700, 9400<br>2026-04-20, 2026-05-11 |
| | The proposed proprietary name / brand name | **TYCOLIN 12/505 POWDER** |

| | | |
|---|---|---|
| | Label Claim | Each 1000 gm contains: Tylosin Tartrate 100 gm, Doxycycline Hyclate 200 gm, Colistin Sulphate 50 gm, Bromhexine HCl 10 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 gram, 500 Gram, 1 Kg, 2.5 Kg, 5 kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | 058963 TYCODOX-PLUS POWDER of UNIVET PHARMACEUTICAL RAWALPINDI |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>upto 1Kg pack size. | |
| 316 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BML-7YV-GQ1J, 2024-11-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-22, |
| | The proposed proprietary name / brand name | **Closan Injection** |
| | Label Claim | Each mL Contains: Closantel.....50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30C |
| | For generic drugs (me-too Status) | Closan Injection by Selmore Pharmaceuticals Pvt. Ltd. DRAP reg. number 058718 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 report recommends DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 317 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MEN-WEZ-9DYV, 2024-11-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-22, |
| | The proposed proprietary name / brand name | **Closan Injection** |
| | Label Claim | Each mL Contains: Closantel = 50 mg |
| | Reference to Finished product specifications | As per Innovators Specification |

| | | |
|---|---|---|
| | Proposed Pack Size | 50mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30C |
| | For generic drugs (me-too Status) | Closan Injection by Selmore Pharmaceuticals Pvt. Ltd. DRAP reg. number 058718 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 report recommends DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 318 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WZN-7EU-2M6D, 2024-08-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-31, |
| | The proposed proprietary name / brand name | **Mycam 10 Injection** |
| | Label Claim | Each mL Contains:-<br>Meloxicam.....10MG |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30C |
| | For generic drugs (me-too Status) | MELOXI-10 INJECTION (049643) M/s selmore Pharmaceuticals Lahore. |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 report recommends DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 319 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LRU-N63-MP83, 2024-08-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-31, |
| | The proposed proprietary name / brand name | **Mycam 7.5 Injection** |
| | Label Claim | Each mL Contains:-<br>Meloxicam.....7.5MG |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30C |

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|---|---|---|
| | For generic drugs (me-too Status) | CAMILOX INJECTION DRAP REG. NO. 071089 M/s Selmore Pharmaceuticals Lhaore. |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 report recommends DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 320 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (37A-H7Q-YGX9, 2024-05-08) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-06, |
| | The proposed proprietary name / brand name | **ENERJECT INJECTION** |
| | Label Claim | Each ml contains: Dextrose.....50mg Calcium Chloride.....2mg Potassium Chloride.....2mg Magnesium Sulfate....2mg Sodium acetate.....7.5mg L-Histidine HCL.....0.02mg DL-Methionine.....0.525mg L-Tryptophane....0.175 L-Cysteine HCL.....0.02mg L-Threonine.....0.35mg L-Isoleucine.....0.525mg L-Arginine HCL....1.425mg L-Phenylalanine.....0.35mg L-Valine.....0.525mg L-Lysine HCL.....0.525mg L-Leucine.....0.6mg Monosodium glutamate....0.08mg Riboflavin.....0.05mg D-Pantothenol....0.1mg Pyridoxine HCL.....0.1mg Nicotinamide.....3mg Thiamine HCL...0.1mg (As per Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 250ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C.Keep away from heat,moisture and reach of children. |
| | For generic drugs (me-too Status) | Enersel injection (112275) of Ms Selmore |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 321 | Case Category | Routine (Najia Saleem) |

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|---|---|---|
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QM2-BTS-MXRY, 2024-11-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-22, |
| | The proposed proprietary name / brand name | **OXYTOCIN INJECTION** |
| | Label Claim | Each mL Contains: Oxytocin .....10IU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)2-8 C |
| | For generic drugs (me-too Status) | OXYTOCIN INJECTION by ISIS Pharmaceuticals and Chemical Works (Reg. No. 019928) |
| | Pharmacotherapeutic Group of (API) | Hormone |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 report recommends DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 322 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9BB-HSN-PTMD, 2024-11-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-22, |
| | The proposed proprietary name / brand name | **OXYTOCIN INJECTION** |
| | Label Claim | Each mL Contains: Oxytocin .....10IU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)2-8 C |
| | For generic drugs (me-too Status) | OXYTOCIN INJECTION by ISIS Pharmaceuticals and Chemical Works (Reg. No. 019928) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026 report recommends DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 323 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **RASCO PHARMA** 5.5KM near Ali Razabad,holiday park,plot #27-28,raiwind road lahore **(000530)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (N34-TQY-JEHW, 2024-05-24) |
| | Detail of Fee Submitted | 30000.0,<br>2023-11-29, |
| | The proposed proprietary name / brand name | **R-STINE TABLET 10MG** |
| | Label Claim | Each film coated tablet contains:<br>Ebastine.....10mg JP specifications |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 1X10,s -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C , Below 60 Humidity |
| | For generic drugs (me-too Status) | Kestine 10mg |
| | Pharmacotherapeutic Group of (API) | Antihistamine |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Bal Pharma Limited, Bangluru, India |
| | Detail of stability batches of drug product | submitted 6 months stability studies data 3 batches of 2000 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Submitted clearance certificate from DRAP |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP data submitted against Kestine tablets of Ms Highnoon batch No. 222471 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted stability studies data of three batches as per zone IV-A conditions |
| | The status in reference regulatory authorities | Drug Regulatory Authority of Pakistan |
| | GMP status of the firm | GMP certificated based on evaluation conducted on 05-01-2024 |
| | Evidence of approval of manufacturing facility | Tablet (General) section confirmed from GMP certificated based on evaluation conducted on 05-01-2024 |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 324 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Evolution Pharmaceuticals (Pvt.) Ltd.** Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. **(000867)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6T4-AUU-L6DQ, 2024-06-11) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-22, |
| | The proposed proprietary name / brand name | **Terbicore 250mg Tablets** |
| | Label Claim | Each Tablet Contains: Terbinafine HCl Equivalent to Terbinafine.....250mg USP Specs |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. |
| | For generic drugs (me-too Status) | LAMISIL 250mg Tablet from Novartis Pharma (Pakistan) Limited, 15 West Wharf Karachi 74 |

| | | |
|---|---|---|
| | | 000, Pakistan |
| | Pharmacotherapeutic Group of (API) | Antifungal |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | SYNERGENE ACTIVE INGREDIENTS PVT LTD PLOT NO:59 D JAWAHAR LAL NEHRU PHARMA CITY, PARWADA MANDAL VISAKHAPATNA, ANDHRA PRADESH PIN CODE:531021 (Air Consignment note) Issued by Copies 1,2 and 3 of the Ai |
| | Detail of stability batches of drug product | 03 batches of 2500 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP submitted against Anibret 250mg tablets of Ms Epharm Laboratories, Karachi. Batch No. AE026 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted both accelerated and real time data of three batches as per zone IV-A conditions |
| | The status in reference regulatory authorities | LAMISIL Tablets 250 mg from Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936 |
| | GMP status of the firm | GMP certificate based on inspection conducted on 11-01-2023 |
| | Evidence of approval of manufacturing facility | Tablet (General) section confirmed vide letter No. F. 1-14/2008-Lic dated 10-07-2017 |
| | **Evaluation Remarks** | |
| | The firm shall submit valid GMP inspection report/ certificate before issuance of registration letter. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit valid GMP inspection report/ certificate before issuance of registration letter. | |
| 325 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Evolution Pharmaceuticals (Pvt.) Ltd.** Plot no. 25,26 & 27, Street S-3, National Industrial Zone, Rawat, Islamabad. **(000867)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QGE-NXX-932Y, 2024-06-13) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-22, |
| | The proposed proprietary name / brand name | **Terbicore 125mg Tablets** |
| | Label Claim | Each Tablets contains: Terbinafine as hydrochloride.....125 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 20° to 25° C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. |
| | For generic drugs (me-too Status) | LAMISIL 125mg Tablet from Novartis Pharma (Pakistan) Limited, 15 West Wharf Karachi 74 000, Pakistan |
| | Pharmacotherapeutic Group of (API) | Antifungal |
| | Name, address of Manufacturing site: | Self Manufacturing |

| | | |
|---|---|---|
| | Name & address of API manufacturer | SYNERGENE ACTIVE INGREDIENTS PVT LTD PLOT NO:59 D JAWAHAR LAL NEHRU PHARMA CITY, PARWADA MANDAL VISAKHAPATNA, ANDHRA PRADESH PIN CODE:531021 (Air Consignment note) Issued by Copies 1,2 and 3 of the Ai |
| | Detail of stability batches of drug product | 3 batches of 750 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE submitted against Anibret 125mg tablets (B. No. AB014) of Ms Epharm Laboratories Karachi. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per zone IV-A conditions |
| | The status in reference regulatory authorities | LAMISIL Tablets 125 mg from Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936 |
| | GMP status of the firm | submitted GMP certificate based on evaluation conducted on 11-01-2023 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | The firm shall submit valid GMP inspection report/ certificate before issuance of registration letter. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit valid GMP inspection report/ certificate before issuance of registration letter. | |
| 326 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Bosch Pharmaceuticals (Pvt) Ltd.** Plot No. 221-223, Sector-23, Korangi Industrial Area **(000350)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SRE-9VB-B7T4, 2024-07-31) |
| | Detail of Fee Submitted | 30000.0,<br>2024-07-26, |
| | The proposed proprietary name / brand name | **Bofalgan Duo ( Paracetamol + Ibuprofen) Tablets 500mg + 200mg** |
| | Label Claim | Each Film Coated Tablet contains: Paracetamol ..... 500mg Ibuprofen..... 200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's, 20's, 30's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Provas Duo Tablets 500mg + 200mg |
| | Pharmacotherapeutic Group of (API) | NSAID |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zenith Chemical Industries (Pvt) Limited. Address: Moaza Dhonday, Jia Bagga, Raiwind Road Lahore - Pakistan |
| | Detail of stability batches of drug product | 3 batches of 3000 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Local purchase from Ms Zenith Chemical Industries Pvt. Ltd. |

| | | |
|---|---|---|
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP data submitted against Provas Duo tablets |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per zone IV-A conditions |
| | The status in reference regulatory authorities | UK. Medicines and Healthcare Regulatory Agency (MHRA) |
| | GMP status of the firm | GMP certificate based on evaluation conducted on 14-02-2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 327 | Case Category | Contract Manufacturing (Najia Saleem) |
| | Name, address of Applicant. | **M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4GT-18L-X785, 2024-08-28) |
| | Detail of Fee Submitted | 75000.0,<br>2024-06-03, |
| | The proposed proprietary name / brand name | **Risdan Oral Disintegrating Tablet 0.5mg** |
| | Label Claim | Each orally disintegrated tablet contains:<br>Risperidone.....0.5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 7’s, 10’s, 14’s, 20-As per SRO |
| | Shelf Life (Unit) | 24 MonthStore below 30°C. Protect from heat, light and moisture. |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Genix Pharma (Pvt.) Ltd.-44, 45-B, Korangi Creek Road, Karachi-75190, Pakistan- |
| | The status in reference regulatory authorities | RISPERDAL Orally Disintegrating Tablets 0.5mg |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The firm initially selected "No" but later on the product of Ms Genix has been approved in 336th meeting of the Registration Board and the firm has also submitted undertaking, module I and extract of minutes. The firm shall submit fee Rs. 9400/- as applicable on cross referred products on contract manufacturing, before issuance of registration letter. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit fee Rs. 9400/- as applicable on cross referred products on contract manufacturing, before issuance of registration letter. | |
| 328 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DUV-HVD-ZRUX, 2024-12-19) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-14, |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **BARICIT 2MG TABLETS** |
| | Label Claim | Each film coated tablet contains:<br>Baricitinib.....2mg (Innovator Spec's) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | JAK inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Three batches of 1500 tablets each (24HT16, 24HT17 and 24HT18) |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Submitted clearance certificate |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP against Barinib 2mg tablet of Ms General pharmaceuticals, Bangladesh |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per zone IV-A conditions |
| | The status in reference regulatory authorities | Olumiant 2mg tablets (USFDA Approved) |
| | GMP status of the firm | New DML granted on 17-01-2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Deferred**<br><br>for submission of both accelerated and real time stability data of 6th month time point for batch 24HT18 since 6th month stability data for only two batches has been submitted. | |
| 329 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WLU-MTL-6DPU, 2024-12-19) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-14, |
| | The proposed proprietary name / brand name | **BARICIT 4MG TABLETS** |
| | Label Claim | Each film coated tablet contains:<br>Baricitinib.....4mg (Innovator Spec's) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | JAK inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Three batches of 1500 tablets each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | submitted clearance certificate |

| | | |
|---|---|---|
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted PE and CDP data against Barigen 4mg tablet of Ms General pharmaceuticals, Bangladesh |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | submitted as per zone IV-A conditions |
| | The status in reference regulatory authorities | Olumiant 4mg tablets (USFDA Approved) |
| | GMP status of the firm | DML granted on 17-01-2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 330 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **ELKO ORGANIZATION (PRIVATE) LIMITED** PLOT NO. 27 & 28, SECTOR-12B, NORTH KARACHI INDUSTRIAL AREA, KARACHI **(000245)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W4N-86D-J67A, 2024-11-24) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-01, |
| | The proposed proprietary name / brand name | **Elkoflor** |
| | Label Claim | Each ml Contains: Florfenicol.....300mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50ml -De-Controlled |
| | Shelf Life (Unit) | 2 Year20 -25 *C |
| | For generic drugs (me-too Status) | Neflox injection / Selmore Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on above stated observation and keeping in view the attitude of the management towards continues improvements their current level of compliance is rated to Good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The firm shall submit details of container closure before issuance of registration letter. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit details of container closure before issuance of registration letter. | |
| 331 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RY5-Z2A-WDSA, 2024-06-27) |
| | Detail of Fee Submitted | 75000.0,<br>2024-06-24, |
| | The proposed proprietary name / brand name | **Flucas 50mcg nasal Spray** |
| | Label Claim | Each Spray Contains: Fluticasone Propionate (USP).....50mcg (Product complies USP |

| | | |
|---|---|---|
| | | Specs) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | Flexosone Nasal Spray By Schazoo Laboratories |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.- |
| | The status in reference regulatory authorities | UK MHRA APPROVED |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The firm initially selected "No" but later on replied in response to a query that the contract manufacturer's product has been approved in 359th meeting of the Registration Board. Furthermore, the firm shall submit the following before issuance of the registration letter. i. A declaration from applicant that they will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site. ii. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website. iii. Fee Rs. 9400/- as applicable on cross referred products on contract manufacturing. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit the following before issuance of the registration letter.<br><br>1. A declaration from applicant that<br><br>i. they will adopt the same source of drug substance, drug product formulation, specifications and container closure as already approved by the Registration Board for the same formulation at the same manufacturing site.<br><br>ii. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website.<br><br>2. Fee Rs. 9400/- as applicable on cross referred products on contract manufacturing. | |
| 332 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Surge Laboratories (Pvt.) Ltd.** 10th KM, Faisalabad Road, Bikhi District, Sheikhupura. **(000484)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TAT-PD7-ULGL, 2024-10-31) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-09, |
| | The proposed proprietary name / brand name | **NEOFEN** |
| | Label Claim | Each 8ml contains Ibuprofen 800mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 8ml x 1s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degree |
| | For generic drugs (me-too Status) | Ubrof Injection 800mg/8ml SAMI |
| | Pharmacotherapeutic Group of (API) | NSAID |

| | | |
|---|---|---|
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Hubei Biocause Heilen Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | 3 batches of 1000 vials |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | clearance certificate submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Ubrof injection 800mg/8ml of Ms Sami |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | as per zone IV-B conditions |
| | The status in reference regulatory authorities | FDA Approved - CALDOLOR (ibuprofen injection), for intravenous use Cumberland Pharmaceuticals Inc. |
| | GMP status of the firm | GMP certificate based on evaluation conducted on 27-09-2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 333 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z6W-A7X-YADX, 2024-08-26) |
| | Detail of Fee Submitted | 30000.0,<br>2024-08-13, |
| | The proposed proprietary name / brand name | **Onsol 4mg Tablets** |
| | Label Claim | Each film coated tablet contains; Ondansetron (as HCl).....4mg (USP Spec's.) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Onsoft 4mg Tablets, Manufacturer: Winlet Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Anti emetic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | CTX Lifesciences Pvt. Ltd. |
| | Detail of stability batches of drug product | Three batches of 1500 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan from Ms Vision Pharmaceuticals, submitted request letter, agreement clearance certificate and DRAP intimation letter. May be verified accordingly. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP against Onsoft of Ms Winlet |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per zone IV-B conditions |
| | The status in reference regulatory authorities | Ondansetron Aurobindo 4mg Tablet, Company: AUROBINDO PHARMA, (NDA): 078539, (USFDA Approved) |
| | GMP status of the firm | DML granted in 2024 |

| | | |
|---|---|---|
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |

| Sr. No. | Observation | Firm's reply |
|---|---|---|
| 1. | The brand name written on fee challan is Odanset while that mentioned throughout the dossier and e-app interface is Onsol, clarify and submit relevant fee challan. | The brand name on the submitted fee challan has been mistakenly written as “Odanset” instead of “Onsol.” However, the fee challan actually pertains to the product “Onsol.” The payment has already been verified through the DRAP e-app system. It is requested to kindly considered the submitted fee chalan for this product Onsol 4mg Tablets. |

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|---|---|---|
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit fee for registration for relevant product before issuance of registration letter. | |
| 334 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZWP-662-S697, 2025-05-21) |
| | Detail of Fee Submitted | 37000.0, 9400<br>2025-05-13, 2026-05-20 |
| | The proposed proprietary name / brand name | **Enro-C Oral Powder** |
| | Label Claim | Each 10gram contains:<br>Enrofloxacin.....2000mg Colistin Sulphate.....4500000IU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50 sachet of 10gm -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 30 |
| | For generic drugs (me-too Status) | Cera-Coli 10gm Oral Powder |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | GMP inspection dated 27-12-2023, report compliance level is rated as Good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 335 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (X78-73M-Z1QV, 2024-11-08) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-07, |
| | The proposed proprietary name / brand name | **COMBI-4 INJECTION** |

| | | |
|---|---|---|
| | Label Claim | each mL Contains: Tylosin Tartrate = 150 mg Gentamicin Sulphate = 60 mg Chlorpheniramine = 7.5 mg Dexamethasone = 2.65 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 30C |
| | For generic drugs (me-too Status) | COMBI-4 INJECTION DRAP REG. NO. 079167 BY DECENT PHARMA. |
| | Pharmacotherapeutic Group of (API) | antibacterial, anti-inflammatory, anti-histamine |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Panel inspection dated 13-02-2026; recommended DML renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 336 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (P7V-MD4-WGLW, 2025-04-18) |
| | Detail of Fee Submitted | 37000.0, 37000<br>2025-04-18, 2025-11-27 |
| | The proposed proprietary name / brand name | **Hexatri-C Oral Powder** |
| | Label Claim | Each Kg Contains: Hexamine 480gm, Sodium Acid Phosphate 160gm, Ascorbic Acid 3gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10kg-De-Controlled,12gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade |
| | For generic drugs (me-too Status) | Exitone Oral Powder of M/s A&K Pharmaceuticals (Reg. No. 033289) |
| | Pharmacotherapeutic Group of (API) | for the treatment of recurrent UTIs |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | DML granted w.e.f. 28-03-2025 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | The composition of reference product (033289 EXITONE ORAL POWDER) as per available record is as follows: Each Kg contains: Hexamine.....480gm Sodium Acid Phosphate.....160gm Ascorbic Acid.....30gm Trihydroxyethyl Rutin.....3gm | |
| | **Decision** | |
| | **Approved**<br><br>upto 1Kg pack size with following label claim:<br><br>Each Kg contains:<br><br>Hexamine.....480gm | |

| | | |
|---|---|---|
| | Sodium Acid Phosphate.....160gm<br>Ascorbic Acid.....30gm<br>Trihydroxyethyl Rutin.....3gm | |
| 337 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (82U-R7D-J2NV, 2024-06-14) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-29, |
| | The proposed proprietary name / brand name | **Xfin 1% Lotion** |
| | Label Claim | Each ml Contains; Terbinafine Hydrochloride.....10mg (JP Spec's) |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Terbisil lotion 1%, Manufacturer: Saffron Pharmaceuticals Pvt. Ltd. |
| | Pharmacotherapeutic Group of (API) | Antifungal |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches of 1L (50 bottles) |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan of API from Ms Seraph, hence may be verified accordingly. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE data submitted against Terbiderm topical solution of Ms Atco Laboratories Limited |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per zone IV-A conditions |
| | The status in reference regulatory authorities | Lamisil® OnceTM 1% cutaneous solution, Manufacturer: Haleon Ireland Limited (Registered in Ireland) |
| | GMP status of the firm | DML granted in 2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | Registration letter shall be issued after verification of loan letter. | |
| | **Decision** | |
| | **Approved**<br><br>Registration letter shall be issued after verification of loan letter. | |
| 338 | Case Category | Export Facilitation (Najia Saleem) |
| | Name, address of Applicant. | **Atco Laboratories Limited** B-18 SITE KARACHI **(000188)** |
| | Application Form Dy. No / Tracking ID & date of submission | (44Q-X35-BW6B, 2026-04-29) |
| | Detail of Fee Submitted | 38700,<br>2026-04-02, |
| | The proposed proprietary name / brand name | **Ruxira Cream** |

| | | |
|---|---|---|
| | Label Claim | Each gram contains: Ruxolitinib (as Ruxolitinib Phosphate).....15mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10gm-De-Controlled,15gm-De-Controlled,20gm-De-Controlled,30gm-De-Controlled,5gm-De-Controlled,60gm-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Donot store and transport above 30 degree centrigrade |
| | For generic drugs (me-too Status) | Ruxozee 1.5% cream |
| | Pharmacotherapeutic Group of (API) | Antineoplastic agents and Protein kinase inhibitors |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Shandong Chenghui Shuangda Pharmaceutical Co.,Ltd |
| | Detail of stability batches of drug product | 3 batches having batch size of 1000g |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Form-3, form-6, form-7, invoice and AWB submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies are performed against Ruxozee 1.5% cream B.No.CX001 Manufatured by Horizon Healthcare(Pvt)Ltd |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | stability study data of 3 batches of drug substance as per IV- A is submitted |
| | The status in reference regulatory authorities | Opzelura Cream 1.5%Manufactured by: Address: Incyte Incorporation 1801 Augustine cutoff Wilmington, DE 19803 |
| | GMP status of the firm | GMP certificate based on evaluation conducted on 23-07-2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 339 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (47U-H1E-QLE2, 2024-08-23) |
| | Detail of Fee Submitted | 30000.0, 2024-08-22, |
| | The proposed proprietary name / brand name | **Onsol 8mg Tablets** |
| | Label Claim | Each film coated tablet contains; Ondansetron (as HCl).....8mg (USP Spec's.) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Oniron 8mg Tablets, Manufacturer: Genome Pharmaceuticals Pvt. Ltd. |
| | Pharmacotherapeutic Group of (API) | 5HT3 receptor antagonist |
| | Name, address of Manufacturing site: | Self Manufacturing |

| | | |
|---|---|---|
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches of 1500 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Borrowed API from Ms Vision Pharmaceuticals Pvt. Ltd, hence may be verified accordingly |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Both PE and CDP data against Oniron tablets of Ms Genome |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | as per zone IV-B conditions |
| | The status in reference regulatory authorities | Ondansetron Aurobindo 8mg Tablet, AUROBINDO PHARMA (NDA): 078539, USFDA Approved |
| | GMP status of the firm | DML granted w.e.f.17-01-2024 |
| | Evidence of approval of manufacturing facility | Submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 340 | Case Category | Priority As Per 257-M of RB (Najia Saleem) |
| | Name, address of Applicant. | **ASTER LIFE SCIENCES** 32-BABAR BLOCK NEW GARDEN TOWN LAHORE **(053520065013801D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (D72-JHY-E7NW, 2025-05-02) |
| | Detail of Fee Submitted | 75000.0, 225000.0<br>2022-05-18, 2025-05-02 |
| | The proposed proprietary name / brand name | **TacroBell SR Capsule 1mg** |
| | Label Claim | Tacrolimus monohydrate (USP) 1.020mg (1mg as tacrolimus) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-Controlled,50's-Controlled |
| | Shelf Life (Unit) | 3 Year(s)Store in a light-resistant, tight container at room temperature (1~30°C) away from moisture |
| | For generic drugs (me-too Status) | NOT AVAILABLE |
| | Pharmacotherapeutic Group of (API) | immunosuppressants |
| | Name, address of Manufacturing site: | Chong Kun Dang Pharmaceuticals Corp.-797-48 Manghyang-ro, Seonggeo-eup, Seobk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea-South Korea |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Not submitted |
| | Name, address of Marketing Authorization Holder: | Chong Kun Dang Pharmaceuticals Corp., 797-48 Manghyang-ro, Seonggeo-eup, Seobk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea, South Korea |
| | Details of Certificates (CoPP/FSC/cGMP): | CoPP submitted |
| | Details of Authorization Letter : | N/A |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | submitted as per zone II |
| | The status in reference regulatory authorities | USFDA, EMA |
| | **Evaluation Remarks** | |

Shortcomings: 1. The submitted copy of letter of authorization was valid till 03-04-2025, re-submit original valid LOA notarized from the country of origin. 2. 3.2.P.2.2.1: Submit Pharmaceutical Equivalence (PE) _ comparison of the developed formulation and the innovator / reference / comparator product of same strength including the results of all the quality tests specified in section 3.2.P.5.1 3. You have submitted comparative dissolution profile (CDP) according to Taiwan guidelines testing 1mg against 5mg tablet. Provide CDP according to the guidelines specified in WHO Technical Report Series No. 992, 2015, Annex 7, Appendix 1 Recommendations for conducting and assessing comparative dissolution profiles and USFDA Guidance for Industry Dissolution Testing of Immediate Release Solid Oral Dosage Forms - Dissolution Profile Comparisons. 4. 3.2.S.4.4: Provide results of analysis of relevant batch(es) of Drug Substance performed by Drug Product manufacturer used during product development and stability studies, along with Certificate of Analysis (CoA) of the same batch from Drug Substance / /Active Pharmaceutical Ingredient manufacture. A discussion and justification shall also be provided for any incomplete analyses of the drug substance / API by Drug Product manufacturer. Deferred in 352nd meeting for the submission of following:

| | | |
|---|---|---|
| 1 | The drug product stability data until completion of the claimed shelf-life studies conducted under Zone IV conditions. | Submitted 36-month long term stability studies data of three commercial batches as per zone IV-B conditions |
| 2 | Complete CDP testing and pharmaceutical equivalence studies as per CTD guidance documents. | submitted |

Moreover, since the submitted copy of letter of authorization was valid till 03-04-2025, the firm shall submit original valid LOA notarized from the country of origin along with original COPP.

**Decision**

**Approved**

The registration letter shall be issued after submission of the following:

i. Original valid LOA notarized from the country of origin since the already submitted copy of letter of authorization was valid at the time of submission till 03-04-2025but is expired now.

ii. Original legalized valid COPP of the applied product

| 341 | | |
|---|---|---|
| | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3JQ-RYH-3EZM, 2024-11-18) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-08, |
| | The proposed proprietary name / brand name | **CLIDA 1% GEL** |
| | Label Claim | Each gram of topical gel contains: Clindamycin (as Phosphate).....10mg (USP Spec's) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | CLYCIN-T 1% Topical Gel |
| | Pharmacotherapeutic Group of (API) | Macrolide antibiotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches of 1Kg each |

| | | |
|---|---|---|
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API borrowed from Ms Biogen Pharma, hence may be verified |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Clycin-T gel 1% |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | as per zone IV-A conditions |
| | The status in reference regulatory authorities | Cleocin T 1% Topical Gel (US FDA Approved) |
| | GMP status of the firm | DML issued w.e.f. 17-01-2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>Registration letter shall be issued after verification of loan letter. | |
| 342 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (43H-P55-PQZ6, 2026-03-19) |
| | Detail of Fee Submitted | 38700,<br>2026-01-16, |
| | The proposed proprietary name / brand name | **LOTINOL Forte 1% Ophthalmic Suspension** |
| | Label Claim | Each ml of Suspension contains: Loteprednol Etabonate ....10 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 5 ml-As per SRO,7.5 ml-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30 degree |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Corticosteroid / Glucocorticoid |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches of 600 bottles each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API borrowed from M/s Winthrox, hence may be verified accordingly |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Inveltys Ophthalmic Suspension by Alcon Laboratories, Inc |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per zone-IVA conditions |
| | The status in reference regulatory authorities | Inveltys ophthalamic suspension USFDA approved |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section Approval Letter Attached in Module 1 |
| | **Evaluation Remarks** | |
| | Registration letter shall be issued after verification of loan letter. | |
| | **Decision** | |
| | **Deferred**<br><br>for review of manufacturing process of applied product in comparison to that of innovator's product. | |

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|---|---|---|
| 343 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7VG-RWE-ATAJ, 2026-03-19) |
| | Detail of Fee Submitted | 38700,<br>2026-01-16, |
| | The proposed proprietary name / brand name | **LOTINOL Mild 0.25% Ophthalmic Suspension** |
| | Label Claim | Each ml of Suspension contains: Loteprednol Etabonate ....2.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 5ml-As per SRO,7.5 ml-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Corticosteroid / Glucocorticoid. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches (EY-001, EY-002, EY-003) of 600 bottles each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API borrowed from Ms Winthrox laboratories, hence may be verified accordingly. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Eysuvis 0.25% w/v Eye Drops, Suspension by Alcon Laboratories, Inc |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted as per zone IV conditions |
| | The status in reference regulatory authorities | EYSUVIS (USFDA approved) |
| | GMP status of the firm | New License |
| | Evidence of approval of manufacturing facility | Section Approval Letter Attached in Module 1 & 3 |
| | **Evaluation Remarks** | |
| | Registration letter shall be issued after verification of loan letter. | |
| | **Decision** | |
| | **Deferred**<br><br>for review of manufacturing process of applied product in comparison to that of innovator's product. | |
| 344 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PLE-QQZ-8UNN, 2024-10-30) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-08, |
| | The proposed proprietary name / brand name | **Trevisol Gel 0.05%** |
| | Label Claim | Each gram contains: Isotretinoin.....<br>0.05% w/w (BP Spec's) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | Oratane Gel 0.05% of Ms Crystolite |
| | Pharmacotherapeutic Group of (API) | Retinoid |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches of 1Kg each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Loan from Ms Biogen, hence may be verified. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Oratane Gel 0.05% of Ms Crystolite |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | one IV-A conditions |
| | The status in reference regulatory authorities | Isotrex Gel 0.05% (MHRA Approved) |
| | GMP status of the firm | DML issued w.e.f. 17-01-2024 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | Firm shall submit following before issuance of the registration letter: 1. valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin. 2. verification of loan letter | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit the following before issuance of the registration letter:<br><br>1. valid approval of API/ DML/GMP certificate of API manufacturer issued by concerned regulatory authority of country of origin.<br><br>2. verification of loan letter | |
| 345 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9JQ-AQZ-L35N, 2024-08-28) |
| | Detail of Fee Submitted | 75000.0,<br>2024-06-14, |
| | The proposed proprietary name / brand name | **Iburin 800mg/200ml** |
| | Label Claim | Each 200mL vial contains: Ibuprofen.....800 mg (As per Innovator's specs.) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 24 Month(s)Store at controlled room temperature 20 °C to 25 °C (68 °F to 77 °F). |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | NSAID |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Zenith Chemical Industries Pvt Ltd |
| | Detail of stability batches of drug product | 2 batches of 2000 vials each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | API loan from Ms Horizon, hence may be verified accordingly |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Caldolor injection 800mg/200ml of Cumberland Pharmaceuticals, USA. |

| | | |
|---|---|---|
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per zone IV-A conditions |
| | The status in reference regulatory authorities | drug by US FDA as (CALDOLOR 800mg/200ml injection). |
| | GMP status of the firm | GMP certificate based on evaluation conducted on 13-04-2021 |
| | Evidence of approval of manufacturing facility | Submitted |

**Evaluation Remarks**

| Sr. No. | Observations | Firm's response |
|---|---|---|
| 1 | Submit valid DML and GMP certificate of the applicant | Not submitted |
| 2 | Submit pictorial evidence of reference pack bearing batch number, date of mfg. used for performance of PE | It is respectfully submitted that the reference product was procured and utilized for the performance of the Pharmaceutical Equivalence (PE) study. However, pictorial evidence was not retained at the time of study execution. The product was supplied in a plastic container, which was discarded after use. |
| 3 | Procurement trail/record of innovator's product used for product development studies. | Invoice for only 1 pack from Life Pharmacy Dubai. |

**Decision**

**Rejected**

since the applicant failed to submit pictorial evidence of reference pack bearing batch number, date of mfg. used for performance of PE as required vide notification No. 14-1/2022-PEC dated 16-01-2023.

| | | |
|---|---|---|
| 346 | Case Category | Priority As Per 257-M of RB (Najia Saleem) |
| | Name, address of Applicant. | **ASTER LIFE SCIENCES** 32-BABAR BLOCK NEW GARDEN TOWN LAHORE **(053520065013801D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7L9-ETN-LMEZ, 2025-05-02) |
| | Detail of Fee Submitted | 75000.0, 225000.0<br>2022-05-18, 2025-05-02 |
| | The proposed proprietary name / brand name | **TacroBell SR Capsule 0.5mg** |
| | Label Claim | Tacrolimus monohydrate 0.510mg (0.5mg as tacrolimus) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-Controlled,50's-Controlled |
| | Shelf Life (Unit) | 3 Year(s)Store in a light-resistant, tight container at room temperature (1~30°C) away from moisture |
| | For generic drugs (me-too Status) | NOT AVAILABLE |
| | Pharmacotherapeutic Group of (API) | Immunosuppressant |
| | Name, address of Manufacturing site: | Chong Kun Dang Pharmaceuticals Corp.-797-48 Manghyang-ro, Seonggeo-eup, Seobk-gu, |

| | |
|---|---|
| | Cheonan-si, Chungcheongnam-do, Republic of Korea-South Korea |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Not submitted |
| Name, address of Marketing Authorization Holder: | Chong Kun Dang Pharmaceuticals Corp., 797-48 Manghyang-ro, Seonggeo-eup, Seobk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea, South Korea |
| Details of Certificates (CoPP/FSC/cGMP): | Confirmed from submitted copy of COPP |
| Details of Authorization Letter : | N/A |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | submitted as per zone II conditions |
| The status in reference regulatory authorities | USFDA, EMA |
| **Evaluation Remarks** | |

| Sr. No. | Observations | Firm's response |
|---|---|---|
| 1 | The submitted copy of letter of authorization was valid till 03-04-2025, re-submit original valid LOA notarized from the country of origin. | We have urged our foreign principal to submit fresh letter of authorization duly apostille /attested by Pakistan Embassy. However, as letter of authorization was valid at the time of submission so kindly consider our application. |
| 2 | 3.2.S.4.3: Provide summarized tabulated results of verification studies including specificity, accuracy and repeatability (method precision) performed by the Drug Product manufacturer | This data is not required for the DP manufacturer to perform. We would have to declare that this was not requested by MFDS and received approval successfully by referring to the Drug substance data. |
| 3 | 3.2.P.2.2.1: Submit Pharmaceutical Equivalence (PE) _ comparison of the developed formulation and the innovator / reference / comparator product including the results of all the quality tests specified in section 3.2.P.5.1 | We have compared the quality results with reference product Advagraf 5mg for TacroBell 5mg and proved the equivalence between the 2 products in 3.2.P.2.2 For the rest of the strengths TacroBell SR 1mg and TacroBell SR 0.5mg we have proved the equivalence between the 2 CKD products |
| 4 | Dissolution testing is not performed at IPC stage; however, extended release of tacrolimus granules is declared in the COA of the Finished Product. Justification shall be submitted for filling Tacrolimus granules without establishing its release profile. | Dissolution of the drug product is according to the in-house dissolution test for extended release. We have developed the product according to the final release specification for which Method validation according to ICH Standards was successfully performed so the IPC for dissolution is not performed |
| 5 | Submit complete analytical record of real time stability data of FPP as per zone IV-A/B conditions up to complete shelf | Real time stability studies: only 2 batches data submitted 1st batch 36 months 2nd batch 12 months only Accelerated studies |

| | | | |
|---|---|---|---|
| | | life, since the already stability data is as per zone-II conditions. | data: 3 batches 6 months The stability study on three commercial batches is yet not completed and foreign principal undertaken that Long term stability testing (Zone IVb, 30± 2°C/75 ± 5 %) will be continued to 36 month in accordance with the relevant protocol of batch no. (EE001AA1, EE002AA1, HE001AA1) and their stability data will be updated and provided accordingly. We commit to report if any of the values are outs of specification with the proposed action. |
| | | | A Comparative Dissolution Test was conducted from July 21–23, 2016 at the Chong Kun Dang Hyo-Jong Research Institute in Yongin-si, South Korea, to evaluate the pharmaceutical equivalence of TacroBell SR Capsule 0.5mg (test drug) against TacroBell SR Capsule 5mg (reference drug). Test Overview Objective: Assess dissolution profile equivalence between test and reference formulations. Result: Declared equivalent under all four test conditions. Drug Details Manufacturer: Chong Kun Dang Pharmaceutical Corp. (both products) API Source: TEVA Czech Industries S.R.O. Batch Info: Test drug: EE001AA1 (Mfg. Sept 05, 2022) Reference drug: EE003AA9 (Mfg. July 14, 2022) API Strength: 0.5 mg (test) vs. 5 mg (reference) |

| Medium | Final time (min) | f2 | Results |
|---|---|---|---|
| QC | 1440 | 61 | Equivalent |
| pH 1.2 | 120 | 55 | Equivalent |
| pH 4.5 | 1440 | 52 | Equivalent |
| pH 6.8 | 1440 | 65 | Equivalent |

All similarity factors exceeded the regulatory threshold, confirming pharmaceutical equivalence per Article 21 of the Pharmaceutical Equivalence Test

| | | |
|---|---|---|
| | | Standards. The choice of CKD's own product as the test drug is based on the fact that both products share a similar release mechanism, and the new formulation was merely developed to improve patient compliance. Furthermore, according to internationally recognized bioequivalence guidelines, if comparative dissolution between the two strengths is demonstrated, a bioequivalence study can be exempted |

Deferred in 352nd meeting for the submission of following:

| | | |
|---|---|---|
| 1 | The drug product stability data until completion of the claimed shelf-life studies conducted under Zone IV conditions. | The firm has referred to CTD guidance document and submitted 36-month long term stability studies data as per zone IV-B conditions for 2 commercial batches |
| 2 | Complete CDP testing and pharmaceutical equivalence studies as per CTD guidance documents. | submitted |

Moreover, since the submitted copy of letter of authorization was valid till 03-04-2025, the firm shall submit original valid LOA notarized from the country of origin along with original COPP, GMP certificate.

**Decision**

**Approved**

with shelf life of 2 years since long term stability data till 36 months of only two commercial batches has been submitted.

The registration letter shall be issued after submission of the following:

i. Original valid LOA notarized from the country of origin since the already submitted copy of letter of authorization was valid at the time of submission till 03-04-2025but is expired now.

ii. Original legalized valid COPP of the applied product

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|---|---|---|
| 347 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (47Y-L6Z-SE31, 2024-10-30) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-25, |
| | The proposed proprietary name / brand name | **Adcracin Cream 0.1% w/w** |
| | Label Claim | Each gram contains: Adapalene Ph. Eur.....1mg (BP Specifications) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 5g, 10g, 15g, 30g, 4-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Yes |

| | | |
|---|---|---|
| | Pharmacotherapeutic Group of (API) | Anti-acne preparations for topical use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Alivus Life Sciences (formerly Glenmark Life Sciences Limited) |
| | Detail of stability batches of drug product | 3 batches of 50 tubes each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Adapco Cream 0.1% (Atco Laboratories Pakistan) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | as per zone IV-B conditions |
| | The status in reference regulatory authorities | HPRA, Ireland Approved [Differin Cream 0.1% (Adapalene) by Galderma International, Ireland] |
| | GMP status of the firm | GMP certificate based on evaluation conducted on 22-05-2023 |
| | Evidence of approval of manufacturing facility | cream/ointment (General) section approval submitted |
| | **Evaluation Remarks** | |
| | The firm shall submit valid GMP certificate of the applicant before issuance of registration letter. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit valid GMP certificate of the applicant before issuance of registration letter. | |
| 348 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B89-B5Y-QY5J, 2024-11-11) |
| | Detail of Fee Submitted | 75000.0,<br>2024-10-28, |
| | The proposed proprietary name / brand name | **Barijak 1mg Tablet** |
| | Label Claim | Each film coated tablet contains:<br>Baricitinib.....1mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10's & 30's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30OC at a dry place, protect from light and heat. |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | JAK inhibitor |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | 3 batches of 1500 tablets each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Submitted invoice and form-6 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP against Olumiant 1mg |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | as per zone IV-A conditions |

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|---|---|---|
| | The status in reference regulatory authorities | OLUMIANT 1MG TABLET;Lilly USA, LLC Indianapolis, IN 46285, USA.;FDA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | submitted |

**Evaluation Remarks**

| Sr. No. | Observation | Firm's response |
|---|---|---|
| 1 | Submit the API procurement document including the DRAP attested commercial invoice/clearance certificate bearing name of the manufacturer and batch number of API. The already submitted commercial invoice is from M/s Universal Pharmaceutical Co. Ltd. | We hereby attached the ADC attested invoice with Form-6. The API Manufacturer name is mentioned of Form-6 while the ADC attested invoice issued from the trader API was procured through Universal Pharmaceutical Co., Ltd. Pharmaceutical Manufacturing is associated with Hongyuan (HY Pharma) Group, often known as Zhejiang Hongyuan Pharmaceutical Co., Ltd. Universal Pharmaceutical Co., Ltd. is primarily known in the industry as a trader and international supply chain partner of Zhejiang Hongyuan. |

**Decision**

**Approved**

| | | |
|---|---|---|
| 349 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WMN-6P4-569X, 2026-01-30) |
| | Detail of Fee Submitted | 38700,<br>2025-12-15, |
| | The proposed proprietary name / brand name | **LOTINOL-T Ophthalmic Suspension** |
| | Label Claim | Each ml of Suspension Contains: Loteprednol Etabonate ....5.0mg Tobramycin .....3.0mg (Innovator's Specs.). |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C in a cool and dry place. |
| | For generic drugs (me-too Status) | Lotinol-T BY Winthrox (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Loteprednol Etabonate: Corticosteroid Tobramycin: Aminoglycoside Antibiotic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Livzon group Fuzhou Fuxing Pharmaceutical CO.LTD. NO.8 Nangang Road, Jiangyin Industrial Concentration Zone Fuqing Fuzhou City Fujian Province P.R China 350309 China,Shanghai Orgpharma Chemical Co., Ltd, 3rd Floor, Middle B, No.88, Beijing East Road, |

| | |
|---|---|
| | Taicang City,Suzhou City Jiangsu P.R.China(China) |
| Detail of stability batches of drug product | 600 bottles of each batch. |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Loan without timely intimation to DRAP |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE data submitted against Lotinol-T Ophthalmic Suspension of M/s Winthrox Laboratories Pvt. Ltd |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability studies are according to zone IV A. |
| The status in reference regulatory authorities | FDA approved |
| GMP status of the firm | New DML |
| Evidence of approval of manufacturing facility | Attached. |

**Evaluation Remarks**

| Sr. No. | Observation | Firm's response |
|---|---|---|
| 1 | Justify broader/relaxed acceptance limit for pH (5.0-6.0); pH of innovator product ranges from 5.7 to 5.9 | Firm has submitted the following justification without giving reference to specific guidelines. · Ophthalmic preparations are generally well tolerated within a pH range of approximately 4.0–8.0 due to the buffering capacity of tear fluid, which rapidly adjusts the pH of instilled formulations toward physiological tear pH (~7.4). Therefore, the proposed pH range falls well within the acceptable physiological limits for ophthalmic administration and is not expected to cause ocular discomfort. · In addition, maintaining the formulation in a slightly acidic pH environment supports the chemical stability of both active ingredients by minimizing potential degradation pathways such as hydrolysis and maintaining optimal physicochemical conditions for the formulation components. This helps preserve the potency of the active substances, maintains the integrity of the suspension system, and ensures consistent product quality during manufacturing as well as throughout the product's shelf life. · Furthermore, the proposed specification encompasses the observed pH range of the innovator product (5.7–5.9) while allowing reasonable manufacturing and |

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|---|---|---|---|
| | | | analytical variability without affecting the safety, efficacy, or overall performance of the ophthalmic preparation. · pH Stability of APIs Loteprednol Etabonate is an ester-based corticosteroid whose stability is influenced by pH. Studies on steroid esters indicate that maximum chemical stability is generally observed in slightly acidic conditions (approximately pH 4 5), while higher alkaline pH may accelerate hydrolytic degradation of the ester linkage. Therefore, maintaining the formulation in a slightly acidic environment helps minimize degradation pathways such as hydrolysis and supports long term stability of the active ingredient in ophthalmic suspensions. · Tobramycin, an aminoglycoside antibiotic widely used in ophthalmic products, exhibits good stability in slightly acidic to near-neutral pH conditions, which are commonly used for ophthalmic formulations. In combination ophthalmic suspensions containing both loteprednol etabonate and tobramycin, studies have shown that the presence of tobramycin can also contribute to improved pH stability of the formulation during storage, resulting in minimal pH drift over time. |
| | Deferred in M-358th meeting for submission of guidelines allowing broader/relaxed acceptance limit pH (5.0-6.0) range contrary to that of the innovator product (5.7 to 5.9) Updated status: The firm has referred to ICH Q6A/Q8(R2), USP <771>, FDA, EMA, and WHO guidelines provided it is supported by adequate development, stability, and safety and efficacy data specific to the product. | | |
| | **Decision** | | |
| | **Deferred**<br><br>for review of manufacturing process of applied product in comparison to that of innovator's product and submission of supported data as required by the referred guidelines. | | |
| 350 | Case Category | Routine (Najia Saleem) | |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** | |
| | Application Form Dy. No / Tracking ID & date of submission | (1JB-M8H-28WZ, 2024-12-02) | |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-18, | |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **Adcracin Gel 0.1% w/w** |
| | Label Claim | Each gram contains: Adapalene .....1mg (BP Specifications) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 5g, 10g, 15g, 30g, 4-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | Anti-acne preparation for topical use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Alivus Life Sciences (formerly Glenmark Life Sciences Limited) |
| | Detail of stability batches of drug product | 3 batches of 50 tubes |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | submitted clearance certificate |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Differin Gel 0.1% w/w (Laboratories GALDERMA France) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | As per zone IV-B conditions |
| | The status in reference regulatory authorities | HPRA, Ireland Approved [Differin Gel 0.1% by Galderma International, Ireland (Manufactured in France)] |
| | GMP status of the firm | GMP certificate based on evaluation conducted on 22-05-2023 |
| | Evidence of approval of manufacturing facility | Cream/ ointment (General) section approval submitted |
| | **Evaluation Remarks** | |
| | The firm shall submit valid GMP certificate of the applicant before issuance of registration letter. | |
| | **Decision** | |
| | **Approved**<br><br>The firm shall submit valid GMP certificate of the applicant before issuance of registration letter. | |
| 351 | Case Category | Routine (Najia Saleem) |
| | Name, address of Applicant. | **QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7WT-TW3-HQP7, 2024-05-29) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-10, |
| | The proposed proprietary name / brand name | **Levocit 5mg** |
| | Label Claim | Each film coated tablet contains Levocetirizine 2HCl..... 5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1 x 10's and 3x10's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30˚C |
| | For generic drugs (me-too Status) | Neo sedil 5mg tablets of Ms Sami |
| | Pharmacotherapeutic Group of (API) | Antihistamine |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | KARUNESH REMEDIES |
| | Detail of stability batches of drug product | 3 batches of 2300 tablets each |

| | | |
|---|---|---|
| | Documents for the procurement of API with approval from DRAP (in case of Import) | clearance certificate submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP submitted against NEO-SEDIL 5mg of Ms Sami (FAK009 10-2023) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 6 months accelerated and 24 months real time stability studies data submitted as per zone IV-A conditions. |
| | The status in reference regulatory authorities | EMC, FDA |
| | GMP status of the firm | DML granted in 2021 |
| | Evidence of approval of manufacturing facility | Section approval letter dated 17-09-2021 |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 352 | Case Category | New Section (Najia Saleem) |
| | Name, address of Applicant. | **Pearl Pharmaceuticals** 204, Street No. 1, I-10/3 Industrial Area, Islamabad **(000479)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4WH-7VW-9WWS, 2026-02-10) |
| | Detail of Fee Submitted | 38700,<br>2026-01-05, |
| | The proposed proprietary name / brand name | **Colbex Infusion 1g/100ml** |
| | Label Claim | Colbex Infusion 1g/100ml Each 100ml Vial Contains: Paracetamol BP.....1gram (Mfg. BP Specifications) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1X1 Vial/pack-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Paracetamol Infusion should be protected from light. |
| | For generic drugs (me-too Status) | Bofalgan BOSCH Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | analgesics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | CITI PHARMA LIMITED 3.5 KM, HEAD BALOKI ROAD, PHOOL NAGAR, KASUR-PAKISTAN |
| | Detail of stability batches of drug product | 3 batches 150 bottles each |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Local purchase from Ms CITI PHARMA LIMITED PAKISTAN |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE against Bofalgan of Ms Bosch |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | CITI PHARMA LIMITED real time 60month and long term 6month data attached in module-3 |
| | The status in reference regulatory authorities | MHRA.Medicines & Healthcare products Regulatory Agency http://www.mhra.gov. |
| | GMP status of the firm | 27-01-2028 |
| | Evidence of approval of manufacturing facility | submitted |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |

| | | |
|---|---|---|
| 353 | Case Category | New License (Najia Saleem) |
| | Name, address of Applicant. | **OPTIMUS LABORATORIES (PVT.) LTD.** 259 F1 Block Wapda Town **(001010)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8LZ-JQ9-EAJM, 2026-01-28) |
| | Detail of Fee Submitted | 38700,<br>2025-12-16, |
| | The proposed proprietary name / brand name | **Timodor Ophthalmic Solution** |
| | Label Claim | Each ml of Solution Contains: Dorzolamide HCl eq. to Dorzolamide.... 20.0mg Timolol Maleate eq. to Timolol ....5.0mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C in a cool and dry place. |
| | For generic drugs (me-too Status) | Timodor by Hansel Pharmaceuticals Pvt.Ltd. |
| | Pharmacotherapeutic Group of (API) | Dorzolamide HCl: Carbonic anhydrase inhibitors Timolol Maleate: Non-selective beta-adrenergic blocker |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | FLAX LABORATORIES B-29/1, MIDC Mahad, Birvadi village, Dist:- Raigad, Maharashtra,India-402301 Mob.: - +91 9833440269 info@flaxlaboratories.com https://www.flaxlaboratories.com,PRECISE BIOPHARMA PVT LTD Plot No. C-384, T.T.C Industrial Area M.I.D.C Pawane Village Vani Mumbai -400703 (INDIA) |
| | Detail of stability batches of drug product | 600 bottles of each batch. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability studies are according to zone IV A. |
| | The status in reference regulatory authorities | FDA approved |
| | GMP status of the firm | New DML |
| | Evidence of approval of manufacturing facility | Attached. |

**Evaluation Remarks**

| Sr. No. | Observation | Firm's response |
|---|---|---|
| 1. | Procurement documents for Dorzolamide HCl | The material is on a loan basis from Medicaid Pharma, Karachi. API is imported as it was some typographical error in clearance certificate and at that time of approval instead of API name the product name was written in Final Clearance certificate. Upon query to attach corrigendum, the firm has committed to submit the required corrigendum and all supporting documents before |

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|---|---|---|---|
| | | | the issuance of the registration letter |
| | **Decision** | | |
| | **Approved**<br><br>Registration letter shall be issued after the following:<br><br>i. submission of the corrigendum letter for the final clearance certificate<br><br>ii. verification of the loan letter. | | |
| 354 | Case Category | Routine (Sabahat Zehra) | |
| | Name, address of Applicant. | **ACME PHARMACEUTICALS** Plot No. 29, Street SS-2, RCCI Industrial Estate Rawat **(000967)** | |
| | Application Form Dy. No / Tracking ID & date of submission | (D3S-EYT-N558, 2025-09-18) | |
| | Detail of Fee Submitted | 38700,<br>2025-09-18, | |
| | The proposed proprietary name / brand name | **SPIROLIN** | |
| | Label Claim | Each 100 gm contains: Bromhexine HCl — 0.5 gm Lincomycin HCl — 5 gm Spectinomycin HCl — 7.5 gm Spiramycin Adipose — 2.5 gm | |
| | Reference to Finished product specifications | As per Innovators Specification | |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm -De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled | |
| | Shelf Life (Unit) | 2 Year(s)below 30C | |
| | For generic drugs (me-too Status) | Brolin-S Oral Powder Reg# 102027 | |
| | Pharmacotherapeutic Group of (API) | MUcolytic, antibiotics | |
| | Name, address of Manufacturing site: | -- | |
| | GMP status of the firm | The firm has maintained SOP's for internal audit and to handle the market complaints. They are concerned with the training of the employees procedures for the waste management are defined it is advised to strengthen the QA to meet the requirements of exis | |
| | Evidence of approval of manufacturing facility | Present | |
| | **Evaluation Remarks** | | |
| | | | |
| | **Decision** | | |
| | **Approved**<br><br>Approved upto 1kg pack size. | | |
| 355 | Case Category | Import (Sabahat Zehra) | |
| | Name, address of Applicant. | **TAB INTERNATIONAL** First Floor, Commercial Plaza No. 137-A, CCA Block A, Khayaban-e-Amin, Defence Road **(05-352-0065-107628D)** | |
| | Application Form Dy. No / Tracking ID & date of submission | (Q5Q-PDS-G5H8, 2024-08-08) | |
| | Detail of Fee Submitted | 300000.0,<br>2024-08-07, | |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **Marbosav 2%** |
| | Label Claim | Marbosav 2% Each ml contains:<br>Marbofloxacin..... 20mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store at Room Temperature |
| | For generic drugs (me-too Status) | Marbostar Star Lab, Marboflox selmore (Annex-G Page#: 27-28) |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | 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): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 356 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XP4-9ZL-4GRZ, 2024-10-07) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-03, |
| | The proposed proprietary name / brand name | **SENSIBLEX 40 mg/mL SOLUTION FOR INJECTION** |
| | Label Claim | Each mL Contains Denaverine HCI...4Omg (equivalent to 36.5 mg Dena'erine) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)<30C |
| | For generic drugs (me-too Status) | SENSIBLEX 40 mg/mL SOLUTION FOR INJECTION BY MUSTAFA BROTHERS FAISLABAD |
| | Pharmacotherapeutic Group of (API) | Spasmolr tic agent |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

| | | |
|---|---|---|
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |
| | **Approved** | |
| 357 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N5A-D58-MBWD, 2024-10-05) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-03, |
| | The proposed proprietary name / brand name | **GONAVET VEYX 50mcg/mL SOLUTION FOR INJECTION** |
| | Label Claim | Each mL Contains Gonadorelin (As hydrochloride)...50mcg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)2 - 8 C |
| | For generic drugs (me-too Status) | MUSTAFA BROTHERS FAISLABAD |
| | Pharmacotherapeutic Group of (API) | Systemic hormonal preparations excl. sex hormone and insulin |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' prtfle. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and doc |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |
| | **Approved** | |
| 358 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L4D-1QA-PDGU, 2025-02-08) |
| | Detail of Fee Submitted | 37000.0,<br>2025-01-14, |
| | The proposed proprietary name / brand name | **SUPER SPRAY** |
| | Label Claim | Each ml contains: Chlortetracycline HCl .. ... 17.8mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 200 mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)<25C |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | SUPER'S SPRAY HUZAIFA INTERNATIONAL Reg# 094481 |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC ANTISEPTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' prtfle. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and doc |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |
| | **Approved** | |
| 359 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (664-M6J-A6P4, 2025-03-28) |
| | Detail of Fee Submitted | 37000.0,<br>2025-03-24, |
| | The proposed proprietary name / brand name | **GENTA-COMBISONE INJECTION** |
| | Label Claim | Each 100 ml contains Tylosin tartrate.....15g Gentamicin sulphate.....6g Chlorpheniramine.....0.75g Dexamethasone.....0.265g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)<30C |
| | For generic drugs (me-too Status) | LEADS PHARMA (PVT.) LTD. |
| | Pharmacotherapeutic Group of (API) | ANTIBACTERIAL ANTI-INFLAMMATORY ANTIHISTAMINE |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |

| | | |
|---|---|---|
| | **Approved** | |
| 360 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6E9-AZ2-MVRZ, 2024-12-05) |
| | Detail of Fee Submitted | 37000.0,<br>2024-12-04, |
| | The proposed proprietary name / brand name | **GLUCAL 44 INJECTION** |
| | Label Claim | EACH mL CONTAINS Calcium Gluconate .....,.440mg Boric acid . ....60mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)<30C |
| | For generic drugs (me-too Status) | GHAZI BROTHERS KARACHI PAKISTAN |
| | Pharmacotherapeutic Group of (API) | Nutritional Supplement |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' profile, building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |
| | **Approved** | |
| 361 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7NM-HWM-QYHD, 2025-03-28) |
| | Detail of Fee Submitted | 37000.0,<br>2025-03-24, |
| | The proposed proprietary name / brand name | **CEMOL ORAL POWDER** |
| | Label Claim | EACH 100 GRAM CONTAINS Paracetamo1..... ....20G Vitamin C..... .....5G PotassiumCarbonate. ....12.5G Sodium Bicarbonate..... ..12.5G Vitamin E.. . .. .....12.5G |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g , 500g , 1kg ,-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)<30C |
| | For generic drugs (me-too Status) | SELMORE PHARMACEUTICALS (PVT.) LTD. |
| | Pharmacotherapeutic Group of (API) | Antipyretic |
| | Name, address of Manufacturing site: | -- |

| | | |
|---|---|---|
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |
| | **Approved** | |
| 362 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9Q6-6AE-XSVE, 2025-03-28) |
| | Detail of Fee Submitted | 37000.0,<br>2025-03-17, |
| | The proposed proprietary name / brand name | **HICOMIX PLUS POWDER** |
| | Label Claim | Each 100 Gram Contains Sulphachlorpyridazine (as Sodium Sa1t)., . 10G Trirnethoprim.... ... . lG |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 5g, 10g, 100g, 250g -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)<30C |
| | For generic drugs (me-too Status) | HILTON PHARMA (PVT.) LTD |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |
| | **Approved** | |
| 363 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GSN-5JE-MMTY, 2025-03-28) |
| | Detail of Fee Submitted | 37000.0,<br>2025-03-24, |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **KLORA ZINE POWDER** |
| | Label Claim | contains Sulphachloropyridazine. . . . . ...30% |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100G,250G,500G,1KG,2-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)<30C |
| | For generic drugs (me-too Status) | INSHAL PHARMACEUTICAL INDUSTRIES |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In view of above inspection proceedings and facilities verified such as company' profile. building, production, in-process controls, quality control testing, machinery equipment, maternal management, air handling, Water treatment system, personnel and do |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Both GMP, DML certificates are pending however recommended report for renewal of DML is attached. | |
| | **Decision** | |
| | **Approved** | |
| 364 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UJ4-8GJ-7SRD, 2025-12-30) |
| | Detail of Fee Submitted | 38700,<br>2025-12-26, |
| | The proposed proprietary name / brand name | **JF-Calfos-T Oral Powder** |
| | Label Claim | Each 100gm contains: Fosfomycin Calcium...20 gm Tylosin as Tartrate...5 gm (as per Innovators specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 kg-De-Controlled,100gm-De-Controlled,10kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in cool & dry place. |
| | For generic drugs (me-too Status) | Fofact Water Soluble Powder |
| | Pharmacotherapeutic Group of (API) | Antibiotics / Electrolytes |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the premises visited, meeting with technical staff and documents reviewed, all the observations were discussed with management and an earlier compliance was assured by the firm’s management. However, based on the current inspection, the good comp |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |

| | | |
|---|---|---|
| | **Approved** | |
| 365 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NDA-ZHQ-R955, 2025-08-19) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-07, |
| | The proposed proprietary name / brand name | **OXYLEVA DS** |
| | Label Claim | Each 100ml contains Levamisole Hcl ..... 3 g Oxyclozanide .....6 g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | LDPE Bottle 100 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Blow 30 degree celcius |
| | For generic drugs (me-too Status) | NAWAZAN DS Reg#101445 |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found Comply with cGMP in terms of process, Control, Maintanance & Document control |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 366 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J69-M5M-1BBZ, 2025-08-19) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-07, |
| | The proposed proprietary name / brand name | **OXYLEVA DS** |
| | Label Claim | Each 100ml Contains: Levamisole HCl..... 3.0gm Oxyclozanide ..... 6.0gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | LDPE Bottle 1000 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Blow 30 degree celcius |
| | For generic drugs (me-too Status) | NAWAZAN DS |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found Comply with cGMP in terms of process, Control, Maintanance & Document control |

| | | |
|---|---|---|
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 367 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (26G-4GE-83A3, 2025-12-30) |
| | Detail of Fee Submitted | 38700,<br>2025-12-26, |
| | The proposed proprietary name / brand name | **JF-Lyte Oral Powder** |
| | Label Claim | Each Kg Contains: Frusemide....20gm Sodium Chloride.....35gm Potasium Chloride...400mg Magnessium Sulphate.....35gm Manganese Sulphate...1gm Calcium Carbonate....45gm (as per Innovators specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 kg-De-Controlled,100gm-De-Controlled,10kg-De-Controlled,25kg -De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in cool & dry place. |
| | For generic drugs (me-too Status) | Nephralyte Powder Reg#071072 |
| | Pharmacotherapeutic Group of (API) | Diuretic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the premises visited, meeting with technical staff and documents reviewed, all the observations were discussed with management and an earlier compliance was assured by the firm’s management. However, based on the current inspection, the good comp |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Approved upto 1kg pack size. | |
| | **Decision** | |
| | **Approved** | |
| 368 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U7W-EEJ-A8R3, 2025-11-27) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **AR OXYMED-95 ORAL POWDER** |

| | | |
|---|---|---|
| | Label Claim | Each 1000Gm contains: Oxytetracycline HCl (BP)..... 950Gm |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 500 gm 1000 gm & 5 Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)store at BELOW 25 C |
| | For generic drugs (me-too Status) | OXYCYCLIN POWDER Reg# 103976 |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | APPROVED |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Approved upto 1 kg pack size. | |
| | **Decision** | |
| | **Approved** | |
| 369 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B8J-3GJ-LE7V, 2025-11-27) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **AR OXYMED-50 ORAL POWDER** |
| | Label Claim | Each 1000 Gm contains: Oxytetracycline (as HCl) ..... 500Gm (Eq. to 540gm of Oxytetracycline HCl) (BP Vet. Specifications) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 500 gm 1000 gm & 5 Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)store at room temperature |
| | For generic drugs (me-too Status) | OXYVETO-50 S SOLUBLE POWDER Reg# 049545 |
| | Pharmacotherapeutic Group of (API) | Tetracycline antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | APPROVED |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Approved upto 1 kg pack size. | |
| | **Decision** | |
| | **Approved** | |
| 370 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (22B-4MY-ERZM, 2025-10-08) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **AR Amanta Med-98 Water Soluble Powder** |

| | | |
|---|---|---|
| | Label Claim | Each 100gm contains:- Amantadine HCl.....98gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 gm., 250 gm., 500 gm., 1000 gm., 2500 gm. 5000-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | Roxidine-98 Water Soluble Powder by Vetrox Pharmaceuticals (Reg#111283) |
| | Pharmacotherapeutic Group of (API) | Antiviral |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Company complies with CGMP |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Formulation contains AMANTADINE as ingredient. And target species mentioned in dossier is POULTRY. | |
| | **Decision** | |
| | **Rejected**<br><br>The Sub-committee on Veterinary Drugs recommended restricting the use of Amantadine formulations to non-food-producing animals only, while the firm has mentioned target species poultry. | |
| 371 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BBT-W89-4SLQ, 2025-10-07) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **AR Med Ofzole Plus Oral Drench** |
| | Label Claim | Each ml contains:<br>Oxfendazole.....22.65mg Cobalt Sulphate.....3.820mg Sodium Selenite.....0.350mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml,150ml, 250 ml, 450 ml, 500 ml, 1000 ml, 250-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | OCS Drench by Evergreen Pharma (Reg#073992) |
| | Pharmacotherapeutic Group of (API) | Antihelmintics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Company complies with CGMP |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 372 | Case Category | Routine (Sabahat Zehra) |

| | | |
|---|---|---|
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J1U-NVW-H8EM, 2025-10-08) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **AR Med Trizole Oral Drench** |
| | Label Claim | Each 100ml contains:<br>Albendazole.....10g<br>Ivermectin.....2g<br>Triclabendazole.....12g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml,150ml, 250 ml, 450 ml, 500 ml, 1000 ml, 250-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | Aximec Oral Drench by Evergreen Pharma (Reg#088863) |
| | Pharmacotherapeutic Group of (API) | Antihelmintics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Company complies with CGMP |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 373 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JZX-UJ3-J9MB, 2025-10-07) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **AR Med Levo Plus Oral Drench** |
| | Label Claim | Each ml contains: Levamisole HCl.....15.00mg Cobalt Sulphate.....3.82mg Sodium Selenite.....0.50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml,150ml, 250 ml, 450 ml, 500 ml, 1000 ml, 250-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | Levogreen Drench by Evergreen Pharma (Reg#073990) |
| | Pharmacotherapeutic Group of (API) | Antihelmintics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Company complies with CGMP |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved** | |
| 374 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)** |
| | Application Form Dy. No / Tracking ID & date of submission | (H8Z-UXJ-LBW2, 2025-10-08) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **AR Med Trilevo Oral Drench** |
| | Label Claim | Levamisole HCl.....37.5mg/ml Triclabendazole.....50mg/ml Cobalt Sulphate.....1.67mg/ml Sodium Selenite....0.035mg/ml |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml,150ml, 250 ml, 450 ml, 500 ml, 1000 ml, 250-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | Tribex Drench by Evergreen Pharma (Reg#073989) |
| | Pharmacotherapeutic Group of (API) | Antihelmintics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Company complies with CGMP |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved** | |
| 375 | Case Category | New License (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Xealth Pharma (Pvt) Ltd** Plot No. A-21, 22, Small Industrial Estate, Bhimber, Azad Kashmir **(001021)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5R1-J49-XLJP, 2026-02-19) |
| | Detail of Fee Submitted | 38700,<br>2026-02-18, |
| | The proposed proprietary name / brand name | **NOVA FEN 25 ORAL LIQUID** |
| | Label Claim | Each 100 ml contains:- Florfenicol.....25 gm Colistin Sulphate.....500MIU (as per innovators specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ML, 150 ML, 250 ML, 500 ML, 1000 ML-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Temperature |
| | For generic drugs (me-too Status) | Arch Rotin 25% Liquid (121913) |
| | Pharmacotherapeutic Group of (API) | Amphenicol Antibiotics |
| | Name, address of Manufacturing site: | -- |

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| | GMP status of the firm | Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved** | |
| 376 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BAARIQ PHARMACEUTICALS** Plot # 600, Sundar Industrial Estate,Sundar Raiwind Road, Lahore **(000715)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZX3-3SL-16ZV, 2025-11-12) |
| | Detail of Fee Submitted | 38700,<br>2025-11-12, |
| | The proposed proprietary name / brand name | **LYSOBAR ORAL POWDER** |
| | Label Claim | Each gm Powder Contains:<br>LYSOZYME.....22 % VITAMIN E 50 SD.....0.5% |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 gm-De-Controlled,1000 gm-De-Controlled,250 gm-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 25 degree |
| | For generic drugs (me-too Status) | APLA-ZEE Oral Powder Reg.no. 097887 |
| | Pharmacotherapeutic Group of (API) | Antibiotic & Nutritionary Supplement |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Inspection of renewal of DML is pending however, fee for renewal has been submitted on time. | |
| | **Decision** | |
| | **Approved** | |
| 377 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BAARIQ PHARMACEUTICALS** Plot # 600, Sundar Industrial Estate,Sundar Raiwind Road, Lahore **(000715)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (TJJ-6YP-RVRH, 2025-11-13) |
| | Detail of Fee Submitted | 38700,<br>2025-11-12, |
| | The proposed proprietary name / brand name | **THIARIQ ORAL LIQUID** |
| | Label Claim | Each ml contains<br>THIAMPHENICOL.....250mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml-De-Controlled,1000 ml-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 25 degree |
| | For generic drugs (me-too Status) | THIAMAX ORAL LIQUID reg# 118454 |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Inspection of renewal of DML is pending however, fee for renewal has been submitted on time. | |
| | **Decision** | |
| | **Approved** | |
| 378 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BAARIQ PHARMACEUTICALS** Plot # 600, Sundar Industrial Estate,Sundar Raiwind Road, Lahore **(000715)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T5X-ZU5-PJML, 2025-11-13) |
| | Detail of Fee Submitted | 38700,<br>2025-11-12, |
| | The proposed proprietary name / brand name | **SILYRIQ ORAL SUSPENSION** |
| | Label Claim | Each ml contains SILYMARIN.....21mg<br>VITAMIN E.....15mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml-De-Controlled,1000 ml-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 25 degree |
| | For generic drugs (me-too Status) | HEPATOCARE ORAL SUSPENSION Reg# 062167 |
| | Pharmacotherapeutic Group of (API) | Immunomodulating + nutritional agents |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the |

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| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Inspection of renewal of DML is pending however, fee for renewal has been submitted on time. | |
| | **Decision** | |
| | **Approved** | |
| 379 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1TE-VDB-L189, 2025-12-31) |
| | Detail of Fee Submitted | 38700,<br>2025-12-29, |
| | The proposed proprietary name / brand name | **TOLTRAMAG-50 ORAL LIQUID** |
| | Label Claim | Each 100ml contains: Toltrazuril ---------- 5 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,25000ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Toltrazone-5 Oral Solution (117059) |
| | Pharmacotherapeutic Group of (API) | Anti-Coccidiosis |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 380 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3BP-V7U-EA5X, 2025-12-31) |
| | Detail of Fee Submitted | 38700,<br>2025-12-29, |
| | The proposed proprietary name / brand name | **AVIBRO-100 ORAL SOLUTION** |
| | Label Claim | Each 100ml contains: Bromhexine HCl ---------- 10 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10 Lit-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |

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| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | EBROM-LYTIC 10% ORAL Liquid (099317) |
| | Pharmacotherapeutic Group of (API) | Mucolytic Agent |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 381 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3PN-N1E-T672, 2025-08-15) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-15, |
| | The proposed proprietary name / brand name | **TRULEVO-SC ORAL LIQUID** |
| | Label Claim | Each 100ml contains: Levamisole HCl ---------- 1.5 gm Cobalt Sulphate ---------- 0.382 gm Sodium Selenite ---------- 0.030 gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | LEVASAR CS Oral Liquid (058884) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 382 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6HR-DMG-1287, 2025-12-30) |
| | Detail of Fee Submitted | 38700,<br>2025-12-29, |

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| | The proposed proprietary name / brand name | **AMPICARE-60 POWDER** |
| | Label Claim | Each gm contains: Amprolium HCl..... 600 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Bio-Amprol 60 Powder (063773) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 383 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AJR-Z1L-8U91, 2025-09-26) |
| | Detail of Fee Submitted | 38700,<br>2025-09-20, |
| | The proposed proprietary name / brand name | **ENTEROFIX ORAL POWDER** |
| | Label Claim | Each 12gm contains: Neomycin Sulphate ..... 400 mg Streptomycin Sulphate .....400 mg Sulphaguanidine .....4 gm Pectin .....400 mg Bismuth Subnitrate .....2 gm Vitamin A Acetate .....80000 IU Kaolin .....4 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,12gm-De-Controlled,250gm-De-Controlled,25gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Diarroban Powder (026438) |
| | Pharmacotherapeutic Group of (API) | Antidiarrheal |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |

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| | **Decision** | |
| | **Approved** | |
| 384 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DZ5-W9P-5EG6, 2025-11-27) |
| | Detail of Fee Submitted | 38700,<br>2025-11-25, |
| | The proposed proprietary name / brand name | **SYN NEO-70 ORAL POWDER** |
| | Label Claim | Each 1000gm contains: Neomycin Sulphate..... 700 gm (As Per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Neo-Hans 70% Water Soluble Powder (102210) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 385 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LXJ-GYJ-HEYD, 2025-12-31) |
| | Detail of Fee Submitted | 38700,<br>2025-12-29, |
| | The proposed proprietary name / brand name | **MAJIDOX-50 ORAL WATER SOLUBLE POWDER** |
| | Label Claim | Each gm contains: Doxycycline Hyclate ..... 500 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled |

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| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Dox Plus 50% Water Soluble Powder (082498) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 386 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9HV-L88-76LB, 2025-08-25) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-21, |
| | The proposed proprietary name / brand name | **LEVAWORM 1.5% ORAL SOLUTION** |
| | Label Claim | Composition: Levamisole HCl ---------- -- 1.5 % W/V |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Sanamisol Oral Solution (025717) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 387 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XW2-ZXE-MQG4, 2025-12-31) |
| | Detail of Fee Submitted | 38700,<br>2025-12-29, |
| | The proposed proprietary name / brand name | **TYLOMAG-100 ORAL POWDER** |

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| | Label Claim | Each 100gm contains: Tylosin Phosphate ..... 10 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm-De-Controlled,25000gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | I-Tylophos Oral Powder (069634) |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 388 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W73-PL3-AZXB, 2025-12-31) |
| | Detail of Fee Submitted | 38700,<br>2025-12-31, |
| | The proposed proprietary name / brand name | **VITA FLUSH ORAL POWDER** |
| | Label Claim | Each 100gm contains: Methenamine ..... 95 gm Vitamin K3 ..... 0.20 gm Vitamin B1 ..... 0.80 gm Vitamin B2 ..... 0.92 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Farlush Powder (033275) |
| | Pharmacotherapeutic Group of (API) | diuretic agent and detoxifying agen |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 389 | Case Category | Routine (Sabahat Zehra) |

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| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R15-LDU-JNEU, 2025-08-25) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-21, |
| | The proposed proprietary name / brand name | **ALBAMAG 2.5% ORAL SUSPENSION** |
| | Label Claim | Each ml Contains: Albendazole ---------- ----- 25 mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Sanazole Oral Suspension (023483) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Approved up to 1 liter pack size. | |
| | **Decision** | |
| | **Approved** | |
| 390 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E97-ZZG-DP1M, 2025-08-25) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-21, |
| | The proposed proprietary name / brand name | **OXAMAG ORAL DRENCH** |
| | Label Claim | Each ml Contains: Oxfendazole ---------- ----- 22.65 mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Oxasel Drench (071084) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |

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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 391 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q9Q-DXB-TDEH, 2025-08-08) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **TRUFENDA-SC ORAL DRENCH** |
| | Label Claim | Each ml Contains: Oxfendazole ---------- ----- 22.65 mg Cobalt Sulphate ---------- ----- 3.82 mg Sodium Selenite ---------- -- 0.35 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Oxfendacon Plus Drench (057194) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 392 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TUL-JZD-9HDR, 2025-10-15) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **PURE-C Oral Powder** |
| | Label Claim | Each gm Contains: Ascorbic Acid (Vitamin C) ... 1,000mg As per Innovattor's Specification |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 20gm, 50gm, 100gm, 500gm, 1000gm, 5Kg, 25Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 25ºC |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | i. SANNAVIT C 100 Oral Powder of M/s. Sanna Labs (Reg. No. 025368) ii. C-Kam 100 Powder of M/s. M.A.Kamil Farma (Reg. No. 119760) |
| | Pharmacotherapeutic Group of (API) | Vitamin Supplement/ Antioxidant |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfacotry |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 393 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TVZ-RHJ-X78R, 2025-10-15) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **GENTACOMPLEX INJECTION** |
| | Label Claim | Each ml contains: Gentamicin (as Sulphate) ... 30mg Sulphadimidine (as Sodium) ... 125mg Trimethoprim ..... 25mg As per Innovator's Specifications |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)b |
| | For generic drugs (me-too Status) | Flax Injection (100ml) of M/s. Nawal Pharmaceuticals, Taxila, Rawalpindi. (Reg. No. 097900) |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfacotry |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 394 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NT6-B63-XDGL, 2025-10-16) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **BIOSON INJECTION** |

| | | |
|---|---|---|
| | Label Claim | Each ml contains: Novaminsulfon ... 40mg Etilefrin as HCl ... 0.2mg Calcium Gluconate ... 100mg Magnesium Gluconate ... 10mg Sodium Salicylate ... 7mg Nicotinamide ... 0.3mg Caffeine ... 10mg Boric Acid ... 10mg (As per Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 25ºC |
| | For generic drugs (me-too Status) | Nicofrin Inj (500ml) of M/s. Leads Pharma (Reg. No. 058863) |
| | Pharmacotherapeutic Group of (API) | NSAID / Analgesic / Antipyretic / Anti-inflammatory / Mineral Supplement / Electrolyte Replenisher / Antiseptic / Antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfacotry |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 395 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E11-SAH-ZHVM, 2025-10-16) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **GTC INJECTION** |
| | Label Claim | Each ml contains: Gentamicin (as Sulphate) ... 50mg Tylosin Factor (A) ... 100mg Colistin Sulphate ... 0.20 m.i.u As per Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 25ºC |
| | For generic drugs (me-too Status) | Gentyle+C Inj (100ml) of M/s. Intervac Pharma (Reg. No. 080723) |
| | Pharmacotherapeutic Group of (API) | Antibiotic/ Antimicrobial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfacotry |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |

| | | |
|---|---|---|
| 396 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Amazon Pharmaceuticals Pvt Ltd** Plot No 10/A & 29/B Small Industrial Estate Bhimber Ajk Kashmir **(000975)** |
| | Application Form Dy. No / Tracking ID & date of submission | (16L-GAG-R3VT, 2025-10-16) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **TYLOZON-20 INJECTION** |
| | Label Claim | Each ml contains: - Tylosin (as Tartrate) ... 200mg As per B.P Specification |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Below 25ºC |
| | For generic drugs (me-too Status) | i. Fartylo 200 Injection (100ml) of M/s. Prix Pharmaceutical (Pvt.) Ltd. (Reg. No. 020761) ii. Tylox-20 Injection (100ml) of M/s. Breeze Pharma (Pvt.) Ltd. (Reg. No. 075655) |
| | Pharmacotherapeutic Group of (API) | Macrolide Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfacotry |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 397 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2U6-GZA-16P5, 2025-08-09) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-08, |
| | The proposed proprietary name / brand name | **DON-98 Water Soluble Powder** |
| | Label Claim | Each gm Contains: Amantadine Hydrochloride ----- 980mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | Ranio Dine 98% Water Soluble Powder of M/s Kayans Pharmaceuticals Industries (Reg. No. 113492) |
| | Pharmacotherapeutic Group of (API) | Antiviral |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |

| | | |
|---|---|---|
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Formulation contains AMANTADINE as an ingredient. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred until the required information on the target species is provided. | |
| 398 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3ER-8V8-1W9A, 2025-08-09) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-08, |
| | The proposed proprietary name / brand name | **GESTOL Powder** |
| | Label Claim | Each 1000gm contains: Propionic Acid Calcium 250gm, Propionic Acid Sodium 400gm, Acetanilide 150gm, Magnesium Oxide 125gm, Iron II Sulphate 400mg, Zinc Sulphate 100mg, Magnesium Sulphate 200mg, Copper Sulphate 450mg, Cobalt Sulphate 400mg, Sodium Molybdate 100mg, Sodium Chloride 20gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | Anigest Powder of M/s Mylab Pvt. Ltd. (Reg. No. 073906) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 399 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4A5-D3U-ER38, 2025-08-09) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-08, |
| | The proposed proprietary name / brand name | **En-C40 Liquid** |

| | | |
|---|---|---|
| | Label Claim | Each 100ml Contains: Enrofloxacin 20gm, Colistin Sulphate 20MIU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,200 L-De-Controlled,25 L-De-Controlled,5 L-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | Aprotin-20 Liquid of M/s Aptly Pharmaceuticals (Reg. No. 093837) |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 400 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VD1-VS1-2PWX, 2025-08-09) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-08, |
| | The proposed proprietary name / brand name | **MILK TASK Powder** |
| | Label Claim | Each Kg contains: Vitamin A 0.8gm, Vitamin D 0.16gm, Vitamin E 0.38gm, Vitamin B1 1gm, Vitamin B2 1.25gm, Vitamin B12 0.001gm, Vitamin B3 6.25gm, Copper Sulphate 0.25gm, Magnesium Sulphate 25gm, Calcium Chloride 0.023gm, Zinc Sulphate 2.17gm, Manganese Sulphate 10gm, Potassium Iodide 0.5gm, Sodium Selenite 0.01gm, Dicalcium Phosphate 150gm, Sodium Chloride 120gm, Vitamin B6 4gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | WHITE GOLD Powder of M/s Leads Pharma (Reg. No. 058842) |
| | Pharmacotherapeutic Group of (API) | Vitamin & Minerals |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |

| | | |
|---|---|---|
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 401 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DR4-B2J-B457, 2025-08-09) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-08, |
| | The proposed proprietary name / brand name | **FEGEST Water Soluble Oral Powder** |
| | Label Claim | Each 1000gm contains: Ca-Propionate 201gm, Na-Propionate 402.7gm, Mag-Sulfate 124gm, Iron Sulfate 0.41gm, Na-Chloride 264.3gm, Vitamin A 750000IU, Vitamin D3 350000IU, Zn-Sulfate 0.11gm, Mn-Sulfate 0.21gm, Cu-Sulfate 0.45gm, Co-Chloride 0.41gm, Na-Selenite 0.11gm, Dicalcium Phosphate 3000mg, Vitamin E 1000mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | Sanatone Water Soluble Oral Powder of M/s Sanna Laboratories (Reg. No. 035128) |
| | Pharmacotherapeutic Group of (API) | Vitamin & Minerals |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 402 | Case Category | Import (Sabahat Zehra) |
| | 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 | (M3V-LW5-TP8L, 2025-08-28) |
| | Detail of Fee Submitted | 300000.0,<br>2025-07-23, |
| | The proposed proprietary name / brand name | **BACTECLEAN-S 50% POWDER** |

| | | |
|---|---|---|
| | Label Claim | Each 1 gm contains: Doxycycline hyclate 500 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 200gm, 1000gm-De-Controlled |
| | Shelf Life (Unit) | 4 Year(s)Sore at room temperature |
| | For generic drugs (me-too Status) | Doxycycline Hyclate VMD 500 mg/g Powder for Use in Drinking Water for Chickens |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | Arab Veterinary Industrial Co. (AVICO)-Arab Veterinary Industrial Co. (AVICO), P.O.BOX 150906 Amman 11115 – Jordan-Jordan |
| | Name, address of Marketing Authorization Holder: | U.M. Enterprises, Plot 12 sector 14 Korangi industrial Karachi, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | Present |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. | |
| 403 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZW7-6Q3-5JNR, 2025-08-05) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-29, |
| | The proposed proprietary name / brand name | **T-TAR Water Soluble Powder** |
| | Label Claim | Each 1000gm Contains: Tylosin Tartrate 500gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10gm-De-Controlled,1kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | Z-TARTRATE Water Soluble Powder of M/s Zoic International (Reg. No. 099413) |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |

| | | |
|---|---|---|
| | Approved up to 1 kg pack size. | |
| 404 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (REG-Z66-S7WN, 2025-08-05) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-29, |
| | The proposed proprietary name / brand name | **TRI-LSO Oral Liquid** |
| | Label Claim | Each ml Contains: Triclabendazole 120mg, Levamisole HCl 75mg, Cobalt Chloride 0.75mg, Sodium Selenite 0.35mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,200 L-De-Controlled,25 L-De-Controlled,5 L-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | Clovetz SC Oral Liquid of M/s Vetz Pharma (Reg. No. 089831) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 405 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NTV-VRA-ZR1Y, 2025-08-05) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-29, |
| | The proposed proprietary name / brand name | **SULDRAZINE Oral Liquid** |
| | Label Claim | Each 100ml Contains: Trimethoprim B.P 8%, Sulfadiazine B.P 40% |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,200 L-De-Controlled,25 L-De-Controlled,5 L-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | TRIZINE Oral Liquid of M/s Attabak Pharmaceuticals (Reg. No. 062162) |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 406 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Faisons Meilleur Pharmaceuticals International (Pvt.) Ltd.** 28-KM, Ferozpur Road, Lahore **(001005)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5U3-EH1-85VX, 2025-08-05) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-29, |
| | The proposed proprietary name / brand name | **OSCO Oral Drench** |
| | Label Claim | Each ml Contains: Oxyclozanide --------- 62.50mg Oxfendazole ---------- 22.65mg Cobalt Sulphate ----- 1.67mg Sodium Selenite ----- 0.50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,200 L-De-Controlled,25 L-De-Controlled,5 L-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 degrees centigrade, Protect from heat & Sunlight. |
| | For generic drugs (me-too Status) | Oxfendaox Plus Oral Drench of M/s Baariq Pharmaceuticals (Reg. No. 075786) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel is of the opinion to recommend the grant of new drug Manufacturing License |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 407 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **VETEC LABORATORIES** Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi **(000893)** |

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|---|---|---|
| | Application Form Dy. No / Tracking ID & date of submission | (GVH-HHZ-ZJYQ, 2025-03-25) |
| | Detail of Fee Submitted | 37000.0,<br>2025-03-12, |
| | The proposed proprietary name / brand name | **VET SONEX** |
| | Label Claim | Each ml contains:<br>Sulphadiazine.....35.50mg<br>Sulphadimidine.....28.40mg Neomycin sulphate.....1.80mg Hyoscine N methyl bromide.....0.04mg<br>Pectin.....7.10mg<br>Kaolin.....103.30mg Vitamin B1.....0.15mg Vitamin B2.....0.22mg Vitamin B6.....0.15mg Vitamin K3.....4mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,25Liter-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room temperature |
| | For generic drugs (me-too Status) | Rexin oral suspension, 118400 |
| | Pharmacotherapeutic Group of (API) | Antibiotic, Antidiarrheal |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | GOOD |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Rs: 9400/- fee has been submitted for the standardization of label claim. | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 408 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **A&K Pharmaceutical,** 94-A, Punjab small industrial Estate, Sargodha Road, Faisalabad **(000534)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YDX-XBZ-QH55, 2025-11-13) |
| | Detail of Fee Submitted | 38700,<br>2025-11-11, |
| | The proposed proprietary name / brand name | **Nicacin-50** |
| | Label Claim | Each ml contains Oxytetracycline HCI ..... 50mg Lignocaine HCI..... 10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s) Store in a cool and dry palace Protect from heat and sun light Keep all medicines out of the reach of the children. |
| | For generic drugs (me-too Status) | OxyJet-50 Injection 50ml Grand Pharma Pvt Ltd Islamabad |
| | Pharmacotherapeutic Group of (API) | Antibiotics |

| | | |
|---|---|---|
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | GOOD |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 409 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **A&K Pharmaceutical,** 94-A, Punjab small industrial Estate, Sargodha Road, Faisalabad **(000534)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BBA-N77-VAY9, 2025-11-13) |
| | Detail of Fee Submitted | 38700,<br>2025-11-11, |
| | The proposed proprietary name / brand name | **Nicacin-50** |
| | Label Claim | Each ml contains Oxytetracycline HCI.....50mg Lignocaine HCI.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s) Store in a cool and dry palace Protect from heat and sun light Keep all medicines out of the reach of the children. |
| | For generic drugs (me-too Status) | 111562 OxyJet-50 Injection 100ml Grand Pharma Pvt Ltd Islamabad |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | GOOD |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 410 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **A&K Pharmaceutical,** 94-A, Punjab small industrial Estate, Sargodha Road, Faisalabad **(000534)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ARL-JJZ-P9MX, 2025-11-13) |
| | Detail of Fee Submitted | 38700,<br>2025-11-11, |
| | The proposed proprietary name / brand name | **Nicacin-100** |
| | Label Claim | Each ml contains Oxytetracycline HCI.....100mg Lignocaine HCI.....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50 ml-De-Controlled |

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|---|---|---|
| | Shelf Life (Unit) | 2 Year(s) Store in a cool and dry palace Protect from heat and sun light Keep all medicines out of the reach of the children. |
| | For generic drugs (me-too Status) | 111563 OxyJet-100 Injection 50ml Grand Pharma Pvt Ltd Islamabad |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | GOOD |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 411 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **A&K Pharmaceutical,** 94-A, Punjab small industrial Estate, Sargodha Road, Faisalabad **(000534)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NPM-LDM-J7YG, 2025-11-14) |
| | Detail of Fee Submitted | 38700,<br>2025-11-11, |
| | The proposed proprietary name / brand name | **Nicacin-100** |
| | Label Claim | Each ml contains Oxytetracycline HCI...100mg Lignocaine HCI....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s) Store in a cool and dry palace Protect from heat and sun light Keep all medicines out of the reach of the children. |
| | For generic drugs (me-too Status) | 111564 OxyJet-100 Injection 100 ml Grand Pharma Pvt Ltd Islamabad |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | GOOD |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 412 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **A&K Pharmaceutical,** 94-A, Punjab small industrial Estate, Sargodha Road, Faisalabad **(000534)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DGB-5JT-5XDR, 2025-10-24) |
| | Detail of Fee Submitted | 38700,<br>2025-10-21, |

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|---|---|---|
| | The proposed proprietary name / brand name | **MILKO-GOLD MINERALS (ORAL)** |
| | Label Claim | EACH 1 KG CONTAINS Vitamin A.....0.8 gm , Vitamin D3.....0.16 gm, Vitamin E..... 0.38gm, Vitamin B1.....1 gm, Vitamin B2.....1.25gm, Vitamin B12.....0.001gm, Vitamin B6.....6.25gm, Copper Sulphate.....0.25gm, Magnesium Sulphate.....25gm, Calcium Chloride.....0.023gm, Zinc Sulphate = 2.17gm , Manganese Sulphate.....10gm, Potassium Iodide .....0.5gm, Sodium Selenite .....0.01gm, Dibasic Calcium Phosphate (Phosphorus) 150gm, Sodium Chloride....20gm, Vitamin B6 .....4gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 kg-De-Controlled,10 kg-De-Controlled,25 kg-De-Controlled,5 kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s) Store in a cool and dry palace Protect from heat and sun light Keep all medicines out of the reach of the children. |
| | For generic drugs (me-too Status) | REG# 058842, M/S LEADS PHARMA ISLAMABAD, WHITE GOLD POWDER |
| | Pharmacotherapeutic Group of (API) | Immunologiocal, Electrolyte, Multivitamins |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | GOOD |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 413 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (14L-9W7-84AA, 2025-08-19) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-07, |
| | The proposed proprietary name / brand name | **OXYLEVA DS** |
| | Label Claim | Each 100ml Contains: Levamisole HCl.....<br>3.0gm Oxyclozanide .....<br>6.0gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | LDPE Bottle 500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Blow 30 degree cecius |
| | For generic drugs (me-too Status) | NAWAZAN DS |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found Comply with cGMP in terms of process, Control, Maintanance & Document control |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |

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| | **Decision** | |
| | **Approved** | |
| 414 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (H25-MRY-D544, 2025-08-24) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-22, |
| | The proposed proprietary name / brand name | **JFTALEX** |
| | Label Claim | Each ml contains: Buparvaquone BP..... 50.0mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 20ml Glass Vial-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Blow 30 degree celcius |
| | For generic drugs (me-too Status) | Parvon M/s Selmore Pharmaceutica |
| | Pharmacotherapeutic Group of (API) | Antiprotozoal |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found Comply with cGMP in terms of process, Control, Maintanance & Document control |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 415 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BAARIQ PHARMACEUTICALS** Plot # 600, Sundar Industrial Estate,Sundar Raiwind Road, Lahore **(000715)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2PS-EY8-PZDM, 2025-11-13) |
| | Detail of Fee Submitted | 38700,<br>2025-11-12, |
| | The proposed proprietary name / brand name | **NOXABECT ORAL LIQUID** |
| | Label Claim | Each 100ml contains NORFLOXACIN.....20gm COLISTIN SULPHATE.....60MIU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100 ml-De-Controlled,1000 ml-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 25 degree |
| | For generic drugs (me-too Status) | COLI-NOR ORAL LIQUID Reg# 049501 |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC |
| | Name, address of Manufacturing site: | -- |

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|---|---|---|
| | GMP status of the firm | Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 416 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BAARIQ PHARMACEUTICALS** Plot # 600, Sundar Industrial Estate,Sundar Raiwind Road, Lahore **(000715)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MBV-D3E-RAMM, 2025-11-12) |
| | Detail of Fee Submitted | 38700,<br>2025-11-12, |
| | The proposed proprietary name / brand name | **NOXARIQ ORAL LIQUID** |
| | Label Claim | Each 100ml contains NORFLOXACIN.....20gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100 ml-De-Controlled,1000 ml-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 25 degree |
| | For generic drugs (me-too Status) | PRIX Pharmaceutical Lahore Reg# 058709 |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and the review of the production facilities, building, equipment, quality control and quality assurance, the |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 417 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NM4-E8D-E3WJ, 2025-08-18) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-12, |
| | The proposed proprietary name / brand name | **BIOPAN INJECTION** |

| | | |
|---|---|---|
| | Label Claim | Each ml contains: - Butylscopolamine.....4mg Metamizole.....500mg (Innovator Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml, 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Room Condition |
| | For generic drugs (me-too Status) | N/A` |
| | Pharmacotherapeutic Group of (API) | Antispasmodics Analgesic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Applied |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | 1. Salt form of scopolamine is different from provided RRA product. 2. Stability is not provided. | |
| | **Decision** | |
| | **Deferred**<br><br>The instant case is deferred because pending confirmation of the exact RRA status, stability profile of drug product as per zone IV A. Based on the AEMPS CIMAVET database, the medicinal product has been suspended in Spain since March 2025. Confirmation of the current regulatory status is required to complete the case assessment. | |
| 418 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (69T-HJ2-GZRQ, 2025-12-08) |
| | Detail of Fee Submitted | 38700,<br>2025-12-02, |
| | The proposed proprietary name / brand name | **Norzin Liquid** |
| | Label Claim | Each 100 ml contains:<br>Norfloxacin.....10gm<br>Sulphamethoxypyridazine.....15gm<br>Trimethoprim.....3gm (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 Liter-De-Controlled,10 Liters-De-Controlled,100mL-De-Controlled,2.5 Liters-De-Controlled,25 Liters-De-Controlled,250mL-De-Controlled,5 Liters-De-Controlled,500mL-De-Controlled,50mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C in a cool and dry place. Protect form light |
| | For generic drugs (me-too Status) | Product Name:: Nortrim-S Oral Liquid, Registration No: 075779, By; Decent Pharma. Plot No. 30, Street No. SS-3, RCCI, Rawat Rawalpindi |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The management is highly inclined towards manufacturing good quality products by |

| | | |
|---|---|---|
| | | improving industry. The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 419 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L6Y-HU1-5TA8, 2025-10-16) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **C-FLOX LIQUID** |
| | Label Claim | Each ml contains:<br>Enrofloxacin.....200mg Colistin Sulphate.....0.20MIU (As per Innovator's Specs.) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 LITER-De-Controlled,10 LITER-De-Controlled,100 ML-De-Controlled,150 ML-De-Controlled,2.5 LITER-De-Controlled,250 ML-De-Controlled,5 LITER-De-Controlled,500 ML-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Keep in Cool and dry place. Keep out of reach of children. |
| | For generic drugs (me-too Status) | Enroflox - C 40 Liquid Reg No: 122380 of Amazone Pharmaceuticals Mirpur, AJK |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>approved up to1liter pack size. | |
| 420 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PVD-275-UGE7, 2025-12-03) |
| | Detail of Fee Submitted | 38700,<br>2025-12-02, |

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|---|---|---|
| | The proposed proprietary name / brand name | **MERIN-E LIQUID** |
| | Label Claim | Each ml contains: Silymarin.....21mg Vitamin E.....15mg (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 Liter-De-Controlled,10 Liters-De-Controlled,100 mL-De-Controlled,2.5 Liters-De-Controlled,25 Liters-De-Controlled,250mL-De-Controlled,5 Liters-De-Controlled,50 mL-De-Controlled,500mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C in a cool and dry place. Protect form light |
| | For generic drugs (me-too Status) | Brand Name: Silinex 20 Oral Liquid Drug Reg. Number: 126029 by Ruth Pharmaceutical 1.5 KM Bhatti Mansoor Road, Main GT Road, Ghakhar, Gujranwala |
| | Pharmacotherapeutic Group of (API) | Hepatoprotective Agent, Antioxidant |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The management is highly inclined towards manufacturing good quality products by improving industry. The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 421 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q5V-PPZ-6AW8, 2025-12-03) |
| | Detail of Fee Submitted | 38700,<br>2025-12-02, |
| | The proposed proprietary name / brand name | **Colinor Liquid** |
| | Label Claim | Each 100 ml contains: Norfloxacin.....20gm Colistin Sulphate .....60MIU (As per Innovator's Specifications.) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 Liter-De-Controlled,10 Liter-De-Controlled,100mL-De-Controlled,2.5 Liter-De-Controlled,25 Liter-De-Controlled,250mL-De-Controlled,5 Liter-De-Controlled,500mL-De-Controlled,50mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C in a cool and dry place. Protect form light |
| | For generic drugs (me-too Status) | Brand Name: N. C Mont Oral Liquid Drug Reg. Number: 049766 by Westmont Pharmaceutical Industry, Mini Industrial Estate, GT Road Gujar Khan |

| | | |
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| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The management is highly inclined towards manufacturing good quality products by improving industry. The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 422 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ULW-NWT-PANR, 2025-12-08) |
| | Detail of Fee Submitted | 38700,<br>2025-12-02, |
| | The proposed proprietary name / brand name | **Bromothol Liquid** |
| | Label Claim | Each ml contains: Bromhexine HCl .....<br>20mg Menthol.....40mg (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 Liter-De-Controlled,10 Liters-De-Controlled,100mL-De-Controlled,2.5 Liters-De-Controlled,25 Liters-De-Controlled,250mL-De-Controlled,5 Liters-De-Controlled,500mL-De-Controlled,50mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C in a cool and dry place. Protect form light |
| | For generic drugs (me-too Status) | Product Name:: BISCOMIN VL-20 ORAL LIQUID Registration No: 099314, By: VETEC LABORATORIES; Plot No. 20, Street S-5, National Industrial Zone (RCCI), Rawat, Rawalpindi |
| | Pharmacotherapeutic Group of (API) | Mucolytic Agent |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The management is highly inclined towards manufacturing good quality products by improving industry. The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |

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|---|---|---|
| 423 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PUL-4Q9-LL5P, 2025-12-09) |
| | Detail of Fee Submitted | 38700,<br>2025-12-02, |
| | The proposed proprietary name / brand name | **Lincopeck Injection** |
| | Label Claim | Each ml contains: Spectinomycin HCl .....100mg Lincomycin HCl ..... 50mg (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C in a cool and dry place. Protect form light |
| | For generic drugs (me-too Status) | Brand Name: Spectolin Injection, Drug Reg. Number: 075606 by: Noble Pharma, Plot no# B-1, Old Industrial Estate, Mirpur, AJK Pakistan |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The management is highly inclined towards manufacturing good quality products by improving industry. The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 424 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QQM-R33-BWJP, 2025-10-22) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **ACENAC POWDER** |
| | Label Claim | Each 100gm contains Amoxicillin as Trihydrate.....,, 10gm Colistin Sulphate.....05gm Neomycin Sulphate.....20gm (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10Kg-De-Controlled,1KG-De-Controlled,2.5Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5Kg-De-Controlled |

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| | Shelf Life (Unit) | 2 Year(s)□ Store at a Cool and dry place. □ Protect from light and children |
| | For generic drugs (me-too Status) | Nc Mox Oral Powder Reg. NO: 087195 of Farm Aid Group, Hattar Industrial Estate Haripur |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 425 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LA3-HPE-ZY3G, 2025-12-08) |
| | Detail of Fee Submitted | 38700,<br>2025-12-02, |
| | The proposed proprietary name / brand name | **Lyso Shell-E Powder** |
| | Label Claim | Each gram contains: Lysozyme (as HCl) .....220mg (22%) Vitamin E .....5mg (0.5%) (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 kg-De-Controlled,10 kg-De-Controlled,100 gram-De-Controlled,2.5 kg-De-Controlled,25 kg-De-Controlled,250 gram-De-Controlled,5 kg-De-Controlled,500 gram-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C in a cool and dry place. Protect form light |
| | For generic drugs (me-too Status) | Brand Name: Ruth-Lysonex, Drug Reg. Number: 126027, by Ruth Pharmaceutical 1.5 KM Bhatti Mansoor Road, Main GT Road, Ghakhar, Gujranwala |
| | Pharmacotherapeutic Group of (API) | Antibiotic, Antioxidant |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The management is highly inclined towards manufacturing good quality products by improving industry. The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |

| | | |
|---|---|---|
| | Approved up to 1 kg pack size. | |
| 426 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DRG-EWU-7JAS, 2025-10-22) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **LEOMYCIN POWDER** |
| | Label Claim | Each 150gm contains: Lincomycin as HCl USP..... 33.3gm Spectinomycin as HCl USP.....66.7gm (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,2.5Kg-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)□ Store at a Cool and dry place. □ Protect from light and children. |
| | For generic drugs (me-too Status) | LINCO - S 100 w/s Powder Registration # 062169 of Attabak Pharma Islamabad, Pakistan |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 427 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NTB-2YV-7P8S, 2025-12-09) |
| | Detail of Fee Submitted | 38700,<br>2025-12-02, |
| | The proposed proprietary name / brand name | **Linco-Mox Powder** |
| | Label Claim | Each 100gm contains Amoxicillin Trihydrate .....20gm Spectinomycin 2HCl .....8.8gm Lincomycin HCl .....8.8gm (As per Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 gram-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,2.5Kg-De-Controlled,250 gram-De-Controlled,25Kg-De- |

| | | |
|---|---|---|
| | | Controlled,500 gram-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C in a cool and dry place. Protect form light |
| | For generic drugs (me-too Status) | Product Name:: Sentirox-20 Oral Powder Registration No: 111501 By; Vetrox Pharmaceuticals, Chak No. 388-JB,12-KM Toba Jhang Road ,Near M-4 Interchange,Toba Tek Singh |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The management is highly inclined towards manufacturing good quality products by improving industry. The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1kg pack size. | |
| 428 | Case Category | Import (Sabahat Zehra) |
| | Name, address of Applicant. | **DDF PAKISTAN** Office No.7, 4th Floor, Plot 63-C, Bukhari Commercial Lane 5, Phase 6, DHA **(0126)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B1X-H8N-GS8Z, 2025-01-13) |
| | Detail of Fee Submitted | 75000.0,<br>2025-01-13, |
| | The proposed proprietary name / brand name | **Ceftionel-50** |
| | Label Claim | ceftiofur (as hydrochloride) 50 mg/ml |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 3 Year(s)Store in dark at room temperature |
| | For generic drugs (me-too Status) | Yes. Ceftionel-50 is a me-too product. It contains ceftiofur (as hydrochloride) 50gm/ml as the active ingredient, which is similar in formulation and therapeutic indication to other registered ceftiof |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | Interchemie werken "De Adelaar" Eesti AS-Vanapere tee 14, Püünsi village, Viimsi municipality, Harju country-Estonia |
| | Name, address of Marketing Authorization Holder: | DDF PAKISTAN, Suite #8, Plot 63-C, Bukhari Commerical Lane, Phase VI, DHA, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | | |

| | | |
|---|---|---|
| | **Decision** | |
| | **Approved** | |
| 429 | Case Category | Import (Sabahat Zehra) |
| | Name, address of Applicant. | **Vetline International** 939-A, Block-J, Phase-1, LDA Avenue-1, Lahore **(05-352-0066-040712D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (X25-N1X-GU97, 2025-09-08) |
| | Detail of Fee Submitted | 313500.0,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **ZOMO-CeftiVAN II** |
| | Label Claim | ZOMO-CeftiVAN II Each vial of Ceftiofur Sodium contains: 4 g of ceftiofur (as Sodium). |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 4 gm vial-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at Room Temperature |
| | For generic drugs (me-too Status) | Naxcel 4gm Zoetis, Accent Ghazi Brothers, Cefent 4gm U.M Enterprises |
| | Pharmacotherapeutic Group of (API) | β -lactam antibiotic |
| | Name, address of Manufacturing site: | Chengdu Zhongmu Biological Pharmaceutical Co., Ltd-No.699, The 3rd Chenglong Avenue, Economic Development District, Chengdu. China-China |
| | Name, address of Marketing Authorization Holder: | Chengdu Zhongmu Biological Pharmaceutical Co., Ltd, No.699, The 3rd Chenglong Avenue, Economic Development District, Chengdu. 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** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 430 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Majestic Pharma** plot # 21,Phase 1A,M-3 Industrial state Sahianwala Faisalabad **(000873)** |
| | Application Form Dy. No / Tracking ID & date of submission | (P3Y-M6B-GJ2W, 2025-08-08) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **TRUALBA-SC ORAL SUSPENSION** |
| | Label Claim | Each 100ml Contains: Albendazole ---------- 2.5 gm Cobalt Chloride ---------- 0.075 gm Sodium Selenite ---------- 0.035 gm |
| | Reference to Finished product specifications | United States Pharmacopeia |

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|---|---|---|
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,120ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature and avoid from heat and sunlight. |
| | For generic drugs (me-too Status) | Alben-par Oral Suspension (062037) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Satisfactory level of GMP Compliance |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Fee challan of Rs: 9,400/- has been paid for change of specs from USP to BP. | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 431 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **NOBLE PHARMA** B-1 OLD INDUSTRIAL AREA **(000652)** |
| | Application Form Dy. No / Tracking ID & date of submission | (699-APG-EJA8, 2025-07-22) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-16, |
| | The proposed proprietary name / brand name | **NOBINICCOX DRENCH** |
| | Label Claim | EACH LITER CONTAINS Niciosomide 250gm Oxfendozale 10gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ML,200ML,500ML,1L,2.5L-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)ROOM TEM |
| | For generic drugs (me-too Status) | NICZOLR DRENCH Reg#063865 |
| | Pharmacotherapeutic Group of (API) | Antihelmenthics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | OVERALL GOOD |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Fee of Rs 9,400/- has been paid for change of specs from USP to BP. | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 432 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8EU-BT4-XTD4, 2025-08-20) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-13, |

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|---|---|---|
| | The proposed proprietary name / brand name | **BROTEN/ BROMITEN/ BRONOX ORAL LIQUID** |
| | Label Claim | Each 100ml contains: Bromhexine HCL (BP) ..... 10gm (Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 Liter-De-Controlled,10 Liter-De-Controlled,100ml-De-Controlled,15 Liter-De-Controlled,2.5 Liter-De-Controlled,20 Liter-De-Controlled,200ml-De-Controlled,25 Liter-De-Controlled,250nl-De-Controlled,5 Liter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at cool and dry place. Protect from direct sun light and heat. |
| | For generic drugs (me-too Status) | Broxine-10 Oral Liquid Reg. No. 119935 of AME Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Secretolytic, Mucolytic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 433 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UVB-9R7-1EA5, 2025-10-11) |
| | Detail of Fee Submitted | 38700,<br>2025-09-30, |
| | The proposed proprietary name / brand name | **Fendox-K Oral Suspension** |
| | Label Claim | Each 100ml. contains Oxfendazole .....2.265%. Vitamin K.....0.5%. (As Per Innovator's Spec) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,10ml-De-Controlled,2.5 Liters-De-Controlled,250ml-De-Controlled,5 Liter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at cool and dry place. Protect from direct sun light and heat |
| | For generic drugs (me-too Status) | OXFA-K ORAL SUSPENSION (Reg. No. 062189) Attabak Pharmaceutical Industries Islamabad |

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|---|---|---|
| | Pharmacotherapeutic Group of (API) | Anthelmintic/ Vitamin K3 |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 434 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Farm Aid Group** Plot #3/2 Phase I & II Hattar Industrial Estate Haripur Pakistan **(000298)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L23-SBE-PU8A, 2025-08-20) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-13, |
| | The proposed proprietary name / brand name | **AXOTIL / MYCOTIL / TILXON 30% ORAL LIQUID** |
| | Label Claim | Each ml contains:- Tilmicosine As Phosphate...30% (As Per Innovator's Spec) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 Liter-De-Controlled,100ml-De-Controlled,10ml-De-Controlled,2.5 Liter-De-Controlled,250ml-De-Controlled,5 Liter-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at cool and dry place. Protect from direct sun light and heat |
| | For generic drugs (me-too Status) | TILOMED 30% Oral Solution (Reg. # 125900) |
| | Pharmacotherapeutic Group of (API) | MACROLIDE ANTIBIOTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on documentation reviewed, technical/ management people met, materials/ processes flow, and detailed physical inspection of the stores, section-wise manufacturing facilities, quality control lab, microbiology lab, and allied facilities, the panel is |
| | Evidence of approval of manufacturing facility | present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 435 | Case Category | Routine (Sabahat Zehra) |

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|---|---|---|
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WEH-VMT-W5NG, 2025-10-01) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **JFIZOL 12% INJECTION** |
| | Label Claim | Each ml contains imidocarb dipropionate ..... 120 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 30 degree celcius |
| | For generic drugs (me-too Status) | IMIPRO Injection |
| | Pharmacotherapeutic Group of (API) | Antiprotozon |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found comply with cGMP in Control, Process and documentation |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Fee of Rs: 9,400/- paid for the change of specs. | |
| | **Decision** | |
| | **Approved** | |
| 436 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T59-MHW-PYGG, 2025-09-30) |
| | Detail of Fee Submitted | 38700,<br>2025-09-24, |
| | The proposed proprietary name / brand name | **JFIZOL 12% INJECTION** |
| | Label Claim | Each ml contains: Imidocarb dipropionate .... 120.0 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml & 50 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 30 degree celcius |
| | For generic drugs (me-too Status) | IMPRO INJECTION |
| | Pharmacotherapeutic Group of (API) | Antiprotozoal |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found comply with cGMP in Control, Process and documentation |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Fee of Rs: 9,400/- paid for the change of specs. | |
| | **Decision** | |
| | **Approved** | |

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| 437 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3GS-M1R-STN8, 2025-08-19) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-07, |
| | The proposed proprietary name / brand name | **OXYKET-LA** |
| | Label Claim | Each ml contains Oxytetracycline HCl..... 200 mg<br>Ketoprofen .....30 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | Glass Vial 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Blow 30 degree celcius |
| | For generic drugs (me-too Status) | OXYFEN-LA Reg#071091 |
| | Pharmacotherapeutic Group of (API) | Antibiotic/NSAIDs |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found Comply with cGMP in terms of process, Control, Maintanance & Document control |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Fee of Rs: 9,400/- paid for the change of specs. | |
| | **Decision** | |
| | **Approved** | |
| 438 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Jfrin Pharmaceuticals Laboratories** Plot No. 16, 17 & 20 Hub Industrial Trading Estate **(000580)** |
| | Application Form Dy. No / Tracking ID & date of submission | (39R-B45-ATMZ, 2025-08-19) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-07, |
| | The proposed proprietary name / brand name | **OXYKET-LA** |
| | Label Claim | Each ml contains Oxytetracycline HCl.....200 mg<br>Ketoprofen .....30 mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | Glass Vial 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Blow 30 degree celcius |
| | For generic drugs (me-too Status) | OXYFEN-LA |
| | Pharmacotherapeutic Group of (API) | AnitibioticNSAID |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Found Comply with cGMP in terms of process, Control, Maintanance & Document control |

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|---|---|---|
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Fee of Rs: 9,400/- paid for the change of specs. | |
| | **Decision** | |
| | **Approved** | |
| 439 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Aamster Laboratories** Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad **(000908)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6J6-2XQ-TT2Y, 2025-08-25) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-25, |
| | The proposed proprietary name / brand name | **NOSTER ORAL POWDER** |
| | Label Claim | Each g contains (As Per Innovator Spec.) - Neomycin sulphate BP 60mg - Oxytetracycline HCl BP 200mg - Streptomycin sulphate BP 20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | OXY MYCIN POWDER (093233) INSHAL PHARMA RAWAT |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 440 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Aamster Laboratories** Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad **(000908)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1PG-56X-5B1B, 2025-08-25) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-25, |
| | The proposed proprietary name / brand name | **LINCO SPIR ORAL POWDER** |
| | Label Claim | Each 1000g powder contains (As Per Innovator Spec.) Spiramycin adipate ..... 75g Lincomycin as HCl ..... 25g |
| | Reference to Finished product specifications | As per Innovators Specification |

| | | |
|---|---|---|
| | Proposed Pack Size | 100g-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled,Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | Z-LINCO-SP W/S POWDER (090656) ZOIC INTERNATIONAL PHARMA LAHORE |
| | Pharmacotherapeutic Group of (API) | Anti-Bacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 441 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Aamster Laboratories** Plot # 18, Street # SS-2 RCCI Industrial Estate, Rawat - Islamabad **(000908)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EDL-RY8-9Q1H, 2025-08-25) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-25, |
| | The proposed proprietary name / brand name | **AASPER-C ORAL POWDER** |
| | Label Claim | Each 100g contains (As Per Innovator Spec.) - Vitamin-C ..... 20g - Asprin ..... 6.7g - Potassium Chloride.....0.3g - Sodium Citrate.....0.7g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled,Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | SPRO-C POWDER (074092) NAWAL PHARMACEUTICALS |
| | Pharmacotherapeutic Group of (API) | Antioxidant, Analgesic,Antipyretic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1kg pack size. | |
| 442 | Case Category | Routine (Sabahat Zehra) |

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| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q44-TUD-8YPQ, 2025-09-05) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-15, |
| | The proposed proprietary name / brand name | **KE - BROM LIQUID** |
| | Label Claim | Each 100ml contains; Bromhexine HCl..... 10gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled,10Liters-De-Controlled,150ml-De-Controlled,1Liter-De-Controlled,2.5Liters-De-Controlled,500ml-De-Controlled,5Liters-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Cool and dry place |
| | For generic drugs (me-too Status) | EBROM-LYTIC 10% LIQUID, Reg.# 099317 by Vetec Laboratories |
| | Pharmacotherapeutic Group of (API) | Bronchodilator, Mucolytic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The company is found Complying Satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1liter pack size. | |
| 443 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UPX-8LD-EAH3, 2025-08-21) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-15, |
| | The proposed proprietary name / brand name | **KE-ENRO LIQUID** |
| | Label Claim | Each ml contains:<br>Enrofloxacin.....200mg Colistin Sulphate.....30mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 Liter-De-Controlled,10 Liter-De-Controlled,100 ml-De-Controlled,150 ml-De-Controlled,2.5 Liter-De-Controlled,5 Liter-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Cool and Dry place |
| | For generic drugs (me-too Status) | Enroflox - C 23 Liquid Reg No: 122382, by Amazon Pharma Mirpur AJK |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | -- |

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|---|---|---|
| | GMP status of the firm | The company is found complying Satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1liter pack size. | |
| 444 | Case Category | Import (Sabahat Zehra) |
| | Name, address of Applicant. | **Snam Pharma** 61-G, Phase 1, Commercial Area, DHA, Lahore **(05-352-0058-036985D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VEZ-LJY-VB76, 2024-03-27) |
| | Detail of Fee Submitted | 75000.0,<br>2024-03-21, |
| | The proposed proprietary name / brand name | **Caniverm Mite Tablets** |
| | Label Claim | Caniverm Mite Tablets 1 Tablet - 0.175 g contains: Fenbendazole: 37.5 mg Pyrantel embonate: 36 mg Praziquantel: 12.5 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 x 1 Tablets-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 25°C |
| | For generic drugs (me-too Status) | New Registration in Pakistan |
| | Pharmacotherapeutic Group of (API) | Benzimidazoles |
| | Name, address of Manufacturing site: | Bioveta, a.s.-Komenskeho 212/12, 683 23 Ivanovice na Hane-Czechia |
| | Name, address of Marketing Authorization Holder: | Bioveta, a.s., Komenskeho 212/12, 683 23 Ivanovice na Hane, Czechia |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. | |
| 445 | Case Category | Import (Sabahat Zehra) |
| | Name, address of Applicant. | **Snam Pharma** 61-G, Phase 1, Commercial Area, DHA, Lahore **(05-352-0058-036985D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (D51-HS4-YTVA, 2024-03-26) |
| | Detail of Fee Submitted | 75000.0,<br>2024-03-21, |
| | The proposed proprietary name / brand name | **Caniverm Forte Tablets** |
| | Label Claim | Caniverm Forte Tablets 1 tablet weighing 0.7 g contains: Active substance(s): Fenbendazolum: |

| | | |
|---|---|---|
| | | 150 mg Pyranteli embonas: 144 mg Praziquantelum: 50 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100 x 1 Tablets-De-Controlled |
| | Shelf Life (Unit) | 2 YearDo not store above 25°C |
| | For generic drugs (me-too Status) | New Registration in Pakistan |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Bioveta, a.s.-Komenskeho 212/12, 683 23 Ivanovice na Hane-Czechia |
| | Name, address of Marketing Authorization Holder: | Bioveta, a.s., Komenskeho 212/12, 683 23 Ivanovice na Hane, Czechia |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy. | |
| 446 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SJ1-W8U-GBGU, 2025-08-02) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |
| | The proposed proprietary name / brand name | **FURA-SAL POWDER** |
| | Label Claim | Each gm powder contains (As Per Innovators Spec.) Furosemide BP .....<br>20mg Sodium Chloride<br>BP.....35mg Magnesium Sulphate<br>BP.....35mg Manganese Sulphate<br>BP.... .....1mg Calcium Carbonate<br>BP.....45mg Potasium Chloride<br>BP.....4mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | ARCH FLUSH POWDER (078298) NAWAL PHARMA TAXILLA |
| | Pharmacotherapeutic Group of (API) | Diuretic,Electolytes Replinishe |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |

| | | |
|---|---|---|
| | Differential fee has been paid by applicant. | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1kg pack size. | |
| 447 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3RQ-793-6NSR, 2025-08-02) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |
| | The proposed proprietary name / brand name | **SAL-DINE 10 POWDER** |
| | Label Claim | Each 100g contains (As Per Innovator Spec.) - Amantadine HCl BP 10.0g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | AMSTERDINE 1 POWDER (101996)<br>AAMSTER LAB RAWAT |
| | Pharmacotherapeutic Group of (API) | Antiviral |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Formulation contains AMANTADINE as an ingredient. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred until the required information on the target species is provided. | |
| 448 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T5Q-6GU-BL88, 2025-08-02) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |
| | The proposed proprietary name / brand name | **DOXY-SAL 50% POWDER** |
| | Label Claim | Each g contains (As per innovator Spec.) Doxycycline HCl 500mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | D-FORT- 50 ORAL POWDER (080963) KOHINOOR INDUSTRIES SAHIWAL |
| | Pharmacotherapeutic Group of (API) | Antibactetrial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 449 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AMN-5V8-BUXE, 2025-08-02) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |
| | The proposed proprietary name / brand name | **ASPI-C POWDER** |
| | Label Claim | Each 1000g contains (As Per Innovator Spec.) - Vitamin-C ..... 200g - Asprin ..... 67g - Potassium Chloride..... 3g - Sodium Citrate..... 7g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | SPRO-C POWDER (074092) NAWAL PHARMACEUTICALS |
| | Pharmacotherapeutic Group of (API) | Antioxidant, Analgesic,Antipyretic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 450 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1TZ-R81-WGNL, 2025-08-02) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **FURBEL POWDER** |
| | Label Claim | Each 100g contains (As per Innovator Specs.)<br>Furosemide BP..... 2gm<br>Belladonna Extract ..... 0.2gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | FLUSH-B W/S POWDER (075742) D-MAARSON PHARMA RAWAT |
| | Pharmacotherapeutic Group of (API) | Diuretic, Anti-spasmodic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Differential fee has been paid by applicant. | |
| | **Decision** | |
| | **Approved** | |
| 451 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7BN-W6A-R31D, 2025-08-02) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |
| | The proposed proprietary name / brand name | **PASCORE-E POWDER** |
| | Label Claim | Each 100 g contains (As Per Innovator Spec.)<br>Vitamin-C BP.....5g Paracetamol BP. .....20g Potassium carbonate BP.....12.5g Sodium Bicarbonate BP.....12.5g Vitamin E BP.....12.5g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | PARACET POWDER (079826) DECENT PHARMA |
| | Pharmacotherapeutic Group of (API) | Analgesic,Antipyretic. Vitamin |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Differential fee has been paid by applicant. | |
| | **Decision** | |

| | | |
|---|---|---|
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 452 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7P2-M4Q-HT8B, 2025-12-13) |
| | Detail of Fee Submitted | 38700,<br>2025-12-09, |
| | The proposed proprietary name / brand name | **Klentox Plus** |
| | Label Claim | Each 1000 gram contains: Proteases..... 100,000 IU Lipases..... 23,000 IU Amylases..... 125,000 IU Mannoses ..... 20,000 IU Bacillus Subtilis ..... 1,000 mg Vitamin E..... 20 gm Vitmain C ..... 40 gm Yeast ... QS ..... 1000 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50g,100g, 250g, 500g, 1000 g, 2500g, 5000 g, 10000 g, 25000 g.-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store Cool and Dry place below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | Energine Oral Powder Reg. No. 033236 |
| | Pharmacotherapeutic Group of (API) | Multivitamins and Mineral |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Approved |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 453 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2ZE-EY2-SP3S, 2025-12-14) |
| | Detail of Fee Submitted | 38700,<br>2025-12-09, |
| | The proposed proprietary name / brand name | **Growvit Powder** |
| | Label Claim | Each kg contains: Vitamin A..... 0.8 grams Vitamin D3..... 0.16 grams Vitamin E..... 0.38 grams Vitamin B1..... 1.00 grams Vitamin B2.....1.25 grams Vitamin B3..... 6.25 grams Vitamin B6 ..... 4.00 gram Vitamin B12..... 0.001 grams Copper Sulphate..... 0.25 grams Magnesium Sulphate ... 25 grams Calcium Chloride..... 0.023 grams Zinc Sulphate.....2.17 grams Maganese Sulphate .....10 grams Potassium Iodide.....0.5 grams |

| | | |
|---|---|---|
| | | Sodium Selenite.....0.01 grams Di Calcium Phosphate...150 grams Sodium Chloride.....120 grams |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50g,100g, 250g, 500g, 1000 g, 2500g, 5000 g, 10000 g, 25000 g-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store Cool and Dry place below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | White Gold Oral Powder Reg. No.058842 |
| | Pharmacotherapeutic Group of (API) | Multivitamins and Minerals |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Approved |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 454 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B55-ZMH-QLXE, 2025-12-18) |
| | Detail of Fee Submitted | 38700,<br>2025-12-09, |
| | The proposed proprietary name / brand name | **DigestAll** |
| | Label Claim | Each 1000 gram powder contains:<br>Proteases..... 100,000 IU<br>Lipases..... 23,000 IU<br>Amylases..... 125,000 IU Mannoses ..... 20,000 IU Bacillus Subtilis ..... 1,000 mg Levamisole ..... 15 gm Vitamin E..... 20 gm Vitamin C ..... 40 gm Sodium Selenite ..... 100 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50g,100g, 250g, 500g, 1000 g, 2500g, 5000 g, 10000 g, 25000 g.-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store Cool and Dry place below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | Immuno EBC Oral Powder Reg. No. 033237" manufactured by Mediexcel Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Multivitamins and Minerals |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Approved |
| | Evidence of approval of manufacturing facility | Multivitamins and Mineral |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |

| | | |
|---|---|---|
| | Approved up to 1 kg pack size. | |
| 455 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DH2-QH7-M2WB, 2025-12-13) |
| | Detail of Fee Submitted | 38700,<br>2025-12-09, |
| | The proposed proprietary name / brand name | **Optimin Oral Powder** |
| | Label Claim | Each 1000 gram powder contains: Propionic acid calcium.....250g Propionic acid sodium..... 400g Acetanilide.....150g Magnesium Oxide.....125g Iron Sulfate.....400mg Zinc Sulfate.....100mg Magnesium Sulfate.....200mg Copper Sulfate.....450mg Cobalt Sulfate.....400mg Sodium Molybdate.....100mg Sodium Chloride..... 20g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50g,100g, 250g, 500g, 1000 g, 2500g, 5000 g, 10000 g, 25000 g-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store Cool and Dry place below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | Biogest Oral Powder Reg. No.074791 |
| | Pharmacotherapeutic Group of (API) | Minerals |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Approved |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1kg pack size. | |
| 456 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HW7-TXG-GBJR, 2025-12-12) |
| | Detail of Fee Submitted | 38700,<br>2025-12-09, |
| | The proposed proprietary name / brand name | **Josaprim Oral Powder** |
| | Label Claim | Each 100 gram powder contains Josamycin ..... 18 MIU Trimethoprim.....10 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 30g, 50g,100g, 250g, 500g, 1000g, 5000g, 10,000g, 25,000g-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store Cool and Dry place below 25 Degree Centigrade |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | Josaprim Water Soluble Powder |
| | Pharmacotherapeutic Group of (API) | Anti-bacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Approved |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Formulation contains josamycin in combination with trimethoprim. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred to Sub-committee on Veterinary Drugs for clarification of the RRA status of the formulation. | |
| 457 | Case Category | Contract Manufacturing (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WY7-LBY-PP9T, 2025-08-06) |
| | Detail of Fee Submitted | 97200.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **SALI COL-50 ORAL POWDER** |
| | Label Claim | Each 100gm powder contains (As Per Innovator Spec.) Amoxicillin as trihydrate ..... 50g Colistin sulphate ..... 50MIU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | AMOX-C MAARSON W/S POWDER (071054) ATTABAK Pharma |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | Aamster Laboratories-Plot # 18 St#SS-2, National Industrial Zone Rawat, Islamabad- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 458 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MMQ-9JW-ZAPG, 2025-08-02) |

| | | |
|---|---|---|
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |
| | The proposed proprietary name / brand name | **FOS-FORD POWDER** |
| | Label Claim | Each gm contains (As Per Innovator Spece)<br>Fosfomycin Calcium ..... 200mg<br>Tylosin as Tartarate.....50mg<br>Fructose 1,6 diphosphate .....180mg<br>Sodium Phosphate.....150mg<br>Magnesium Phosphate .....100mg<br>Sodium Chloride QS to make.....1000mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | ARCH FORTYL POWDER Powder (120883)<br>ARCHARD PHARMA BHIMBER |
| | Pharmacotherapeutic Group of (API) | Antibactetrial,Electolytes Replinisher |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 459 | Case Category | Contract Manufacturing (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M1V-G5A-21VR, 2025-08-06) |
| | Detail of Fee Submitted | 97200.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **SALI COL-20 ORAL POWDER** |
| | Label Claim | Each 100gm powder contains (As Per Innovator Spec.) Amoxicillin as trihydrate ..... 20g<br>Colistin sulphate ..... 80MIU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | AMOXITIN W/S POWDER (071062)<br>ATTABAK PHARMA ISLAMABAD |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | Aamster Laboratories-Plot # 18 St#SS-2, National Industrial Zone Rawat, Islamabad- |

| | | |
|---|---|---|
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 460 | Case Category | Contract Manufacturing (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y1X-S7M-2RYX, 2025-08-06) |
| | Detail of Fee Submitted | 97200.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **NEOMOX-C 350 ORAL POWDER** |
| | Label Claim | Each Kg powder contains (As Per Innovator Spec.) Amoxicillin as trihydrate BP..... 100g Colistin sulphate BP..... 50g Neomycin sulphate BP..... 200g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | NEO AC W/S POWDER (079844) DECENT Pharma |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | Aamster Laboratories-Plot # 18 St#SS-2, National Industrial Zone Rawat, Islamabad- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 461 | Case Category | Contract Manufacturing (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SAZ-RP2-NQEE, 2025-08-06) |
| | Detail of Fee Submitted | 97200.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **SPECLIN MOX ORAL POWDER** |

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| | Label Claim | Each 100gm powder contains (As Per Innovator Spec.) Lincomycin Base BP..... 8.8g Spectinomycin Base BP..... 8.8g Amoxicillin Trihydrate BP.... 20g Eq. to Amoxicillin Base .... 17.43g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | ALMYCIN ORAL POWDER (085475) VETZ PHARMA KOTRI SINDH |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Aamster Laboratories-Plot # 18 St#SS-2, National Industrial Zone Rawat, Islamabad- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 462 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WG2-G9R-3QB5, 2025-12-01) |
| | Detail of Fee Submitted | 38700,<br>2025-11-26, |
| | The proposed proprietary name / brand name | **MEC-TAD INJECTION 50ML** |
| | Label Claim | Each ml contains: - Ivermectin.....10.5mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 25c. |
| | For generic drugs (me-too Status) | I-MECTIN INJECTION by M/S. INTERNATIONAL PHARMA, LAHORE (REG NO. 063618) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |

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| 463 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YMT-5LH-BBX7, 2025-12-01) |
| | Detail of Fee Submitted | 38700,<br>2025-11-26, |
| | The proposed proprietary name / brand name | **MEC-TAD INJECTION 10ML** |
| | Label Claim | EACH ML CONTAINS:-<br>IVERMECTIN.....10.5MG (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 25c. |
| | For generic drugs (me-too Status) | I-MECTIN INJECTION by M/S. INTERNATIONAL PHARMA, LAHORE (REG NO. 063618) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 464 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UQH-QX9-Y5D5, 2025-12-02) |
| | Detail of Fee Submitted | 38700,<br>2025-11-26, |
| | The proposed proprietary name / brand name | **MEC-TAD INJECTION 100ML** |
| | Label Claim | EACH ML CONTAINS:-<br>IVERMECTIN.....10.5MG (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 25c. |
| | For generic drugs (me-too Status) | I-MECTIN INJECTION by M/S. INTERNATIONAL PHARMA, LAHORE (REG NO. 063618) |
| | Pharmacotherapeutic Group of (API) | Antihelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |

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| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved** | |
| 465 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9GS-3SG-8XLE, 2025-12-18) |
| | Detail of Fee Submitted | 38700,<br>2025-11-26, |
| | The proposed proprietary name / brand name | **Ampoad-90 Water Soluble Powder** |
| | Label Claim | Each 100gm contains Amprolium HCl.....90gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1Kg,500g,100g,10g,250g,2.5Kg,5Kg,10Kg,25Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 30c. |
| | For generic drugs (me-too Status) | Amcox Powder by M/S. ATTABAK PHARMACEUTICALS, ISLAMABAD (Reg No. 053917) |
| | Pharmacotherapeutic Group of (API) | Anticoccidial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 466 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (568-DV1-P6LM, 2025-12-04) |
| | Detail of Fee Submitted | 38700,<br>2025-11-26, |
| | The proposed proprietary name / brand name | **ParaGuard Plus Oral Drench** |
| | Label Claim | Each 1ml contains: Oxfendazole.....25mg Oxyclozanide.....62.50mg Cobalt Sulphate.....2mg Sodium Selenite.....0.50mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1L,500mL,100mL,250mL,150mL,450mL,2.5L,5L De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 30c. |
| | For generic drugs (me-too Status) | SHINA RAPID DRENCH by M/S. M/S. MALLARD PHARMACEUTICAL, MULTAN |

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| | | (REG NO. 079219) |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 467 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q41-VD1-EWXP, 2025-12-18) |
| | Detail of Fee Submitted | 38700,<br>2025-12-09, |
| | The proposed proprietary name / brand name | **Oxarise Forte Oral Drench** |
| | Label Claim | EACH ML CONTAINS:- OXFENDAZOLE 25mg (USP Specs) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1L,500mL,100mL,250mL,150mL,450mL,2.5L,5L De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 30c. |
| | For generic drugs (me-too Status) | AREX DRENCH by M/S. M/S. LEADS PHARMA, ISLAMABAD (REG NO. 046670) |
| | Pharmacotherapeutic Group of (API) | ANTHELMINTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 liter pack size. | |
| 468 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W7H-NBR-JBZ9, 2025-08-02) |
| | Detail of Fee Submitted | 37000.0,<br>2025-08-01, |
| | The proposed proprietary name / brand name | **SAL-TYL 98 POWDER** |
| | Label Claim | Each 100g contains BP -Tylosin Tartrate 98g |
| | Reference to Finished product specifications | As per Innovators Specification |

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|---|---|---|
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | AMSETYL-98 ORAL POWDER (101999) AAMSTER LABORATORIES RAWAT |
| | Pharmacotherapeutic Group of (API) | Antibactetrial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The panel recommends grant of DML |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 469 | Case Category | Contract Manufacturing (Sabahat Zehra) |
| | Name, address of Applicant. | **M/s. Salford Laboratories (Pvt) Ltd** Plot No. 23-A, Small Industrial Estate, Bhimber, Azad Jammu & Kashmir **(001009)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TSU-Q5J-LAZL, 2025-08-06) |
| | Detail of Fee Submitted | 97200.0,<br>2025-08-06, |
| | The proposed proprietary name / brand name | **MOX FORD 60% ORAL POWDER** |
| | Label Claim | Each gm powder contains (BP) Amoxicillin Trihydarte eq to Amoxicillin BP..... 600mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100g-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,250g-De-Controlled,25Kg-De-Controlled,500g-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | TRIGER W/S POWDER (080958) SELMORE PHARMA LAHORE |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Aamster Laboratories-Plot # 18 St#SS-2, National Industrial Zone Rawat, Islamabad- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 470 | Case Category | New License (Sabahat Zehra) |
| | Name, address of Applicant. | **Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi |

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| | | **(001018)** |
| | Application Form Dy. No / Tracking ID & date of submission | (82A-GMJ-2JRX, 2025-12-16) |
| | Detail of Fee Submitted | 38700,<br>2025-12-11, |
| | The proposed proprietary name / brand name | **oxflor - N 1000 ORAL POWDER** |
| | Label Claim | Each 100gm powder contains: Oxytetracycline Hcl BP..... 300mg Florfenicol ..... 100mg Neomycin sulphate BP ..... 150mg (INNOVATORS Spec.) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100g, 250g, 500g, 1kg, -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)□ Store at a Cool and dry place. □ Protect from light and children. □ Opened packs should be used promptly. |
| | For generic drugs (me-too Status) | RABIX W/S ORAL POWDER (109138) HAAROLDS PHARMACEUTICAL BHMBER |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | OK |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 471 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **ELKO ORGANIZATION (PRIVATE) LIMITED** PLOT NO. 27 & 28, SECTOR-12B, NORTH KARACHI INDUSTRIAL AREA, KARACHI **(000245)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SNP-AUS-UJTR, 2025-12-22) |
| | Detail of Fee Submitted | 38700,<br>2025-11-07, |
| | The proposed proprietary name / brand name | **Dorex injection** |
| | Label Claim | Each ml contains: Doramectin .....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25 - 30 C |
| | For generic drugs (me-too Status) | DORAMEC INJECTION Selmore Pharmaceuticals (Pvt) Ltd |
| | Pharmacotherapeutic Group of (API) | Antiparasitic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Good |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
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| | **Decision** | |

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| | **Approved** | |
| 472 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **ELKO ORGANIZATION (PRIVATE) LIMITED** PLOT NO. 27 & 28, SECTOR-12B, NORTH KARACHI INDUSTRIAL AREA, KARACHI **(000245)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y7P-AZH-D9T2, 2025-11-27) |
| | Detail of Fee Submitted | 38700,<br>2025-11-07, |
| | The proposed proprietary name / brand name | **Sterone Injection** |
| | Label Claim | Each ml contains : Progesterone.....25mg USP Specification . |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25 -30 c |
| | For generic drugs (me-too Status) | Progesterone injection / Star Laboratory Lahore |
| | Pharmacotherapeutic Group of (API) | Hormone |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Good |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 473 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **ELKO ORGANIZATION (PRIVATE) LIMITED** PLOT NO. 27 & 28, SECTOR-12B, NORTH KARACHI INDUSTRIAL AREA, KARACHI **(000245)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YAS-V5H-MMHD, 2025-12-26) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **D- COL Oral Powder** |
| | Label Claim | Each kg Contains: Doxycycline Hcl .....200gm , Tylosine Tartrate .....100gm Colistin Sulphate .....500MIU Bromhexine Hcl .....5gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 kg-De-Controlled,100gm-De-Controlled,2.5 kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25 to 30 C |
| | For generic drugs (me-too Status) | CTD BROMO Oral Powder, Reg : 114788 / Medhouse Pharmaceuticals |

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|---|---|---|
| | Pharmacotherapeutic Group of (API) | Antibiotic / Antibacterial, Macrolide & Mucolytic expectorant |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Good |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 474 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Q. Track Pharma** Plot No. D-90-91, Sector-D H.I.T.E Lasbella, Hub, Balochistan. **(000982)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J9A-A22-87Y6, 2024-10-16) |
| | Detail of Fee Submitted | 75000.0, 18000.0<br>2023-11-28, 2024-10-17 |
| | The proposed proprietary name / brand name | **Metherliv Injection** |
| | Label Claim | Each ml contains:Artemether.....80mg (International Pharmacopoeia Specifications) |
| | Reference to Finished product specifications | The International Pharmacopeia |
| | Proposed Pack Size | as per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | Product Name: Arceva Injection Strength: 80mg/ml Composition: Each ml contains: Artemether…..80mg (International Pharmacopoeia Specifications) Manufactured By: Sami Pharmaceuticals Reg. No.: 0856 |
| | Pharmacotherapeutic Group of (API) | Antimalarial |
| | Name, address of Manufacturing site: | Winthrox Laboratories Pvt. Ltd.-K-219-A, SITE, Super Highway, Phase II, Karachi- |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | T-01, T-02, T-03 |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | ATMS/119003, ATMS/119004, ATMS/119005 |
| | The status in reference regulatory authorities | WHO approved in Essential Medicines List |
| | GMP status of the firm | present |
| | Evidence of approval of manufacturing facility | attached |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |

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| 475 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Decent Pharma** Plot No. 30, Street No. SS-3, RCCI, RAWAT **(000766)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JYD-194-YE5M, 2025-12-19) |
| | Detail of Fee Submitted | 38700,<br>2025-12-09, |
| | The proposed proprietary name / brand name | **SIPRACOL INJECTION 50ML** |
| | Label Claim | Each 100 ml contains: Sipramycin Adipate..... 32 MIU Colistin Sulfate .....10 MIU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50 ml-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store Cool and Dry place below 25 Degree Centigrade |
| | For generic drugs (me-too Status) | Spiracol Injection Reg. No. 058861 |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Approved |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 476 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1XN-Q32-8DG4, 2025-12-18) |
| | Detail of Fee Submitted | 38700, 9400<br>2025-12-09, 2026-07-03 |
| | The proposed proprietary name / brand name | **Novatil Forte Injection 500mL** |
| | Label Claim | EACH ML CONTAINS:- ETILEFRIN.....0.2GM CAFFEINE.....10MG SODIUM SALICYLATE.....7MG NOVAMINSULFON.....40MG NICOTINAMIDE.....0.3MG CALCIUM GLUCONATE....100MG MAGNESIUM GLUCONATE..10MG BORIC ACID.....10MG SORBITOL.....200MG SODIUM OXYBENZYLPHOSPHINIC ACID 5MG METHYL PARAHYDROXYBENZOATE 0.7MG WATER FOR INJECTION Q.S TO...1ML |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 500mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 25c. |
| | For generic drugs (me-too Status) | GESITON INJECTION by M/S. SELMORE PHARMACEUTICALS, LAHORE (REG NO. |

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| | | 057001) |
| | Pharmacotherapeutic Group of (API) | ANTIHYPERTENSIVE, CALCIUM REPLENISHES, CNS STIMULANT |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | Rs 9,400/- has been submitted for the revision of label claim. | |
| | **Decision** | |
| | **Approved** | |
| 477 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (77E-99D-BS4M, 2025-12-18) |
| | Detail of Fee Submitted | 38700, 9400<br>2025-12-09, 2026-07-03 |
| | The proposed proprietary name / brand name | **Novatil Forte Injection 250mL** |
| | Label Claim | EACH ML CONTAINS:-<br>ETILEFRIN.....0.2GM<br>CAFFEINE.....10MG SODIUM<br>SALICYLATE.....7MG<br>NOVAMINSULFON.....40MG<br>NICOTINAMIDE.....0.3MG CALCIUM<br>GLUCONATE....100MG MAGNESIUM<br>GLUCONATE..10MG BORIC<br>ACID.....10MG<br>SORBITOL.....200MG SODIUM<br>OXYBENZYLPHOSPHINIC ACID 5MG<br>METHYL PARAHYDROXYBENZOATE<br>0.7MG WATER FOR INJECTION Q.S TO...1ML |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 250mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a cool and dry place, below 25c. |
| | For generic drugs (me-too Status) | GESITON INJECTION by M/S. SELMORE PHARMACEUTICALS, LAHORE (REG NO. 057001) |
| | Pharmacotherapeutic Group of (API) | ANTIHYPERTENSIVE, CALCIUM REPLENISHES, CNS STIMULANT |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | present |
| | **Evaluation Remarks** | |
| | Rs 9,400/- has been submitted for the revision of label claim. | |
| | **Decision** | |
| | **Approved** | |

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| 478 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8GU-S18-TUMU, 2025-08-13) |
| | Detail of Fee Submitted | 37000.0, 1700<br>2025-06-30, 2026-07-03 |
| | The proposed proprietary name / brand name | **Flunizole Injection 10ml** |
| | Label Claim | Each ml contains: Flunixin Meglumine 50mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25 degree. Protect from direct sunlight and heat. |
| | For generic drugs (me-too Status) | Flumag Injection by M/S Zakfas Pharma Multan Reg#046539 |
| | Pharmacotherapeutic Group of (API) | Antiinflamatory |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 479 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **BIORISE PHARMACEUTICALS** 19KM, LAHORE ROAD, MULTAN **(000934)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4BQ-VSJ-JW5R, 2025-08-13) |
| | Detail of Fee Submitted | 37000.0, 1700<br>2025-06-30, 2026-07-03 |
| | The proposed proprietary name / brand name | **Flunizole Injection 100ml** |
| | Label Claim | Each ml contains: Flunixin Meglumine 50mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25 degree. Protect from direct sunlight and heat. |
| | For generic drugs (me-too Status) | Flumag Injection by M/S Zakfas Pharma Multan Reg#046539 |
| | Pharmacotherapeutic Group of (API) | Anti-inflammatory |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Firm is working at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |

| | | |
|---|---|---|
| | **Approved** | |
| 480 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MBJ-9JW-874A, 2025-10-10) |
| | Detail of Fee Submitted | 38700,<br>2025-09-25, |
| | The proposed proprietary name / brand name | **MELOXISHELL INJECTION 100ML** |
| | Label Claim | Each ml contains Meloxicam .....10mg (BP Vet. Specifications) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Keep in Cool and dry place. Keep out of the reach of children. |
| | For generic drugs (me-too Status) | MELOXISHELL INJECTION, Reg. # 080514 of Inshal Pharmaceuticals Islamabad |
| | Pharmacotherapeutic Group of (API) | NSAIDs |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 481 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HNE-3PJ-VHRH, 2025-10-11) |
| | Detail of Fee Submitted | 38700,<br>2025-09-25, |
| | The proposed proprietary name / brand name | **KETOSHELL INJECTION 100ML** |
| | Label Claim | Each ml contains Ketoprofen .....100mg (BP Vet, Specifications) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s) Keep in Cool and dry place. Keep out of the reach of children. |
| | For generic drugs (me-too Status) | KETOSHELL INJECTION, Reg. # 080517 of Inshal Pharmaceutical Industries Rawat, Islamabad |
| | Pharmacotherapeutic Group of (API) | analgesic, Anti inflamatory |
| | Name, address of Manufacturing site: | -- |

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|---|---|---|
| | GMP status of the firm | The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 482 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Inshal Pharmaceutical Industries** Plot No. 02, Street no. SS-2, National Industrial Zone Rawat Islamabad **(000698)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SNP-ZAB-5MR4, 2025-10-10) |
| | Detail of Fee Submitted | 38700,<br>2025-09-25, |
| | The proposed proprietary name / brand name | **OXY SHELL 5% INJECTION 100ML** |
| | Label Claim | Each ml contains:- Oxytetracycline As HCl .....50mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | -2 Year(s)Keep in Cool and dry place. Keep out of the reach of children. |
| | For generic drugs (me-too Status) | OXYSHELL 5% INJECTION Reg. # 080513 of Inshal Pharmaceutical Industries Islamabad |
| | Pharmacotherapeutic Group of (API) | Antibacterial |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The company is found complying satisfactory level of GMP as of today. |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 483 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QN2-268-U5RV, 2025-12-01) |
| | Detail of Fee Submitted | 38700,<br>2025-11-27, |
| | The proposed proprietary name / brand name | **TF-Zol** |
| | Label Claim | Each ml contains: Triclabendazole .....50mg Fenbendazole.....25mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 100ml-De-Controlled,150ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled |

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|---|---|---|
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | Trifen Act Liquid, Reg. No: 063776, Mallard Pharmaceuticals (PVT) Ltd. |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up t 1 liter pack size. | |
| 484 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L1N-2W6-S5QL, 2025-10-01) |
| | Detail of Fee Submitted | 38700,<br>2025-09-30, |
| | The proposed proprietary name / brand name | **Predikem Injection** |
| | Label Claim | Each ml contains Prednisolone acetate.....25mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | Acetosol-25 DS injection, International Pharma Labs Lahore (PVT) Ltd., Reg# 099031 |
| | Pharmacotherapeutic Group of (API) | Corticosteroids |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 485 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DW4-9BN-UBL7, 2025-12-01) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **LG Mox** |
| | Label Claim | Each Kg contains: Amoxicillin Trihydrate ..... 50gm Lysozyme HCl.....10gm Guaifenesin ..... 35gm |
| | Reference to Finished product specifications | United States Pharmacopeia |

| | | |
|---|---|---|
| | Proposed Pack Size | 100gm-De-Controlled,10Kg-De-Controlled,1Kg-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | Lyzomox Water Soluble Powder, Reg. No: 079842, Decent Pharmaceuticals (PVT) Ltd. |
| | Pharmacotherapeutic Group of (API) | Antibiotic, Mucolytic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 486 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YAV-6RJ-XP4M, 2025-12-01) |
| | Detail of Fee Submitted | 38700,<br>2025-11-27, |
| | The proposed proprietary name / brand name | **Hepstoc Injection** |
| | Label Claim | Each ml contains: Phenoxy-2 methyl-2 Propionic acid.....100mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | Hepasel injection, Reg.No: 046518, Selmore pharmaceutical (PVT) Ltd. |
| | Pharmacotherapeutic Group of (API) | Fibrates/ PPAR-α agonist |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 487 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z38-7DY-NP1W, 2025-09-18) |
| | Detail of Fee Submitted | 38700,<br>2025-09-17, |
| | The proposed proprietary name / brand name | **Tylo Top Powder** |

| | | |
|---|---|---|
| | Label Claim | Each Kg Contains: Tylosin Tartrate - 500gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100gm-De-Controlled,1Kg-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | Tylo-50 Powder, Symans Pharmaceuticals, Reg. No: 063847 |
| | Pharmacotherapeutic Group of (API) | Macrolide Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 488 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MPR-4ZY-ZSLQ, 2025-09-18) |
| | Detail of Fee Submitted | 38700,<br>2025-09-17, |
| | The proposed proprietary name / brand name | **Tylo Super Powder** |
| | Label Claim | Each 100gm Contains Tylosin Tartrate..... 98gm |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 100gm-De-Controlled,1Kg-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | Amsetyl-98 Powder, Mylab Pharmaceuticals, Reg. No: 101999 |
| | Pharmacotherapeutic Group of (API) | Macrolide Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved**<br><br>Approved up to 1 kg pack size. | |
| 489 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U3S-U5U-YZV3, 2025-10-01) |

| | | |
|---|---|---|
| | Detail of Fee Submitted | 38700,<br>2025-10-01, |
| | The proposed proprietary name / brand name | **Lecosel Bolus** |
| | Label Claim | Each Bolus Contains Oxyclozanide.....625mg Oxfendazole.....275mg Cobalt sulphate.....30mg Sodium selenite.....3mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 50's-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | Galied Bolus, International Pharma Labs (PVT) Ltd. , Reg# 078222 |
| | Pharmacotherapeutic Group of (API) | Anthelmintic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |
| 490 | Case Category | Routine (Sabahat Zehra) |
| | Name, address of Applicant. | **Leads Pharma (Pvt) Ltd.** Plot#81-A, Street#6, I-10/3, Industrial Area **(000392)** |
| | Application Form Dy. No / Tracking ID & date of submission | (G3G-RET-83GT, 2025-12-01) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **Trifen SC** |
| | Label Claim | Each ml contains: Triclabendazole .....50mg Fenbendazole.....25mg Selenium (as Sodium Selenite) ..... 0.5mg Cobalt (as Cobalt Sulphate) .....1.67mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled,150ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)25-30 C |
| | For generic drugs (me-too Status) | TRIBENZOL PLUS SUSPENSION, 046526, ZAKFAS PHARMACEUTICALS |
| | Pharmacotherapeutic Group of (API) | Anthelmintic & Minerals |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommended for DML Renewal |
| | Evidence of approval of manufacturing facility | Present |
| | **Evaluation Remarks** | |
| | | |
| | **Decision** | |
| | **Approved** | |

| | | |
|---|---|---|
| 491 | Case Category | Export Facilitation (Saima Hussain) |
| | Name, address of Applicant. | **Bosch Pharmaceuticals (Pvt) Ltd.** Plot No. 221-223, Sector-23, Korangi Industrial Area **(000350)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SXX-EH6-9TRP, 2025-05-22) |
| | Detail of Fee Submitted | 37000.0,<br>2025-01-08, |
| | The proposed proprietary name / brand name | **Meglim Tablets 500mg** |
| | Label Claim | Each film coated tablet contains: Imeglimin Hydrochloride.....500mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's, 10's, 14's, 20'-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at Room Temperature |
| | For generic drugs (me-too Status) | Glymeg Tablets 500mg |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Metrochem API Pvt. Ltd. Address: Unit-IV, Plot No:34B, 40B & 60B, JN, Pharma City, Thanum (V), Parawada(M), Visakhapatnam-5311021, Andhra Pradesh, India |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Pharmaceuticals and Medical Devices Agency (PMDA), Japan |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 492 | Case Category | Contract Manufacturing (Saima Hussain) |
| | Name, address of Applicant. | **OBS Pharma (Pvt) Ltd** 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan **(000243)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VXB-93V-41JX, 2024-11-12) |
| | Detail of Fee Submitted | 93000.0,<br>2024-10-31, |
| | The proposed proprietary name / brand name | **Finerenone 10mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Finerenone.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | as per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore Below 30 degree |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Wimits Pharmaceuticals pvt ltd-Plot No 129 Sundar industrial estate raiwind road lahore- |
| | The status in reference regulatory authorities | KERENDIA(finerenone) 10mg tablet Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | Firm informed that the product of their contract acceptor, M/s Wimits, has already been approved as per the Minutes of the 353rd Meeting of the Registration Board held on 14th–15th January 2026. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.12/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit adeclaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentionednotification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is alsoneeded as part of module-1 of Form 5F. | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit fee of pre-registration variation as per the latest fee SRO. | |
| 493 | Case Category | Contract Manufacturing (Saima Hussain) |
| | Name, address of Applicant. | **OBS Pharma (Pvt) Ltd** 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan **(000243)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DPH-4LN-R6JR, 2024-11-12) |
| | Detail of Fee Submitted | 93000.0,<br>2024-10-31, |
| | The proposed proprietary name / brand name | **Finerenone 20mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains:<br>Finerenone.....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | as per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore Below 30 degree |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Wimits Pharmaceuticals pvt ltd-Plot No 129 Sundar industrial estate raiwind road lahore- |
| | The status in reference regulatory authorities | KERENDIA(finerenone) 10mg tablet Bayer Healthcare Pharmaceutical Inc., Whippany, NJ 07981 Manufactured in Germany |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | Firm informed that the product of their contract acceptor, M/s Wimits, has already been approved as per the Minutes of the 353rd Meeting of the Registration Board held on 14th–15th January 2026. In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.12/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit adeclaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the | |

| | | |
|---|---|---|
| | above-mentionednotification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is alsoneeded as part of module-1 of Form 5F. | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit for pre-registration variation as per the latest fee SRO. | |
| 494 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HWP-QJU-BJQL, 2024-08-29) |
| | Detail of Fee Submitted | 30000.0,<br>2024-08-13, |
| | The proposed proprietary name / brand name | **Vonop 20mg Tablets** |
| | Label Claim | Each film coated tablet contains: Vonoprazan Fumarate (equivalent to vonoprazan).....20mg (Innovator Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearBelow 30ºC |
| | For generic drugs (me-too Status) | Vonozan Tablets 20 mg, Manufacturer: Getz Pharmaceutical (Pvt.)Limited |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | Voquezna 20mg Tablet, Company: Phathom, (NDA): 215151 (USFDA Approved) |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm informed that the product was approved on contract manufacturing basis and then they had transferred from M/s Seraph Pharmaceuticals, Islamabad to their own facility M/s Solaris Life Sciences (Pvt.) Ltd. They have got the approval of change in manufacturing site of already registered drug product. Therefore, have they have to withdraw this application for registration. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board rejected the application as withdrawn by the firm | |
| 495 | Case Category | Export Facilitation (Saima Hussain) |
| | Name, address of Applicant. | **Atco Laboratories Limited** B-18 SITE KARACHI **(000188)** |

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|---|---|---|
| | Application Form Dy. No / Tracking ID & date of submission | (XAH-VJ2-U61V, 2026-02-04) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **BEMVATOR-EZ Tablet** |
| | Label Claim | Each film coated tablet contains: Bempedoic Acid 180mg Ezetimibe 10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 strip x 10 Tablets-De-Controlled,2 strips x 10 Tablets-De-Controlled,3 strips x 10 Tablets-De-Controlled |
| | Shelf Life (Unit) | 2 YearNot Store and Transport above 30 degree centigrade. |
| | For generic drugs (me-too Status) | BMP-E 180mg + 10mg per Tablet manufactured by Hilton Pharma (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Bempedoic Acid, “Hyperlipidemic Agent”. Ezetimibe, “Selective Cholesterol-Absorption Inhibitors” |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Enaltec Labs Private Limited.,Zhejiang Tianyu Pharmaceutical Co., Ltd., |
| | Detail of stability batches of drug product | 06 Months Data of Accelerated Stability and 06 Months Data of Long-Term Stability attached in Module 03. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API Procurement Document and Sale Invoice is attached in module 3. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence Study Report and Comparative Dissolution Profile are Attached under Module 3. |
| | 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 of Bempedoic Acid, 06 Months Data of Accelerated Stability and 36 Months Data of Long-Term Stability of Ezetimibe attached in Module 03. |
| | The status in reference regulatory authorities | NEXLIZET Tablets Manufactured by: Esperion Therapeutics, Inc. 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108. |
| | GMP status of the firm | GMP attached |
| | Evidence of approval of manufacturing facility | Evidence of Manfacturing Facility is attached. |
| | **Evaluation Remarks** | |
| | (Bempedoic Acid) Submit long term stability data of drug substance as per zone-IV condition till the claimed re-test date. Firm informed, it is respectfully submitted that we are currently in communication with the API manufacturer to obtain the requisite stability data and supporting documentation. Upon receipt of the complete response from the API supplier, the same will be submitted to DRAP at the earliest for your review and evaluation. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of long-term stability data of drug substance as per zone-IV condition till the claimed re-test date. | |
| 496 | Case Category | Export Facilitation (Saima Hussain) |

| | | |
|---|---|---|
| | Name, address of Applicant. | **Indus Pharma (Pvt.) Ltd.** Plot No 26,27,63,64,65,66 & 67 Sector 27, Korangi Industrial Area, Karachi. **(000124)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1LL-YRJ-Z7GR, 2025-09-26) |
| | Detail of Fee Submitted | 37000.0,<br>2025-04-22, |
| | The proposed proprietary name / brand name | **Dyclo-P Sachet** |
| | Label Claim | Each sachet contains: Diclofenac Potassium USP ..... 50mg (Product Specifications: USP) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1’s, 9's, 30’s -As per SRO |
| | Shelf Life (Unit) | 2 YearStore Below 30°C protect from heat and light |
| | For generic drugs (me-too Status) | Maxit Sachet 50mg |
| | Pharmacotherapeutic Group of (API) | Non-Steroidal Anti-Inflammatory Drug |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | AMOLI ORGANICS PVT. LIMITED, Plot No. 322/4, 40 Shed Area, G.I.D.C., Vapi- 396195, District-Valsad, State-Gujarat, INDIA |
| | Detail of stability batches of drug product | 40°C ± 2°C, 75 % ± 5% RH (Accelerated) 30°C ± 2°C, 65 % ± 5% RH (Long-Term) |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance Certificate No. E-8988182882491 Date of issue: 17-Apr-2024 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached in Module 03 (3.2.P.2) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 40°C ± 2°C, 75 % ± 5% RH (Accelerated) 30°C ± 2°C, 65 % ± 5% RH (Long-Term) |
| | The status in reference regulatory authorities | Voltfast Sachets 50 mg Powder for Oral Solution, Novartis Pharmaceuticals UK Limited, HPRA |
| | GMP status of the firm | Certificate No. 11/2024-DRAP (K) Dated 26th January 2024 |
| | Evidence of approval of manufacturing facility | Attached in Module 01 (1.3.5) |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 497 | Case Category | New Section (Saima Hussain) |
| | Name, address of Applicant. | **Pharmatec Pakistan (Pvt.) Limited** D-86/A, S.I.T.E., Karachi - 75700, Pakistan **(000024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J5P-GGR-6RHQ, 2026-04-30) |
| | Detail of Fee Submitted | 38700,<br>2025-12-19, |
| | The proposed proprietary name / brand name | **Xylotec 2% Jelly** |
| | Label Claim | Each gm of jelly contains: Lidocaine HCl ..... 20mg (USP Specification) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 15gm-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30 degree centigrade |

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| For generic drugs (me-too Status) | Xyloaid Jelly 2% (Manufacturer: Barrett Hodgson Pakistan (Pvt.) Ltd.) |
| Pharmacotherapeutic Group of (API) | Pharmacotherapeutic group: Local anesthetics, amides ATC code: N01BB02 |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | N/A |
| Detail of stability batches of drug product | Attached in Module 3 sub section 3.2.P.8.3 |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Attached in stability annexures |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | CDP not applicable, PE attached in Module 3.2.P.2 |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in Module 3 sub section 3.2.S.7.3 |
| The status in reference regulatory authorities | Lidocaine Hydrochloride Jelly USP, 2% (USFDA Approved) |
| GMP status of the firm | Attached in Module 1 |
| Evidence of approval of manufacturing facility | Attached in Module 1 Sub-section 1.3.5 |

**Evaluation Remarks**

| Sr.no. | Observations | Response of the Firm |
|---|---|---|
| 1. | justification is required for not including the sterility test in the finished product specification. Based on the submitted stability data, only a microbiological examination test has been included, which is applicable to non-sterile preparations. However, the applied formulation is a sterile preparation, and sterility testing is a mandatory requirement as per the United States Pharmacopeia / British Pharmacopoeia monographs. | Firm replied that, the submitted stability data were generated from laboratory-scale development batches used for formulation development and registration purposes. Terminal sterility testing was not included in the development stability protocol; therefore, sterility data are not available for these batches. For commercial manufacturing, sterility testing will be included as a mandatory release requirement in accordance with USP <71> and BP requirements. Additionally, terminal sterility testing will be incorporated into the stability program for commercial-scale batches, where applicable. In view of the above, we respectfully request acceptance of the submitted stability data generated from development batches. |
| 2. | Clarify the sterilization procedure adopted for the Lidocaine Jelly filled in aluminum tubes. Specifically, state whether the finished product is subjected to terminal sterilization or manufactured and filled under aseptic conditions. If terminal sterilization will be done then provide complete details of the sterilization method which can be used without adversely affecting the quality, safety, efficacy, or container-closure integrity of the product. Furthermore, submit supporting documentary evidence from recognized international standards, pharmacopeias, and/or regulatory guidelines (e.g., EU GMP Annex 1, WHO GMP Guidelines, USP, BP, or relevant ICH guidance) justifying the | Firm replied that, Lidocaine Jelly filled in aluminum tubes was manufactured at trial stage under a controlled process without terminal sterilization. The product was processed and filled to ensure product physical & analytical quality during development studies. The trial batches were manufactured during the development phase for formulation optimization and process understanding. At that stage, the commercial manufacturing process, including terminal sterilization, was not finalized. The commercial process is currently under development and will include terminal sterilization as a final step after sealing of aluminum tubes. This process is subject to completion of validation activities prior to |

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| | suitability of the selected sterilization approach for Lidocaine Jelly packaged in aluminum tubes. Furthermore, provide a scientific justification for not adopting the same manufacturing process for the trial batches as that intended for the commercial-scale batches. Additionally, provide references to relevant international regulatory guidelines that permit the manufacture of trial batches using a different process compared to the proposed commercial manufacturing process. | routine commercial manufacturing. It was decided that for commercial manufacturing, terminal sterilization to be introduced for the filled and sealed aluminum tubes. However, the terminal sterilization cycle is currently under development and has not yet been fully validated. The process will only be implemented after successful validation demonstrating achievement of required sterility assurance level without impacting product quality, stability, or container-closure integrity. For this purpose, we will conduct another trial to develop terminal sterilization cycle in autoclave at 121˚C for 30 minutes. |

**Decision**

**Deferred**

Firm shall submit evidence of approval of the sterile cream/ointment/gel manufacturing facility, issued by the Licensing Division.

| 498 | | |
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| | Case Category | New Section (Saima Hussain) |
| | Name, address of Applicant. | **Pharmatec Pakistan (Pvt.) Limited** D-86/A, S.I.T.E., Karachi - 75700, Pakistan **(000024)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PHT-QPB-51GJ, 2026-03-17) |
| | Detail of Fee Submitted | 38700,<br>2025-12-19, |
| | The proposed proprietary name / brand name | **Sudif 2% Cream** |
| | Label Claim | Each gm of cream contains: Fusidic Acid ..... 20mg (BP Specification) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 15gm-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30 degree centigrade |
| | For generic drugs (me-too Status) | Fusil Cream (Manufacturer: TABROS PHARMA (PVT). LTD.) |
| | Pharmacotherapeutic Group of (API) | Pharmacotherapeutic group: Topical antibiotics<br>ATC Code: D06AX01 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | N/A |
| | Detail of stability batches of drug product | Attached in Module 3 sub section 3.2.P.8.3 |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached in stability annexures |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | CDP not applicable, PE attached in Module 3.2.P.2 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in Module 3 sub section 3.2.S.7.3 |
| | The status in reference regulatory authorities | Fusidic acid 20mg/g cream (EMC Approved) |
| | GMP status of the firm | Attached in Module 1 |
| | Evidence of approval of manufacturing facility | Attached in Module 1 Sub-section 1.3.5 |
| | **Evaluation Remarks** | |

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| | Submit DRAP attested API commercial invoice/Procurement documents. Firm in their reply informed that they have received the material on a free-of-charge (FOC) basis directly at their facility through a courier service and as an evidence firm submit Free of cost letter from the API Manufacturer along with commercial invoice without attestation from DRAP. | |
| | **Decision** | |
| | **Approved** | |
| 499 | Case Category | Export Facilitation (Saima Hussain) |
| | Name, address of Applicant. | **OBS Pharma (Pvt) Ltd** 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan **(000243)** |
| | Application Form Dy. No / Tracking ID & date of submission | (57A-5U7-DWYE, 2026-04-20) |
| | Detail of Fee Submitted | 97200,<br>2026-01-15, |
| | The proposed proprietary name / brand name | **OBS-Keto Tablet** |
| | Label Claim | Each film coated tablet contains: α-Ketoanalogue to isoleucine (Calcium-salt) .....67mg α-Ketoanalogue to leucine (Calcium-salt) .....101mg α-Ketoanalogue to Phenylalanine (Calcium-salt) ..... .....68mg α-Ketoanalogue to valine (Calcium-salt) .....86mg α-hydroxyanalogue to DL-methionine (Calcium-salt) .....59mg L-lysine acetate.....105mg L-threonine.....53mg L-tryptophan.....23mg L-histidine.....38mg L-tyrosine.....30mg Total nitrogen content per tablet.....36mg Calcium content per tablet.....0.05g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10x10's -As per SRO,1x10's -As per SRO,2x10's -As per SRO,3x10's -As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C. |
| | For generic drugs (me-too Status) | Ketoalfa Tablet manufactured by Genome Pharmaceuticals Pharmaceuticals (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Amino acids, including combinations with polypeptides |
| | Name, address of Manufacturing site: | Seraph Pharmaceuticals -Plot#210, Industrial Triangle, Kahuta Road, Islamabad, Pakistan.- |
| | Name & address of API manufacturer | Cleargreens Pharmaceuticals (Pvt.) Ltd. Address: 001, Dev Prime Near Vodafone Tower, Corporate Road Makarba, Railway Crossing, Prahlad Nagar, Ahmedabad, Gujarat 380051, India.,Zhangjiagang Huachang Pharmaceutical Co.Ltd Address: No.1,Nanhai Road,Yangze River International Chemical Industrial Park,Zhangjiagang city, Jiangsu Province,P.R. (China) |
| | Detail of stability batches of drug product | Submitted. |

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|---|---|---|
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Submitted |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Submitted |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted. |
| | The status in reference regulatory authorities | Ketosteril Tablet(Approved by Federal Institute for Drugs & Medical Devices, Germany) |
| | GMP status of the firm | GMP certificate of Manufacturer (Seraph Pharmaceuticals) has been issued based on the evaluation conducted on 17-12-2023 and is valid for three years from the date of inspection. |
| | Evidence of approval of manufacturing facility | The Central Licensing Board has approved the grant of the tablet (general) section in its 253rd meeting held on 15th & 16th May, 2017 |
| | **Evaluation Remarks** | |
| | The firm has submitted exactly same assay method verification reports for the following drug substances as submitted by another applicant along with their registration application. The reported verification results appear to be exactly the same, raising concerns regarding the authenticity and originality of the submitted data. The following parameters are exactly same in both registration applications: α-Ketoanalogue to Isoleucine (Calcium Salt): Accuracy, Intermediate Precision, Specificity, and Robustness. α-Hydroxyanalogue to DL-Methionine (Calcium Salt): Specificity, Precision, and Robustness. L-Histidine: Accuracy, Intermediate Precision, Specificity, and Robustness. L-Threonine: Entire assay method verification report. L-Lysine Acetate: Intermediate Precision, Specificity, and Robustness. L-Tryptophan: Specificity and Robustness. L-Tyrosine: System Suitability, Specificity, Accuracy, Robustness, and Ruggedness. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application considering that the firm has submitted exactly same assay method verification reports for the following drug substances as submitted by another applicant along with their registration application. The following parameters are exactly same in both registration applications:<br><br>• **α-Ketoanalogue to Isoleucine (Calcium Salt):** Accuracy, Intermediate Precision, Specificity, and Robustness.<br>• **α-Hydroxyanalogue to DL-Methionine (Calcium Salt):** Specificity, Precision, and Robustness.<br>• **L-Histidine:** Accuracy, Intermediate Precision, Specificity, and Robustness.<br>• **L-Threonine:** Entire assay method verification report.<br>• **L-Lysine Acetate:** Intermediate Precision, Specificity, and Robustness.<br>• **L-Tryptophan:** Specificity and Robustness.<br>• **L-Tyrosine:** System Suitability, Specificity, Accuracy, Robustness, and Ruggedness<br><br>The above-mentioned reported verification results appear to be exactly the same, raising concerns regarding the authenticity and originality of the submitted data. | |
| 500 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QBR-N9T-AW4U, 2026-05-19) |
| | Detail of Fee Submitted | 75000,<br>2026-05-14, |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **Geptix 750mg Tablets** |
| | Label Claim | Gepotidacin 750mg/Tablet |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80, 90 & 100's Tablets-As per SRO |
| | Shelf Life (Unit) | 2 YearBelow 30°C |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | Gepotidacin mesylate is classified as a first-in-class triazaacenaphthylene antibacterial. It acts as a bacterial type II topoisomerase inhibitor. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China |
| | Detail of stability batches of drug product | Attached in Module 3 in section 3.2.P.8 |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Attached in Module 1 in section 1.6.5 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached in Module 3 in section 3.2. P.2.2 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in Module 3 in section 3.2. S.7 |
| | The status in reference regulatory authorities | BLUJEPA (Gepotidacin) tablets, for oral use; Tablets: 750 mg; Approval: 2025; Manufactured for: GlaxoSmithKline (GSK), Durham, NC 27701. |
| | GMP status of the firm | Attached in Module 1 in section 1.3.5 |
| | Evidence of approval of manufacturing facility | Attached in Module 1 in section 1.3.5 |
| | **Evaluation Remarks** | |
| | The firm has submitted falsified characterization data under Section 3.2.S.3, as evidenced by the submitted spectra. The spectra belong to those disclosed in the patent document of the innovator, GlaxoSmithKline Intellectual Property Development Ltd., available in publicly accessible Google Patents records, and do not appear to have been generated for the submitted drug substance by the drug substance manufacturer. The firm has misrepresented them as original characterization data pertaining to the submitted Drug Master File (DMF), thereby misleading the evaluator. This observation raises serious concerns regarding the authenticity, reliability, and data integrity of the submitted DMF. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board was apprised that the firm has submitted falsified characterization data under Section 3.2.S.3, as the submitted spectra (Mass Spectrometry, H-NMR, and IR spectra) belong to those disclosed in patent document of the innovator, GlaxoSmithKline Intellectual Property Development Ltd., available in publicly accessible Google Patents records. This observation raises serious concerns regarding the authenticity, reliability, and integrity of the submitted Drug Master File (DMF) of drug substance. Based on these finding, the Registration Board decided to reject the instant application. | |
| 501 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)** |

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| Application Form Dy. No / Tracking ID & date of submission | (SGA-DPM-X7SE, 2026-02-10) |
| Detail of Fee Submitted | 75000,<br>2025-07-23, |
| The proposed proprietary name / brand name | **Lembo 5mg Tablets** |
| Label Claim | Lemborexant 5mg/Tablet |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80, 90 & 100's Tablets-As per SRO |
| Shelf Life (Unit) | 2 YearBelow 30°C |
| For generic drugs (me-too Status) | NA |
| Pharmacotherapeutic Group of (API) | Lemborexnt: Hypnotic / Sedative Orexin (hypocretin) receptor antagonist |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China |
| Detail of stability batches of drug product | Attached in Module 3 in section 3.2.P.8 |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached in Module 3 in section 3.2.P.8 |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached in Module 3 in section 3.2. P.2.2 |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in Module 3 in section 3.2. S.7 |
| The status in reference regulatory authorities | DAYVIGO (Lemborexant) tablets, for oral use, Tablets: 5mg & 10mg, Initial U.S. Approval: December 23, 2019, Distributed by: Eisai Inc. Woodcliff Lake, NJ 07677 |
| GMP status of the firm | Attached in Module 1 in section 1.3.5 |
| Evidence of approval of manufacturing facility | Attached in Module 1 in section 1.3.5 |

**Evaluation Remarks**

The firm has submitted falsified characterization data under Section 3.2.S.3, as evidenced by the submitted spectra. The spectra (Mass spectrum,H-NMR and IR spectrum) belong to those disclosed in the patent document of Shanghai Syncores Technologies Inc Ltds, Zhejiang Huahai Pharmaceutical Co Ltd, Shanghai Aobo Bio Pharmaceutical Technology Co Ltd available in publicly accessible Google Patents records and have not been generated for the submitted drug substance by the drug substance manufacturer. The firm has misrepresented them as original characterization data pertaining to the submitted Drug Master File (DMF), thereby misleading the evaluator. This observation raises serious concerns regarding the authenticity, reliability, and data integrity of the submitted DMF.

**Decision**

**Rejected**

Registration Board was apprised that the firm has submitted falsified characterization data under Section 3.2.S.3, as the submitted spectra (Mass Spectrometry, H-NMR, and IR spectra) belong to those disclosed in patent document of M/s. Shanghai Syncores Technologies Inc. Ltd., M/s. Zhejiang Huahai Pharmaceutical Co. Ltd., and M/s. Shanghai Aobo Bio Pharmaceutical Technology Co. Ltd., available in publicly accessible Google Patents records. This observation raises serious concerns regarding the authenticity, reliability, and integrity of the submitted Drug Master File (DMF). Based on these finding, the Registration Board decided to reject the instant application.

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| 502 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)** |
| | Application Form Dy. No / Tracking ID & date of submission | (429-YQP-TPJ5, 2026-02-04) |
| | Detail of Fee Submitted | 75000,<br>2025-09-25, |
| | The proposed proprietary name / brand name | **Lembo 10mg Tablets** |
| | Label Claim | Lemborexant 10mg/Tablet |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80, 90 & 100's Tablets-As per SRO |
| | Shelf Life (Unit) | 2 YearBelow 30°C |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | Lemborexnt: Hypnotic / Sedative Orexin (hypocretin) receptor antagonist |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China |
| | Detail of stability batches of drug product | Attached in Module 3 in section 3.2.P.8 |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached in Module 3 in section 3.2.P.8 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached in Module 3 in section 3.2. P.2.2 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in Module 3 in section 3.2. S.7 |
| | The status in reference regulatory authorities | DAYVIGO (Lemborexant) tablets, for oral use, Tablets: 5mg & 10mg, Initial U.S. Approval: December 23, 2019, Distributed by: Eisai Inc. Woodcliff Lake, NJ 07677 |
| | GMP status of the firm | Attached in Module 1 in section 1.3.5 |
| | Evidence of approval of manufacturing facility | Attached in Module 1 in section 1.3.5 |
| | **Evaluation Remarks** | |
| | The firm has submitted falsified characterization data under Section 3.2.S.3, as evidenced by the submitted spectra. The spectra (Mass spectrum, H-NMR and IR spectrum) belong to those disclosed in the patent document of Shanghai Syncores Technologies Inc Ltds, Zhejiang Huahai Pharmaceutical Co Ltd, Shanghai Aobo Bio Pharmaceutical Technology Co Ltd available in publicly accessible Google Patents records and have not been generated for the submitted drug substance by the drug substance manufacturer. The firm has misrepresented them as original characterization data pertaining to the submitted Drug Master File (DMF), thereby misleading the evaluator. This observation raises serious concerns regarding the authenticity, reliability, and data integrity of the submitted DMF. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board was apprised that the firm has submitted falsified characterization data under Section 3.2.S.3, as the submitted spectra (Mass Spectrometry, H-NMR, and IR spectra) belong to those disclosed in patent document of M/s. Shanghai Syncores | |

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|---|---|---|
| | Technologies Inc. Ltd., M/s. Zhejiang Huahai Pharmaceutical Co. Ltd., and M/s. Shanghai Aobo Bio Pharmaceutical Technology Co. Ltd., available in publicly accessible Google Patents records. This observation raises serious concerns regarding the authenticity, reliability, and integrity of the submitted Drug Master File (DMF). Based on these finding, the Registration Board decided to reject the instant application. | |
| 503 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Medizan Laboratories (Pvt) Ltd** Plot No.313 Industrial Triangle Kahuta Road Islamabad **(000572)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q3A-JN4-43VZ, 2026-05-04) |
| | Detail of Fee Submitted | 75000,<br>2026-02-11, |
| | The proposed proprietary name / brand name | **Tasimet 20mg Capsules** |
| | Label Claim | Tasimelteon 20mg/Capsule |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2, 4, 6, 8, 10, 14, 20, 28, 30, 40, 50, 60, 70, 80, 90 & 100's Tablets-As per SRO |
| | Shelf Life (Unit) | 2 YearBelow 30°C |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | Tasimelteon is Psycholeptics, specifically melatonin receptor agonists |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | GANSU HAOTIAN PHARMACEUTICAL CO., LTD No.11, Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China |
| | Detail of stability batches of drug product | Attached in Module 3 in section 3.2.P.8 |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached in Module 3 in section 3.2.P.8 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached in Module 3 in section 3.2. P.2.2 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in Module 3 in section 3.2. S.7 |
| | The status in reference regulatory authorities | HETLIOZ® (Tasimelteon) capsules, for oral use Tablets: 80mg, Initial U.S. Approval: 2014, Distributed by: Vanda Pharmaceuticals Inc. Washington, D.C. 20037 USA |
| | GMP status of the firm | Attached in Module 1 in section 1.3.5 |
| | Evidence of approval of manufacturing facility | Attached in Module 1 in section 1.3.5 |
| | **Evaluation Remarks** | |
| | The firm has submitted falsified characterization data under Section 3.2.S.3, as evidenced by the submitted spectra. The spectra belong to those disclosed in the patent document of the Zhejiang Jingxin Pharmaceutical Co Ltd, available in publicly accessible Google Patents records, and do not appear to have been generated for the submitted drug substance by the drug substance manufacturer. The firm has misrepresented them as original characterization data pertaining to the submitted Drug Master File (DMF), thereby misleading the evaluator. This observation raises serious concerns regarding the authenticity, reliability, and data integrity of the submitted DMF. | |
| | **Decision** | |
| | **Rejected** | |

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|---|---|---|
| | Registration Board was apprised that the firm has submitted falsified characterization data under Section 3.2.S.3, as the submitted spectra (Mass Spectrometry, H-NMR, and IR spectra) belong to those disclosed in patent document of Zhejiang Jingxin Pharmaceutical Co Ltd, available in publicly accessible Google Patents records. This observation raises serious concerns regarding the authenticity, reliability, and integrity of the submitted Drug Master File (DMF) of drug substance. Based on these finding, the Registration Board decided to reject the instant application. | |
| 504 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore **(000782)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UBW-X1Q-VYXB, 2026-05-14) |
| | Detail of Fee Submitted | 75000,<br>2026-04-06, |
| | The proposed proprietary name / brand name | **Isaco 100mg Capsules** |
| | Label Claim | Each capsule contains 186 mg of Isavuconazonium sulfate equivalent to Isovuconazole....100mg (As per Innovator's specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2x 7's Capsules in blister pack-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 ºC in a dry place away from direct heat or sunlight. |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Isavuconazonium Sulfate is the sulfate ester form of isavuconazonium, a prodrug of the triazole antifungal agent isavuconazole, an antifungal agent used for the treatment of invasive aspergillosis and invasive mucormycosis. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Shandong Kehui Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | Performed ISH-001, ISH-002, Each of 5000 Capsules |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached with invoice number CI20211124HZ01 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed with CRESEMBA Capsule (US FDA) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Conducted at Zone IV-a stability conditions |
| | The status in reference regulatory authorities | US FDA |
| | GMP status of the firm | Valid w.e.f 17-06-2025 |
| | Evidence of approval of manufacturing facility | DML# 000782 |
| | **Evaluation Remarks** | |
| | Firm was asked to, provide a detailed discussion on the stereochemistry of the drug substance, including the characterization and control of its chiral centers, supported by appropriate scientific literature. In response, firm submitted characterization data under Section 3.2.S.3.1 that are exactly same to those submitted by another applicant in a separate registration application, despite the fact that the active pharmaceutical ingredients (APIs) in the two applications are supplied by different drug substance manufacturers. | |
| | **Decision** | |
| | **Rejected** | |

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| | Registration Board decided to reject the instant application, as review of the firm's submitted response revealed that the characterization data provided are exactly same to those submitted by another applicant in a separate registration application, despite the fact that the active pharmaceutical ingredients (APIs) in the two applications are sourced from different drug substance manufacturers. The submission of identical characterization data for APIs manufactured by different manufacturers raises serious concerns regarding the authenticity and reliability of the submitted data. | |
| 505 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Horizon HealthCare (Pvt) Ltd** plot no 33 sunder industrial estate lahore **(000782)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5T2-G79-QP46, 2026-05-14) |
| | Detail of Fee Submitted | 75000,<br>2026-04-06, |
| | The proposed proprietary name / brand name | **Isaco 40mg Capsules** |
| | Label Claim | Each capsule contains 74.5 mg of Isavuconazonium sulfate equivalent to Isovuconazole....40mg (As per Innovator's specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 2x 7's Capsules in blister pack-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 ºC in a dry place away from direct heat or sunlight. |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Isavuconazonium Sulfate is the sulfate ester form of isavuconazonium, a prodrug of the triazole antifungal agent isavuconazole, an antifungal agent used for the treatment of invasive aspergillosis and invasive mucormycosis. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Shandong Kehui Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | ISL-001 ISL-002 Each of 5000 Capsules |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Attached with invoice number CI20211124HZ01 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Performed with CRESEMBA Capsule (US FDA) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Conducted at Zone IV-a stability conditions |
| | The status in reference regulatory authorities | US FDA |
| | GMP status of the firm | Valid w.e.f 17-06-2025 |
| | Evidence of approval of manufacturing facility | DML# 000782 |
| | **Evaluation Remarks** | |
| | Firm was asked to provide a detailed discussion on the stereochemistry of the drug substance, including the characterization and control of its chiral centers, supported by appropriate scientific literature. In response, the firm submitted characterization data under Section 3.2.S.3.1 that are exactly same to those submitted by another applicant in a separate registration application, despite the fact that the active pharmaceutical ingredients (APIs) in the two applications are supplied by different drug substance manufacturers. | |
| | **Decision** | |
| | **Rejected** | |

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| | Registration Board decided to reject the instant application, as review of the firm's submitted response revealed that the characterization data provided are exactly same to those submitted by another applicant in a separate registration application, despite the fact that the active pharmaceutical ingredients (APIs) in the two applications are sourced from different drug substance manufacturers. The submission of identical characterization data for APIs manufactured by different manufacturers raises serious concerns regarding the authenticity and reliability of the submitted data. | |
| 506 | Case Category | Export Facilitation (Saima Hussain) |
| | Name, address of Applicant. | **Atco Laboratories Limited** B-18 SITE KARACHI **(000188)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VR9-2LL-J63Y, 2025-10-15) |
| | Detail of Fee Submitted | 75000.0,<br>2025-07-16, |
| | The proposed proprietary name / brand name | **MELONITE ORAL SOLUTION** |
| | Label Claim | Each ml contains: Melatonin ..... 1mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 120ml-De-Controlled,30ml-De-Controlled,60ml-De-Controlled,90ml-De-Controlled |
| | Shelf Life (Unit) | 24 MonthNot Store and Transport above 30 degree centigrade. |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Biogenic Amine |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Anhui Haikang Pharmaceutical Co. Ltd. |
| | Detail of stability batches of drug product | 03 Months Data of Accelerated Stability and 03 Months Data of Long-Term Stability attached in Module 03. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | API Procurement Document and Sale Invoice is attached in module 3. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Pharmaceutical Equivalence Study Report Attached under Module 3, for Oral Solution, Comparative dissolution is not applicable. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 06 Months Data of Accelerated Stability and 09 Months Data of Long-Term Stability attached in Module 03. |
| | The status in reference regulatory authorities | Melatonin 1 mg/1 ml Oral solution Manufactured by: Thame Laboratories. Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU U.K. |
| | GMP status of the firm | GMP attached |
| | Evidence of approval of manufacturing facility | Evidence of Manfacturing Facility is attached. |
| | **Evaluation Remarks** | |
| | Firm initially submitted a document under Section 3.2.S.7.1 (Stability Summary and Conclusions), stating that three production batches of Melatonin manufactured using the current manufacturing process had been placed on the stability monitoring program under accelerated conditions (40 ± 2°C/75 ± 5% RH) and long-term conditions (25 ± 2°C/60 ± 5% RH). However, the stability data sheets submitted under Section 3.2.S.7.3 indicated that the long-term stability studies had been conducted under Zone IVa conditions (30 ± 2°C/65 ± 5% RH) and included data covering only 12 months. When asked to clarify the discrepancy in the reported long-term stability conditions, the firm submitted a revised Stability Summary and Conclusions, correcting the long-term storage condition to 30 ± 2°C/65 ± 5% RH. Furthermore, the firm stated that it was submitting the updated long-term stability data of the drug substance covering 12 months. The firm also informed that it had | |

already communicated with the API manufacturer regarding the availability of stability data covering the complete claimed re-test period. The firm committed that the updated stability data and supporting documents would be submitted to DRAP immediately upon receipt from the API manufacturer for further review.

**Decision**

**Deferred**

Deferred for submission of the following:

1. Clarification from both the drug product manufacturer and the drug substance manufacturer regarding the discrepancy observed between the stability storage conditions reported in the stability summary and the corresponding stability data sheets. The stability documents provided under Sections 3.2.S.7.1, 3.2.S.7.2, and 3.2.S.7.3 indicate long-term stability data generated under storage conditions of 25 ± 2°C/60 ± 5% RH, whereas the submitted stability data sheets specify long-term storage conditions of 30 ± 2°C/65 ± 5% RH. The firm is required to provide a detailed clarification for this inconsistency, supported by appropriate documentary evidence, including track and trace records, to establish the source, authenticity, and linkage of the submitted stability data with the relevant batches and storage conditions.
2. Submission of long-term stability data of the drug substance under Zone IV storage conditions up to the claimed re-test date.

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| Case Category | Import (Saima Hussain) |
| Name, address of Applicant. | **GENOME PHARMA** RCCI Industrial Estate, Plot No. C-19, Access Road, Rawat,Islamabad. **(DHO-ISB-2257)** |
| Application Form Dy. No / Tracking ID & date of submission | (B5X-GYP-1J5S, 2025-06-02) |
| Detail of Fee Submitted | 300000.0,<br>2024-10-25, |
| The proposed proprietary name / brand name | **CetroART** |
| Label Claim | Each Vial contains: Cetrorelix... 0.25 mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 1's -As per SRO |
| Shelf Life (Unit) | 2 Year2-8 C |
| For generic drugs (me-too Status) | Cetrotide 0.25mg injection |
| Pharmacotherapeutic Group of (API) | Gonadotropin-releasing Hormone Antagonists |
| Name, address of Manufacturing site: | Varian Pharmed-Plot 1534 2nd Golshid St, 2nd Golrokh St, West Ghazali Blvd. Eshtehard Industrial Town, Alborz, Iran-Iran |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached |
| Name, address of Marketing Authorization Holder: | Genome Pharma, RCCI Industrial Estate, Plot No. C-19, Access Road, Rawat, Islamabad., Pakistan |
| Details of Certificates (CoPP/FSC/cGMP): | Attached |
| Details of Authorization Letter : | Attached |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached |
| The status in reference regulatory authorities | Cetrotide 0.25mg injection |

**Evaluation Remarks**

Firm submitted the free sale certificate dated 14/11/2024 mentioned that the product Cetrorelix (as Acetate) 250 mcg (brand CetroArt) is marketed in Islamic Republic of Iran since 22/05/2022. Firm submitted CoPP Ref: 665/759 Date: 5/4/2025 Address of the certifying authority: Division of Drugs

and Controlled Materials Food and Drug Administration Ministry of Health Tehran, Iran Firm has not submitted the letter of Authorisation.

| Sr.no. | Observations | Response of the Firm |
|---|---|---|
| 1. | Submit the pharmaceutical equivalence study report conducted in comparison with the innovator/reference product. | Firm replied that, we performed a pharmaceutical equivalence assessment by analyzing the innovator product Cetrotide® in our laboratory and comparing its critical quality attributes with our product CetroART®.A complete Certificate of Analysis (COA) was generated for both the reference product and our test product. The COAs of Cetrotide® and COAs of CetroART® are attached. |
| 2. | Provide a scientific justification for performing lyophilization on the bulk injectable solution prior to filling, instead of conducting lyophilization after filling into vials, as practiced by the innovator product. | Firm submitted a revised manufacturing procedure only change one step in the previous submitted manufacturing procedure i.e. Then, transfer the filtered solution to liquid filling machine. Calculate the sufficient amount of liquid according to assay result to equivalent 0.25 mg cetrorelix. and fill 1.1 times the calculated liquid volume as overfill into each vial. Vials transfer to freeze dryer. 9. Freeze samples at -30º C for 4 hours.10. In primary drying apply the vacuum to 0.15 millibar for 24 hours.11. In secondary drying increase the vacuum to 0.06 millibar for a further 53 hours Manufacturing procedure has not included the step of stoppering prior keep in freeze dryer, further same lyophilization condition has kept both for bulk as prior submitted and filled ampoule, both documents seems to be same |
| 4. | Submit documentary evidence demonstrating that the reference product approved by a Stringent Regulatory Authority (SRA) in which Water for Injection (WFI) is packaged in ampoule as a diluent instead of a prefilled syringe, as used in the innovator product. | Firm replied that, ASPORELIX 0.25 mg is an injectable product containing 0.25 mg of Cetrorelix (as acetate). It is approved by the European Medicines Agency, and its diluent, Water for Injection (WFI), is packaged in an ampoule, similar to our product. However the submitted reference can not be verified from the official of ema. |

Registration Board in its 357th meeting deferred the instant case due to following reasons: Case has deferred for submission of following shortcomings: Submit valid and legalized letter of Authorization pertaining to the applied product. Submit current batch manufacturing record of those batches which are manufactured using the revised manufacturing method. Firm submit the letter of authorization dated 21-04-2026. Further, firm submit the Batch manufacturing record of batch no.4024002 manufacturing date 01-12-2024 which is manufactured using the revised manufacturing method.

**Decision**

**Approved**

Subject to compliance of current Import Policy for finished drugs along with submission of valid and original legalized COPP before issuance of registration letter. Further, firm shall submit fee for pre-registration variation as per the latest fee SRO.

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| 508 | Case Category | Export Facilitation (Saima Hussain) |
| | Name, address of Applicant. | **Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MDN-A71-BPM9, 2026-05-21) |

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| Detail of Fee Submitted | 75000,<br>2026-01-13, |
| The proposed proprietary name / brand name | **Gutriva Tablets 2mg** |
| Label Claim | Each Film-coated Tablet contains: Etrasimod arginine equivalent to Etrasimod .... 2mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | As per DPC/SRO-As per SRO |
| Shelf Life (Unit) | 24 MonthStore below 30°C Protect from Heat, Light and Moisture |
| For generic drugs (me-too Status) | NA |
| Pharmacotherapeutic Group of (API) | Sphingosine-1-phosphate (S1P) receptor modulators |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Gansu Haotian Pharmaceutical Co., Ltd. No. 11 Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China |
| Detail of stability batches of drug product | Batch size: PDS-455/25, PDS-456/25 / 10000 Tablets |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | DIL-C-2ED948 |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Accelerated stability study, Long term stability study: HT20230302ETR, HT20230307ETR, HT20230312ETR |
| The status in reference regulatory authorities | Velsipity Tablets 2mg (UKMHRA) |
| GMP status of the firm | Valid till 16-Jan-2027 |
| Evidence of approval of manufacturing facility | DML no. 000028 |

**Evaluation Remarks**

Correlate the comparative dissolution results with the solubility characteristics of the innovator product, as reported in the literature available on the official website of the Reference Regulatory Authority (RRA). Furthermore, provide a scientific rationale for the dissolution behavior observed at pH 1.2, where approximately 50% of the drug is released within the first 10 minutes, followed by a marked decline in the measured drug release to below 1% at 60 minutes. Firm in their stated that the active pharmaceutical ingredient, Etrasimod, is a BCS Class II compound characterized by low aqueous solubility and high permeability. According to literature available, Etrasimod exhibits very little solubility at pH values below 8 and has a reported solubility of approximately 0.0045 mg/mL at pH 8.1. These data demonstrate that Etrasimod possesses inherently poor solubility throughout acidic and near-neutral physiological pH conditions. In view of these physicochemical characteristics, the dissolution profile observed at pH 1.2, where approximately 50% of the drug is released within the first 10 minutes followed by a decline in dissolved drug concentration, can be attributed primarily to the intrinsic solubility limitations of etrasimod. Upon exposure to the dissolution medium, rapid tablet disintegration and wetting may result in an initial increase in the apparent dissolved drug concentration. However, due to the extremely low equilibrium solubility of etrasimod under acidic conditions, the dissolved drug concentration may subsequently decrease as the system approaches solubility equilibrium, resulting in the observed dissolution trend. Firm was again asked to scientifically justify the attainment of solubility equilibrium during dissolution testing in pH 1.2 medium, by providing a detailed explanation of the underlying physicochemical properties of the API, including its pH-dependent solubility profile and any other relevant characteristics that may contribute to the establishment of solubility equilibrium under acidic condition. Submit your response along with the supporting innovator literature that specifically describes that unique solubility characteristics that is responsible for the observed dissolution behavior in low-pH media. Firm again replied that, during dissolution, drug molecules dissolve until the concentration in solution reaches the equilibrium solubility limit of etrasimod in the acidic medium. Once this

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| | saturation concentration is reached, a dynamic equilibrium is established between dissolved and undissolved drug. Therefore, the observed dissolution behavior in pH 1.2 medium with 0.2 % Tween 20 is governed by the equilibrium solubility of etrasimod under acidic conditions rather than by the formulation itself. The low-pH medium cannot maintain high concentrations of dissolved etrasimod because the API possesses inherently poor solubility in such state. However, the innovator literature only mentioned that the etrasimod exhibits very little solubility at pH values below 8 and has a reported solubility of approximately 0.0045 mg/mL at pH 8.1. The innovator literature does not discuss the specific characteristic of attaining solubility equilibrium at low pH. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred to again perform the comparative dissolution profiling of the applied product against the innovator/reference product to verify the dissolution behavior and establish the similarity of the dissolution profiles. | |
| 509 | Case Category | Import (Saima Hussain) |
| | 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 | (BV6-S4X-ABPP, 2026-03-16) |
| | Detail of Fee Submitted | 313500,<br>2025-12-10, |
| | The proposed proprietary name / brand name | **Bicutamide 50mg Tablets** |
| | Label Claim | Each film coated tablet contains: Bicalutamide ... 50mg |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 7’s, 10’s, 14’s, 20’s, 28’s & 30’s-Controlled |
| | Shelf Life (Unit) | 60 MonthStore below 30°C |
| | For generic drugs (me-too Status) | Geperprostin 50mg Tablets by Novartis Pakistan Ltd. |
| | Pharmacotherapeutic Group of (API) | Anti-Androgens |
| | 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 st Floor, Plot No. 54-C, Al Murtaza Commercial Lane-2, Phase VIII, DHA, Karachi. , Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP certificate of FP Manufacturer attached in Module I. |
| | Details of Authorization Letter : | Not applicable for imported product |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached in Module III, section 3.2.S.7. |
| | The status in reference regulatory authorities | Casodex 50mg Film-Coated Tablets, France ANSM |
| | **Evaluation Remarks** | |
| | We, Pharmacare Premium Ltd., manufacturer of Bicutamide 50mg would like to justify the use of in-house method instead of adopting specification as per British Pharmacopeia (BP) or United States Pharmacopoeia (USP) for testing the finish product. Pharmacare Premium Ltd. is a pharmaceutical company based in Malta, Europe and therefore, the company primarily refers to European | |

Pharmacopeia (Ph.Eur.) which does not have any monograph for Bicalutamide tablets. However, Bicalutamide API is tested according to Ph.Eur. monograph and relevant CEP. Furthermore, at the time when the formulation was developed, no pharmacopeial monograph was available for FP. For this reason, the FP manufacturer developed in-house analytical method, which are fully validated and validations are presented in section 3.2.P.5.3, demonstrating that the analytical method are suitable for their intended use. A comparison between the in-house specifications established by Pharmacare Premium Ltd. and the pharmacopoeia specifications described in BP and USP is presented below.

| Test | Pharmacare | British Pharmacopoeia | USP |
|---|---|---|---|
| ID by IR | Complies with reference standard | IR spectrum of test product is concordant with the reference spectrum of bicalutamide | The UV spectrum of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay |
| ID by Retention Time | Complies with reference standard | In the Assay, the retention time of the principal peak in the chromatogram obtained with test solution is similar to that of principal peak in the chromatogram obtained with standard solution | The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay |
| Assay | 95.0%–105.0% | 95.0%–105.0% | 90.0%–110.0% |
| Related substance / Impurities | Max unknown impurities: 0.2%Total unspecified impurities: 0.5%Disregard any peaks less than 0.01% of the test solution concentration (LOD) | Imp. C: 0.15%Maximum unspecified impurities: 0.2%Total unspecified impurities: 0.7%Disregard any peak less than 0.1% | Bicalutamide Aminobenzonitrile: NMT 0.1% |
| Dissolution | NLT 80% (Q) in 30 min | NLT 75% (Q) in 45 min | NLT 80% (Q) in 45 min |

However, the dissolution method recommended by USP have dissolution medium 1.0% w/v sodium lauryl sulfate in water with rotating speed between 50-75rpm 1000 mL and BP Use Apparatus 2, rotating the paddle at 50 revolutions per minute. Use 900 mL of a 1.0% w/v solution of sodium dodecyl sulfate, at a temperature of 37°, as the medium, while the applicant use 2% Sodium Dodecyl Sulfate (SDS) Dissolve 20g of SDS in 1000mL of Purified Water. Allow to SDS to fully dissolve and the foam to dissipate with the rotating speed 100rpm. Registration Board in its 357th meeting decided as under: The case is deferred for confirmation of export of the same product from the same manufacturing site to any country of a stringent regulatory authority or to a country whose regulatory agency is included in the DRAP approved list of RRAs. OR Submit bioequivalence study data conducted against the reference/innovator product. In response, the firm submitted comparative in vitro dissolution profile data for Casodex® 50 mg film-coated tablets (UK, Lot No. CM783), Bicalutamide Medinsa 50 mg film-coated tablets (Bio-batch, Spain, Lot No. 050631), and Bicalutamide Pharmacare 50 mg film-coated tablets (Malta, Lot No. 6MK01). The comparative dissolution studies were performed using the analytical method described in the relevant USP monograph and the analytical method provided under Section 3.2.P.5.2 of the dossier. The submitted results indicate that the in vitro dissolution behavior of Bicalutamide 50 mg film-coated tablets

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| | manufactured by Pharmacare Premium is comparable to that of Bicalutamide 50 mg film-coated tablets manufactured by Medinsa and the reference product, Casodex® 50 mg film-coated tablets. Furthermore, Pharmacare Premium also informed that Bicalutamide manufactured by Pharmacare Premium is registered in three European countries: Malta, Portugal and Bulgaria. The MA holder in Malta and Portugal is Pharmacare Premium Ltd., while in Bulgaria Pharmacare Premium Ltd. is used as manufacturer only. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of revised finished product specifications along with the corresponding analytical procedures in compliance with the requirements of an official pharmacopoeial monograph (USP or BP). The justification and comparative data submitted by the firm are considered inadequate and scientifically unacceptable; therefore, the firm is required to revise the specifications and analytical procedures accordingly. | |
| 510 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000900)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7VU-GDE-3D5Q, 2024-10-09) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-27, |
| | The proposed proprietary name / brand name | **Vonothan 20 mg Tablet** |
| | Label Claim | Each Film coated Tablet contains: Vonoprazan as Fumarate.....20mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10s, 20s, 30s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Vonoiza 20 mg Tablet |
| | Pharmacotherapeutic Group of (API) | Potassium-competitive acid blocker |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Enantiotech Corporation., Ltd. No.6 Zhongjing Road, Zhongshan Torch Hi-tech Industrial Development Zone Zhongshan City, Guangdong Province, China |
| | Detail of stability batches of drug product | Stability data of three batches T037 01-2024 12-2025 1200 Tablets 2x7s T038 01-2024 12-2025 1200 Tablets 2x7s T039 01-2024 12-2025 1200 Tablets 2x7s |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan of 1kg API has taken from M/s. Welmark |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP have performed against VONIZA 20MG TABLET |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of three batches has submitted by the firm |
| | The status in reference regulatory authorities | Voquenza 20mg Tablets M/s Phathom Pharmaceuticals, Inc., Buffalo Grove, IL, 60089, U.S.A. |
| | GMP status of the firm | Issuance of DML (Afresh) dated 5th March,2019 is submitted by the firm |
| | Evidence of approval of manufacturing facility | Issuance of DML (Afresh) dated 5th March,2019 mentioned that firm has tablet (general) section |
| | **Evaluation Remarks** | |

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| | The firm submitted exactly same Comparative Dissolution Profile (CDP) data at pH 4.5 and pH 6.8, as well as Pharmaceutical Equivalence data, for both strengths of the applied product. The only apparent difference between the submitted reports is the strength of the applied tablet indicated in the report header, while the underlying data remain same. Initially, the firm submitted drug substance stability data of M/s. Xianqiang Pharmaceutical Co., Ltd., China, whereas the API manufacturer identified under Section 3.2.S.2 of the dossier is M/s. Enantiotech Co. Ltd. Upon clarification, the firm submitted drug substance stability data corresponding to M/s. Enantiotech Co. Ltd. and explained that the previously submitted stability data had been inadvertently included during the initial dossier compilation. The firm also submitted exactly same assay verification reports for both the drug substance and the drug product, despite the fact that both assay methods differ in chromatographic conditions and sample preparation procedures. When firm was asked to justify this discrepancy, the firm stated that the similarity in the analytical reports resulted from standardized documentation practices and the use of a common RP-HPLC analytical platform with UV detection at 254 nm for the same active ingredient. The firm further stated that the analytical procedures, sample matrices, and intended applications for the drug substance and drug product are distinct and are independently controlled | |
| | **Decision** | |
| | **Rejected**<br><br>The Registration Board decided to reject the instant application, as the submitted dossier contains significant inconsistencies that raise serious concerns regarding the authenticity, reliability, and integrity of the submitted data.<br><br>The firm submitted exactly same Comparative Dissolution Profile (CDP) data at pH 4.5 and pH 6.8, as well as identical Pharmaceutical Equivalence (PE) data, for both strengths of the applied product. The only apparent difference between the reports is the strength of the applied tablet indicated in the report header, whereas the underlying experimental data remain identical.<br><br>Furthermore, the firm initially submitted drug substance stability data pertaining to M/s. Xianqiang Pharmaceutical Co., Ltd., China, whereas the API manufacturer identified under Section 3.2.S.2 of the dossier is M/s. Enantiotech Co. Ltd. Although, upon clarification, the firm submitted stability data corresponding to M/s. Enantiotech Co. Ltd. and explained that the previously submitted data had been inadvertently included during the initial dossier compilation.<br><br>Moreover, the firm submitted same assay verification reports for both the drug substance and the drug product despite the fact that the respective assay methods differ in chromatographic conditions and sample preparation procedures. Submission of same verification data for analytically different methods is scientifically unjustifiable and further questions the credibility of the submitted data. | |
| 511 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **Athan Pharmaceuticals** Plot # 84/2,Block A, Phase 5 , Industrial Estate Hattar, KPK, **(000900)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RDB-U8Z-PVYZ, 2024-10-22) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-27, |
| | The proposed proprietary name / brand name | **Vonothan 10 mg Tablet** |
| | Label Claim | Each Film coated tablet contains: Vonoprazan as Fumurate .....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10s, 20s, 30s-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Vonoiza 10 mg Tablet |
| | Pharmacotherapeutic Group of (API) | Potassium-competitive acid blocker |
| | Name, address of Manufacturing site: | Self Manufacturing |

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| Name & address of API manufacturer | Enantiotech Corporation., Ltd. No.6 Zhongjing Road, Zhongshan Torch Hi-tech Industrial Development Zone Zhongshan City, Guangdong Province, China |
| Detail of stability batches of drug product | T034 01-2024 12-2025 1200 Tablets 2x7s T035 01-2024 12-2025 1200 Tablets 2x7s T036 01-2024 12-2025 1200 Tablets 2x7s |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Loan of 1kg API has taken from M/s. Welmark |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | PE and CDP have performed against VONIZA 10MG TABLET |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data of three batches has submitted by the firm |
| The status in reference regulatory authorities | Voquenza 10mg Tablets M/s Phathom Pharmaceuticals, Inc., Buffalo Grove, IL, 60089, U.S.A. |
| GMP status of the firm | Issuance of DML (Afresh) dated 5th March,2019 is submitted by the firm |
| Evidence of approval of manufacturing facility | Issuance of DML (Afresh) dated 5th March,2019 mentioned that firm has tablet (general) section |

**Evaluation Remarks**

The firm submitted exactly same Comparative Dissolution Profile (CDP) data at pH 4.5 and pH 6.8, as well as Pharmaceutical Equivalence data, for both strengths of the applied product. The only apparent difference between the submitted reports is the strength of the applied tablet indicated in the report header, while the underlying data remain same. Initially, the firm submitted drug substance stability data of M/s. Xianqiang Pharmaceutical Co., Ltd., China, whereas the API manufacturer identified under Section 3.2.S.2 of the dossier is M/s. Enantiotech Co. Ltd. Upon clarification, the firm submitted drug substance stability data corresponding to M/s. Enantiotech Co. Ltd. and explained that the previously submitted stability data had been inadvertently included during the initial dossier compilation. The firm also submitted exactly same assay verification reports for both the drug substance and the drug product, despite the fact that both assay methods differ in chromatographic conditions and sample preparation procedures. When firm was asked to justify this discrepancy, the firm stated that the similarity in the analytical reports resulted from standardized documentation practices and the use of a common RP-HPLC analytical platform with UV detection at 254 nm for the same active ingredient. The firm further stated that the analytical procedures, sample matrices, and intended applications for the drug substance and drug product are distinct and are independently controlled

**Decision**

**Rejected**

The Registration Board decided to reject the instant application, as the submitted dossier contains significant inconsistencies that raise serious concerns regarding the authenticity, reliability, and integrity of the submitted data.

The firm submitted exactly same Comparative Dissolution Profile (CDP) data at pH 4.5 and pH 6.8, as well as identical Pharmaceutical Equivalence (PE) data, for both strengths of the applied product. The only apparent difference between the reports is the strength of the applied tablet indicated in the report header, whereas the underlying experimental data remain identical.

Furthermore, the firm initially submitted drug substance stability data pertaining to M/s. Xianqiang Pharmaceutical Co., Ltd., China, whereas the API manufacturer identified under Section 3.2.S.2 of the dossier is M/s. Enantiotech Co. Ltd. Although, upon clarification, the firm submitted stability data corresponding to M/s. Enantiotech Co. Ltd. and explained that the previously submitted data had been inadvertently included during the initial dossier compilation.

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| | Moreover, the firm submitted same assay verification reports for both the drug substance and the drug product despite the fact that the respective assay methods differ in chromatographic conditions and sample preparation procedures. Submission of same verification data for analytically different methods is scientifically unjustifiable and further questions the credibility of the submitted data. | |
| 512 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7EW-UBX-7LVD, 2024-06-26) |
| | Detail of Fee Submitted | 30000.0,<br>2024-04-29, |
| | The proposed proprietary name / brand name | **Dycure 50mg Capsule** |
| | Label Claim | Each Capsule Contains; Diacerein .....50mg (IP Spec's) |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearBelow 30ºC |
| | For generic drugs (me-too Status) | Diora 50mg Capsules, Manufacturer: Getz Pharma (Pvt.) Limited |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Evolugen 50 mg capsules, Manufacturer: EG LABO – Labortaroies EUROGENERICS (Registered in France) |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The submitted chromatograms bear the name of analyst which is not included in the list of employees of the applicant. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for verification of employment details of the analyst mentioned in the submitted chromotograms. | |
| 513 | Case Category | Any Other (Saima Hussain) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RV9-9HR-5786, 2024-12-02) |
| | Detail of Fee Submitted | 75000.0,<br>2024-10-04, |

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| The proposed proprietary name / brand name | **DOTINAB Tablet 2mg** |
| Label Claim | Each Tablet contains: Dotinurad.....2mg (Innovator's Specification) |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 7's,10's,14's,20's,2-As per SRO |
| Shelf Life (Unit) | 2 Year(s)Store below 30°C. |
| For generic drugs (me-too Status) | N/A |
| Pharmacotherapeutic Group of (API) | Anti-Gout (Preparation increasing excretion of uric acid) |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Beijing Jincheng Taier Pharmaceutical Co., Ltd. |
| Detail of stability batches of drug product | Batch no. 853DS01 batch size 5000 tablet Batch no. 853DS02 batch size 5000 tablet |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Firm submitted the clearance certificate dated 06-03-2024 |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Firm submitted the pharmaceutical equivalence and comparative dissolution profile against Urece tablet 2mg |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted (temp. 40±2ºC/ 75±5% RH and temp. 30±2ºC/ 65±5% RH) |
| The status in reference regulatory authorities | PMDA approved: URECE Tablets 2mg manufactured by Fuji Yakuhin Co., Ltd. |
| GMP status of the firm | Firm submitted GMP certificate dated 26-07-2023 |
| Evidence of approval of manufacturing facility | Firm submitted the evidence of availability of facility of non-sterile inhalation liquid |

**Evaluation Remarks**

The applied formulation is listed only in the PDF of approved drugs uploaded on the official PMDA Japan website. However, the applied drug is not found in the PMDA Japan database, which provides detailed information through product information leaflets. Further, applied formulation is not available in any other approved RRA. 1. Provide the evidence of approval status of applied formulation in the approved reference regulatory agencies other than PMDA (Japan). Firm again submitted the same reference of PMDA Japan in their reply. 2. Submit documented evidence, such as a prescription information leaflet, to confirm the product description, including label claims and coating details of the reference product. Firm submitted the prescription information leaflet to confirm the product description, including label claims and coating details of the reference product but that document is not available on the official website of PMDA Japan. 3. Provide details regarding the discontinuation or withdrawal of the applied formulation from the approved reference regulatory agencies (if any). Firm in their reply stated that "Dotinurad Tablet is approved and Marketed product, no discontinuation or withdrawal information is available" , however the statement is not supported with any official document of reference product. 4. Provide details of indication/usage, dosage/administration details, contraindications and warning and precautions of applied product along with reference. Firm submitted the Product information leaflet in their reply that is not available on the official website of PMDA Japan. 5. Provide information regarding the qualitative composition of reference product that was used as the basis for developing the applied formulation. Firm submitted the qualitative composition of reference product without any supporting document. 6. Provide detailed information regarding any specific manufacturing requirements for the applied formulation, such as specialized equipment, unique processes, or specific environmental conditions along with confirmation of availability of same at the manufacturing site. The firm stated in their reply that the tablet is manufactured using the wet granulation method and that all the necessary equipment for producing the applied formulation is available at the manufacturing site. 7. Submit reference of acceptance limit of dissolution testing that has been adopted for the applied product. Firm replied that since dissolution specification is not available ,therefore they follow USP General chapter <1092 > and USFDA guidance document

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| | for setting the dissolution acceptance limit. Registration Board in its 353rd meeting decided as under: The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product. Firm submitted Public Assessment Report (Pharmaceutical Interview Form) of the innovator product, which is verifiable on the PMDA website. The Public Assessment Report discusses the solubility characterization of the API and specifies the dissolution conditions for the innovator product as follows: Dissolution Medium: Water Volume: 900 mL Apparatus: Paddle Rotation Speed: 50 rpm Sampling Time: 45 minutes The firm adopted the same dissolution conditions recommended for the innovator product and conducted dissolution studies of applied product (0.5 mg, 1 mg, and 2 mg) using the dissolution method described in the PMDA document. Furthermore, the firm has committed to revise the finished product specification, particularly the dissolution test conditions, to align with those of the innovator product. In addition, the firm submitted the Risk Management Plan (RMP) for the drug product, along with evidence of notification of the Pharmacovigilance Officer to the Pharmacy Services Division. | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter. | |
| 514 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HBJ-XYU-WT49, 2024-12-02) |
| | Detail of Fee Submitted | 75000.0,<br>2024-09-27, |
| | The proposed proprietary name / brand name | **DOTINAB Tablet 1mg** |
| | Label Claim | Each Tablet contains: Dotinurad.....1mg (Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's,10's,14's,20's,2-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C. |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Anti-Gout (Preparation increasing excretion of uric acid) |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Beijing Jincheng Taier Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | Batch no. 852DS01 batch size 5000 tablet Batch no. 852DS02 batch size 5000 tablet |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm submitted the clearance certificate dated 06-03-2024 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Firm submitted the pharmaceutical equivalence and comparative dissolution profile against URECE 1 mg Tablet |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted (temp. 40±2ºC/ 75±5% RH and temp. 30±2ºC/ 65±5% RH) |
| | The status in reference regulatory authorities | PMDA approved: URECE Tablets 1mg manufactured by Fuji Yakuhin Co., Ltd. |
| | GMP status of the firm | Firm submitted GMP certificate dated 26-07-2023 |

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| | Evidence of approval of manufacturing facility | Firm submitted the GMP certificate incudes tablet (General section) |
| | **Evaluation Remarks** | |
| | The applied formulation is listed only in the PDF of approved drugs uploaded on the official PMDA Japan website. However, the applied drug is not found in the PMDA Japan database, which provides detailed information through product information leaflets. Further, applied formulation is not available in any other approved RRA. 1. Provide the evidence of approval status of applied formulation in the approved reference regulatory agencies other than PMDA (Japan). Firm again submitted the same reference of PMDA Japan in their reply. 2. Submit documented evidence, such as a prescription information leaflet, to confirm the product description, including label claims and coating details of the reference product. Firm submitted the prescription information leaflet to confirm the product description, including label claims and coating details of the reference product but that document is not available on the official website of PMDA Japan. 3. Provide details regarding the discontinuation or withdrawal of the applied formulation from the approved reference regulatory agencies (if any). Firm in their reply stated that "Dotinurad Tablet is approved and Marketed product, no discontinuation or withdrawal information is available" , however the statement is not supported with any official document of reference product. 4. Provide details of indication/usage, dosage/administration details, contraindications and warning and precautions of applied product along with reference. Firm submitted the Product information leaflet in their reply that is not available on the official website of PMDA Japan. 5. Provide information regarding the qualitative composition of reference product that was used as the basis for developing the applied formulation. Firm submitted the qualitative composition of reference product without any supporting document. 6. Provide detailed information regarding any specific manufacturing requirements for the applied formulation, such as specialized equipment, unique processes, or specific environmental conditions along with confirmation of availability of same at the manufacturing site. The firm stated in their reply that the tablet is manufactured using the wet granulation method and that all the necessary equipment for producing the applied formulation is available at the manufacturing site. 7. Submit reference of acceptance limit of dissolution testing that has been adopted for the applied product. Firm replied that since dissolution specification is not available ,therefore they follow USP General chapter <1092 > and USFDA guidance document for setting the dissolution acceptance limit. Registration Board in its 353rd meeting decided as under: The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product. Firm submitted Public Assessment Report (Pharmaceutical Interview Form) of the innovator product, which is verifiable on the PMDA website. The Public Assessment Report discusses the solubility characterization of the API and specifies the dissolution conditions for the innovator product as follows: Dissolution Medium: Water Volume: 900 mL Apparatus: Paddle Rotation Speed: 50 rpm Sampling Time: 45 minutes The firm adopted the same dissolution conditions recommended for the innovator product and conducted dissolution studies of applied product (0.5 mg, 1 mg, and 2 mg) using the dissolution method described in the PMDA document. Furthermore, the firm has committed to revise the finished product specification, particularly the dissolution test conditions, to align with those of the innovator product. In addition, the firm submitted the Risk Management Plan (RMP) for the drug product, along with evidence of notification of the Pharmacovigilance Officer to the Pharmacy Services Division. | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter. | |
| 515 | Case Category | New Molecule/Formulation (Saima Hussain) |
| | Name, address of Applicant. | **Nabiqasim Industries (Pvt) Ltd.,** 17/24, Korangi Industrial Area, Karachi. **(000105)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5P4-RAB-HL8S, 2024-12-02) |

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| Detail of Fee Submitted | 75000.0,<br>2024-09-27, |
| The proposed proprietary name / brand name | **DOTINAB Tablet 0.5mg** |
| Label Claim | Each Tablet contains: Dotinurad.....0.5mg (Innovator's Specification) |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 7's,10's,14's,20's,2-As per SRO |
| Shelf Life (Unit) | 2 Year(s)Store below 30°C. |
| For generic drugs (me-too Status) | N/A |
| Pharmacotherapeutic Group of (API) | Anti-Gout (Preparation increasing excretion of uric acid) |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | Beijing Jincheng Taier Pharmaceutical Co., Ltd. |
| Detail of stability batches of drug product | Batch no. 851DS01 batch size 5000 tablet Batch no. 851DS02 batch size 5000 tablet |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm submitted the clearance certificate dated 06-03-2024 |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Firm submitted the pharmaceutical equivalence and comparative dissolution profile against Urece Tablet 0.5mg G053 (Fuji. Pharmaceutical Co. Ltd.) |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Submitted (temp. 40±2ºC/ 75±5% RH and temp. 30±2ºC/ 65±5% RH) |
| The status in reference regulatory authorities | PMDA approved: URECE Tablets 0.5mg manufactured by Fuji Yakuhin Co., Ltd. |
| GMP status of the firm | Firm submitted GMP certificate dated 26-07-2023 |
| Evidence of approval of manufacturing facility | Firm submitted the GMP certificate incudes tablet (General section) |

**Evaluation Remarks**

The applied formulation is listed only in the PDF of approved drugs uploaded on the official PMDA Japan website. However, the applied drug is not found in the PMDA Japan database, which provides detailed information through product information leaflets. Further, applied formulation is not available in any other approved RRA. 1. Provide the evidence of approval status of applied formulation in the approved reference regulatory agencies other than PMDA (Japan). Firm again submitted the same reference of PMDA Japan in their reply. 2. Submit documented evidence, such as a prescription information leaflet, to confirm the product description, including label claims and coating details of the reference product. Firm submitted the prescription information leaflet to confirm the product description, including label claims and coating details of the reference product but that document is not available on the official website of PMDA Japan. 3. Provide details regarding the discontinuation or withdrawal of the applied formulation from the approved reference regulatory agencies (if any). Firm in their reply stated that "Dotinurad Tablet is approved and Marketed product, no discontinuation or withdrawal information is available" , however the statement is not supported with any official document of reference product. 4. Provide details of indication/usage, dosage/administration details, contraindications and warning and precautions of applied product along with reference. Firm submitted the Product information leaflet in their reply that is not available on the official website of PMDA Japan. 5. Provide information regarding the qualitative composition of reference product that was used as the basis for developing the applied formulation. Firm submitted the qualitative composition of reference product without any supporting document. 6. Provide detailed information regarding any specific manufacturing requirements for the applied formulation, such as specialized equipment, unique processes, or specific environmental conditions along with confirmation of availability of same at the manufacturing site. The firm stated in their reply that the tablet is manufactured using the wet granulation method and that all the necessary equipment for producing the applied formulation is

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| | available at the manufacturing site. 7. Submit reference of acceptance limit of dissolution testing that has been adopted for the applied product. Firm replied that since dissolution specification is not available ,therefore they follow USP General chapter <1092 > and USFDA guidance document for setting the dissolution acceptance limit. Registration Board in its 353rd meeting decided as under: The case is deferred for submission of the detailed Public Assessment Report (PAR) of the innovator product to support the solubility characterization of the API as provided by the API manufacturer, and to justify the dissolution conditions adopted for the drug product. Firm submitted Public Assessment Report (Pharmaceutical Interview Form) of the innovator product, which is verifiable on the PMDA website. The Public Assessment Report discusses the solubility characterization of the API and specifies the dissolution conditions for the innovator product as follows: Dissolution Medium: Water Volume: 900 mL Apparatus: Paddle Rotation Speed: 50 rpm Sampling Time: 45 minutes The firm adopted the same dissolution conditions recommended for the innovator product and conducted dissolution studies of applied product (0.5 mg, 1 mg, and 2 mg) using the dissolution method described in the PMDA document. Furthermore, the firm has committed to revise the finished product specification, particularly the dissolution test conditions, to align with those of the innovator product. In addition, the firm submitted the Risk Management Plan (RMP) for the drug product, along with evidence of notification of the Pharmacovigilance Officer to the Pharmacy Services Division. | |
| | **Decision** | |
| | **Approved**<br><br>Firm shall submit fee for pre-registration variation as per the latest fee SRO prior the issuance of Registration letter. | |
| 516 | Case Category | Export Facilitation (Saima Hussain) |
| | Name, address of Applicant. | **Pacific Pharmaceutical Ltd** 30 km Multan Road Lahore **(000295)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W7H-WUL-TXWL, 2025-05-12) |
| | Detail of Fee Submitted | 37000.0,<br>2025-02-14, |
| | The proposed proprietary name / brand name | **AspiVon** |
| | Label Claim | Each Each film coated tablet contains: Vonoprazan as fumarate (as outer immediate release layer) ...10 mg Aspirin (as enteric coated inner core) ...100 mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 3 x 10's-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30 C |
| | For generic drugs (me-too Status) | Vpirin (Vonoprazan + Aspirin 10mg + 100mg) Tablet Horizon Healthcare (Pvt) Ltd. |
| | Pharmacotherapeutic Group of (API) | Vonoprazan fumarate-Proton Pump Inhibitor/Aspirin-Analgesic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Hebei Jingye Medical Technology Corp., LTD. East of Jingyi Road, West zone, Costal-port economic technology department zone, Cangzhou Bohai New Area,YibinHongguang Pharmaceutical Co., Ltd. Luolong county Nanxi District, Yibin City, Sichuan Province, China |
| | Detail of stability batches of drug product | Provided in Module 3 (Drug Product) |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Provided in Module 3 |

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| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Provided in Module 3 (Drug Product) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided in Module 3 (Drug Substance) |
| | The status in reference regulatory authorities | Cabpirin Tablet by Takeda Pharmaceutical Co., Ltd. Drug Consultation Office 2-1-1 NihonbashiHoncho, Chuo-ku, Tokyo, Japan. |
| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 517 | 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,<br>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 | |

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| | 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 ℃ 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:100RPM, acceptance limit: Not less than 75%(Q) of the labeled amount of Olaparib is dissolved in 60 minutes. Registration Board in its 356th meeting decided as under: 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. The firm, in its response, submitted the Bioequivalence Study Report for Olanib 150 mg Tablet. Upon review, it was observed that the demographic data of all enrolled subjects, including age, height, weight, body mass index (BMI), and race, are exactly same to those presented in the Bioequivalence Study Report of Elopag 50 mg Tablet. Furthermore, it is to be informed that the bioequivalence study for Olanib 150 mg Tabletwas reportedly conducted in 2020, whereas the bioequivalence study for Elopag 50 mg Tablet was reportedly conducted in 2017. The submission of identical demographic data for all study participants across two different studies conducted for different drug products raises serious concerns regarding the authenticity, reliability, and integrity of the submitted data. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, as review of the submitted bioequivalence study report for Olanib 150 mg Tablet revealed significant discrepancies. It was observed that the demographic characteristics of all enrolled subjects, including age, height, weight, body mass index (BMI), and race, are identical to those presented in the bioequivalence study report for Elopag 50 mg Tablet.<br><br>Furthermore, the bioequivalence study for Elopag 50 mg Tablet was reportedly conducted in 2017, whereas the bioequivalence study for Olanib 150 mg Tablet was reportedly conducted in 2020. The submission of identical demographic data for all study participants in two separate bioequivalence studies conducted for different drug products at different times is scientifically implausible and raises serious concerns regarding the authenticity, reliability, and integrity of the submitted data. | |
| 518 | 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,<br>2025-06-02, |
| | The proposed proprietary name / brand name | **Elopag 50 Tablet** |
| | Label Claim | Each Film Coated Tablet Contains.....<br>Eltrombopag Olamine INN Equivalent to 50 mg Eltrombopag. |

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| 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) |

**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 | 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 |

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| | | size distribution test during drug substance analysis. | 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. |

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| 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 |

Registration Board in its 356th meeting decided as under: 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. The firm, in its response, submitted the Bioequivalence Study Report for Elopag 50 mg Tablet. Upon review, it was observed that the demographic data of all enrolled subjects, including age, height, weight, body mass index (BMI), and race, are exactly same to those presented in the Bioequivalence Study Report of Olanib 150 mg Tablet. Furthermore, it is to be informed that the bioequivalence study for Elopag 50 mg Tablet was reportedly conducted in 2017, whereas the bioequivalence study for Olanib 150 mg Tablet was reportedly conducted in 2020. The submission of identical demographic data for all study participants across two different studies conducted for

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| | different drug products raises serious concerns regarding the authenticity, reliability, and integrity of the submitted data. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, as review of the submitted bioequivalence study report for Elopag 50 mg Tablet revealed significant discrepancies. It was observed that the demographic characteristics of all enrolled subjects, including age, height, weight, body mass index (BMI), and race, are identical to those presented in the bioequivalence study report for Olanib 150 mg Tablet.<br><br>Furthermore, the bioequivalence study for Elopag 50 mg Tablet was reportedly conducted in 2017, whereas the bioequivalence study for Olanib 150 mg Tablet was reportedly conducted in 2020. The submission of identical demographic data for all study participants in two separate bioequivalence studies conducted for different drug products at different times is scientifically implausible and raises serious concerns regarding the authenticity, reliability, and integrity of the submitted data. | |
| 519 | 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,<br>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: |

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| | | 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 |

Registration Board in its 356th meeting decided as under: 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. Registration Board in its 356th meeting decided as under: 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. The firm, in its response, submitted the Bioequivalence Study Report for Elopag 50 mg Tablet. Upon review, it was observed that the demographic data of all enrolled subjects, including age, height, weight, body mass index (BMI), and race, are exactly same to those presented in the Bioequivalence Study Report of Olanib 150 mg Tablet. Furthermore, it is to be informed that the bioequivalence study for Elopag 50 mg Tablet was reportedly conducted in 2017, whereas the bioequivalence study for Olanib 150 mg Tablet was reportedly conducted in 2020. The submission of identical/exactly same demographic data for all study participants across two different studies conducted for different drug products raises serious concerns regarding the authenticity, reliability, and integrity of the submitted data.

**Decision**

**Rejected**

Registration Board decided to reject the instant application, as review of the submitted bioequivalence study report for Elopag 50 mg Tablet revealed significant discrepancies. It was observed that the demographic characteristics of all enrolled subjects, including age, height, weight, body mass index (BMI), and race, are identical to those presented in the bioequivalence study report for Olanib 150 mg Tablet.

Furthermore, the bioequivalence study for Elopag 50 mg Tablet was reportedly conducted in 2017, whereas the bioequivalence study for Olanib 150 mg Tablet was reportedly conducted in 2020. The submission of identical demographic data for all study participants in two separate bioequivalence studies conducted for different drug products at different times is scientifically implausible and raises serious concerns regarding the authenticity, reliability, and integrity of the submitted data.

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| 520 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **fozan pharmaceuticals Industries (Pvt) Ltd** 36-A hayatabad Industrial estate, Peshawar **(000567)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (SDA-L89-NVZD, 2024-11-27) |
| | Detail of Fee Submitted | 37000.0,<br>2024-11-08, |
| | The proposed proprietary name / brand name | **Tropide 50mg** |
| | Label Claim | Each Film Coated Tablet Contains; Itopride HCL .....50mg (Innovators Spec's) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearBelow 30 degree C° |
| | For generic drugs (me-too Status) | GANATON Tablets 50mg Abbot Laboratories |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Prayosha Healthcare Pvt. Ltd. |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Alkapride 50mg Tablet (The Nile Co. for pharmaceutical and Chemical Industries) |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Pharmaceutical Equivalence data, Comparative dissolution Profile report and stability data of drug product as submitted by another firm along with their registration application. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and stability data of drug product that had been submitted by M/s. Solaris Life Sciences Private Limited, along with its registration application. | |
| 521 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EVG-X5L-4D5U, 2024-07-11) |
| | Detail of Fee Submitted | 30000.0,<br>2024-04-29, |
| | The proposed proprietary name / brand name | **Solopride 50mg Tablets** |
| | Label Claim | Each Film Coated Tablet Contains; Itopride HCl.....50mg (Innovator Spec's) |
| | Reference to Finished product specifications | As per Innovators Specification |

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| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearBelow 30ºC |
| | For generic drugs (me-too Status) | Ganaton Tablets 50mg, Manufacturer: Abbott Labortries Pakistan limited. |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | Alkapride 50mg Tablets Manufacturer: The Nile Co. for pharmaceutical and Chemical Industries (Registered in Egypt) |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Pharmaceutical Equivalence data, Comparative dissolution Profile report and stability data of drug product as submitted by another firm along with their registration application. | |
| | **Decision** | |
| | **Deferred**<br><br>For verification of employment details of the analyst mentioned in the submitted chromatograms. | |
| 522 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **Briell Pharmaceuticals (Pvt.) Ltd.** 538-C, Sundar Industrial Estate, Lahore **(000862)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HYQ-MQ8-33MS, 2026-03-02) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-07-03, 2025-10-10 |
| | The proposed proprietary name / brand name | **VONO-B 10MG TABLET** |
| | Label Claim | Each Tablet Contains Vonoprazane .....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearAmbient |
| | For generic drugs (me-too Status) | Manufacturer Name: GETZ PHARMA Brand Name & Strength: : VONOZAN 10MG TABLET Composition Vonoprazane Each Tablet Contains Vonoprazane 10mg /Tablet |
| | Pharmacotherapeutic Group of (API) | Attached |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Guangdong Xianqiang Pharmaceutical Co. China |
| | Detail of stability batches of drug product | Attached |

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| | Documents for the procurement of API with approval from DRAP (in case of Import) | Attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached |
| | The status in reference regulatory authorities | PMDA Japan Approved |
| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report, assay validation report of drug product and chromatograms of stability data of drug product as submitted by another firm along with their registration application. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and chromatograms of stability data that had been submitted by M/s. Mediate Pharmaceutical Pvt Ltd., Karachi, along with its registration application. | |
| 523 | Case Category | Routine (Saima Hussain) |
| | Name, address of Applicant. | **Briell Pharmaceuticals (Pvt.) Ltd.** 538-C, Sundar Industrial Estate, Lahore **(000862)** |
| | Application Form Dy. No / Tracking ID & date of submission | (85H-7S9-EM41, 2026-02-27) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-07-03, 2025-10-10 |
| | The proposed proprietary name / brand name | **VONO-B 20MG TABLET** |
| | Label Claim | Each Tablet contains Vonoprazane .....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearAmbient |
| | For generic drugs (me-too Status) | Manufacturer Name: GETZ PHARMA Brand Name & Strength: : VONOZAN 20MG TABLET Composition Vonoprazane Each Tablet Contains Vonoprazane 20MG /Tablet |
| | Pharmacotherapeutic Group of (API) | Attached |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Guangdong Xianqiang Pharmaceutical Co. China |
| | Detail of stability batches of drug product | Attached |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Attached |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Attached |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Attached |
| | The status in reference regulatory authorities | PMDA Japan Approved |

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| | GMP status of the firm | Attached |
| | Evidence of approval of manufacturing facility | Attached |
| | **Evaluation Remarks** | |
| | Firm has submitted exactly same assay verification report of drug substance performed by drug product manufacturer, Comparative dissolution Profile report and assay validation report of drug product as submitted by another firm along with their registration application. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and chromatograms of stability data that had been submitted by M/s. Mediate Pharmaceutical Pvt Ltd., Karachi, along with its registration application. | |
| 524 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4YE-47Q-93ZX, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Axcen Injection 100ml** |
| | Label Claim | Each mL Contains: Flunixin (as Meglumine)..... 50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25□C. Protect from heat and light |
| | For generic drugs (me-too Status) | Phoenix Injection by M/s. Mylab (Pvt.) Ltd., (Reg. No.: 073914) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 525 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6P6-47P-GPQB, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Encure-10 Injection 100ml** |
| | Label Claim | Each mL Contains:<br>Enrofloxacin.....100mg |
| | Reference to Finished product specifications | British Pharmacopeia |

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| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°C. Protect from heat & light |
| | For generic drugs (me-too Status) | Enroxsel-10 Injection by M/s. Selmore Pharmaceutical (Pvt.) Ltd., (Reg. No.: 049640) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 526 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7L6-3YB-5R5N, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Wormec Injection 100ml** |
| | Label Claim | Each 100mL Contains: Ivermectin.....1gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°C. Protect from heat & light |
| | For generic drugs (me-too Status) | Actimec Injection by M/s. Selmore Pharmaceutical (Pvt.) Ltd., (Reg. No.: 034595) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 527 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7SZ-X8X-RLU6, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Nimtol Injection 100ml** |
| | Label Claim | Each mL Contains: Oxytetracycline (as Hydrochloride)....300mg Flunixin (as Meglumine)....20mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |

| | | |
|---|---|---|
| | Shelf Life (Unit) | 2 YearStore below 25°C. Protect from heat & light |
| | For generic drugs (me-too Status) | Duasol Injection by M/s. Selmore Pharmaceutical (Pvt.) Ltd. (Reg. No.: 049640) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 528 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DYZ-U6L-BXXB, 2025-11-21) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Wormec DS Injection 10ml** |
| | Label Claim | Each mL Contains: Ivermectin .....20mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°C. Protect from heat & light |
| | For generic drugs (me-too Status) | Selmec Injection by M/s. Selmore Pharmaceutical (Pvt.) Ltd. (Reg. No.: 071087) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 529 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GH4-EQ5-S222, 2025-11-21) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Wormec DS Injection 100ml** |
| | Label Claim | Each mL Contains: Ivermectin .....20mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°C. Protect from heat & light |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | Farmec-2 Injection by M/s. Leads Pharma (Pvt.) Ltd. (Reg. No.: 063722) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 530 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NYR-7UY-1EYY, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Axcen Injection 10ml** |
| | Label Claim | Each mL Contains: Flunixin (as Meglumine) USP..... 50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25□C. Protect from heat and light. |
| | For generic drugs (me-too Status) | Loxin Injection by M/s. Selmore Pharmaceutical (Pvt.) Ltd., (Reg. No.: 035098) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 531 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Vetz Pharmaceutical Pvt Ltd** Plot No. Q-1, Site Kotri, Sindh **(000813)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E6U-9Q1-THNP, 2025-10-24) |
| | Detail of Fee Submitted | 38700,<br>2025-10-23, |
| | The proposed proprietary name / brand name | **Vetz-Com Injection** |
| | Label Claim | Each ml contains:- Meloxicam BP.....7.5 mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at below 25° C. Protect from heat & light. Store in cool & dry place. |
| | For generic drugs (me-too Status) | Camilox Injection |
| | Pharmacotherapeutic Group of (API) | |

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|---|---|---|
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In conclusion of the inspection it is interpreted that the management was focused/committed towards continous improvement and intends to expand its operations to effectively contribute in export markets while serving with good quality products availabili |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 532 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Vetz Pharmaceutical Pvt Ltd** Plot No. Q-1, Site Kotri, Sindh **(000813)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HWD-MPB-TVTQ, 2025-10-24) |
| | Detail of Fee Submitted | 38700,<br>2025-10-23, |
| | The proposed proprietary name / brand name | **Melovetz Injection** |
| | Label Claim | Each ml contains:- Meloxicam (BP) 10 mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at below 25° C. Protect from heat & light. Store in cool & dry place. |
| | For generic drugs (me-too Status) | Elax-10 Injection |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | In conclusion of inspection it is interpreted that the management was focused/committed towards continuous improvement and intends to expand its operation to effectively contribute in export markets while serving with good quality products availability in |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 533 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TNH-QUY-8JS9, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Ketowan Injection 100ml** |
| | Label Claim | Each mL Contains: Ketoprofen BP.....100mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. Protect from heat & light |

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| | For generic drugs (me-too Status) | Ketoject Injection by M/s. Selmore Pharmaceutical (Pvt.) Ltd., (Reg. No.: 043141) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 534 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WWM-MGS-36H3, 2025-11-21) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Metrym-5 Injection 100ml** |
| | Label Claim | Each mL Contains: Meloxicam BP.....5mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. Protect from heat & light |
| | For generic drugs (me-too Status) | Meloxibar-5 Injection by M/s. Baariq Pharmaceuticals (Reg. No.: 088607) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 535 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y7H-AW9-MNPS, 2025-11-19) |
| | Detail of Fee Submitted | 38700,<br>2025-11-18, |
| | The proposed proprietary name / brand name | **Metrym Injection 10ml** |
| | Label Claim | Each mL Contains: Meloxicam BP.....20mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. Protect from heat & light |
| | For generic drugs (me-too Status) | Veticam Plus Injection by M/s. Vetz Pharmaceutical (Pvt.) Ltd., (Reg. No.: 088607) |
| | Pharmacotherapeutic Group of (API) | |

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| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the stated conditions their current GMP compliance level is rated as good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 536 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YN6-LYB-S1W6, 2025-11-26) |
| | Detail of Fee Submitted | 38700,<br>2025-11-25, |
| | The proposed proprietary name / brand name | **Hepawan Injection 100ML** |
| | Label Claim | Each ml Contains: Phenoxy-2-Methyl-2-Propionic Acid..... 100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Yearbelow 25 |
| | For generic drugs (me-too Status) | Hepasel Injection (Reg No. 046518) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | based on the stated observation their current GMP compliance level is rated as Good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 537 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **QAS International** Plot No. 153/155, Mustafabad Tehsil Kamoki Gujranwala, Pakistan **(000968)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2B7-URM-JJNM, 2025-11-08) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **TyDox (Water Soluble Powder)** |
| | Label Claim | Each 100 gm contains: Tylosin Tartrate B.P(Vet) ....20gm Doxycycline Hyclate (B.P) equal to Doxycycline...40gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10gm, 20gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room temperature. Protect from direct sun light |
| | For generic drugs (me-too Status) | DOXITYL |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |

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| | GMP status of the firm | N/A |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 538 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **QAS International** Plot No. 153/155, Mustafabad Tehsil Kamoki Gujranwala, Pakistan **(000968)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DVV-76M-L72V, 2025-08-28) |
| | Detail of Fee Submitted | 38700.0, 2025-08-21, |
| | The proposed proprietary name / brand name | **Furatylozone Water Soluble Powder** |
| | Label Claim | Each kg contains: Tylosin Tartrate 25 gm Erythromycin Thiocyanate 30 gm Furaltadone 50gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10gm, 20gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg,-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room Temperature. Protect from direct sunlight. |
| | For generic drugs (me-too Status) | Tylofurcin |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | N/A |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Deferred for review of sub-committee on veterinary drugs regarding therapeutic requirements keeping in view safety, efficacy & quality parameters. | |
| | **Decision** | |
| | **Deferred** | |
| 539 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **QAS International** Plot No. 153/155, Mustafabad Tehsil Kamoki Gujranwala, Pakistan **(000968)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8XN-XPP-RAM2, 2025-11-08) |
| | Detail of Fee Submitted | 38700, 2025-10-15, |
| | The proposed proprietary name / brand name | **NeoMix (Water Soluble Powder)** |
| | Label Claim | Neomycin...70gm/100g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10gm, 20gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room temperature. Protect from direct sun light |
| | For generic drugs (me-too Status) | NEO RUTH |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |

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|---|---|---|
| | GMP status of the firm | N/A |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 540 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **QAS International** Plot No. 153/155, Mustafabad Tehsil Kamoki Gujranwala, Pakistan **(000968)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MLE-X2T-3TQ3, 2025-12-13) |
| | Detail of Fee Submitted | 38700,<br>2025-10-15, |
| | The proposed proprietary name / brand name | **Neoflostin water soluble powder** |
| | Label Claim | Each gm contains: Oxytetracycline HCL USP.....300mg Florfenicol....100mg Neomycin Sulphate BP....150mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10gm,20gm,50gm,100gm,250gm,500gm,1Kg,5Kg De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at room Temperature. Protect from direct sunlight |
| | For generic drugs (me-too Status) | FLORON Water soluble powder |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | N/A |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 541 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **QAS International** Plot No. 153/155, Mustafabad Tehsil Kamoki Gujranwala, Pakistan **(000968)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YNX-B74-DBJ6, 2025-08-29) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-21, |
| | The proposed proprietary name / brand name | **Pipraqas Water Soluble Powder** |
| | Label Claim | Each 1000gm contains: Piperazine Citrate 500 gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10gm, 20gm, 50gm, 100gm, 250gm, 500gm, 1Kg, 2.5Kg,-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore at room Temperature. Protect from direct sunlight. |
| | For generic drugs (me-too Status) | Citradin |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | N/A |

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| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 542 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **S.J & G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E94-8BE-TXPB, 2025-09-08) |
| | Detail of Fee Submitted | 38700.0,<br>2025-09-04, |
| | The proposed proprietary name / brand name | **Prosyl** |
| | Label Claim | Each mL contains: Dinoprost USP..... 5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 20mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)As per requirement |
| | For generic drugs (me-too Status) | DPROST 0.5% Injection |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Facility of M/s. SJG Fazul Ellahie, Karachi was found to be operating in compliance with the requirements of Good Manufacturing Practices. Detailed inspection report was also prepared on GMP Audit proforma separately. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Deferred for justification for need of applied pack size (20ml) as applied pack is not registered already. | |
| | **Decision** | |
| | **Deferred** | |
| 543 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **S.J & G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WUH-HXT-24XY, 2025-09-08) |
| | Detail of Fee Submitted | 38700.0,<br>2025-09-04, |
| | The proposed proprietary name / brand name | **Prosyl** |
| | Label Claim | Each mL contains: Dinoprost..... 5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 5mL-De-Controlled |
| | Shelf Life (Unit) | 2 YearAs per requirement |
| | For generic drugs (me-too Status) | DPROST 0.5% Injection |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Facility of M/s. SJG Fazul Ellahie, Karachi was found to be operating in compliance with the requirements of Good Manufacturing Practices. Detailed inspection report was also prepared on GMP Audit proforma separately. |

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|---|---|---|
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 544 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **S.J & G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EAU-8L2-ZWA7, 2025-11-20) |
| | Detail of Fee Submitted | 38700,<br>2025-11-17, |
| | The proposed proprietary name / brand name | **Vetacycline Injection 100mL** |
| | Label Claim | Each mL Contains: Oxytetracycline (HCl) USP.....50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100 mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30 C |
| | For generic drugs (me-too Status) | Geomycin 50mg/ml Injection |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The facility of M/s. SJG Fazal Ellahie karachi was found to be operating in compliance with the requirements of Good Manufactering Practices. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 545 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **S.J & G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VS2-8HA-RGP1, 2025-09-08) |
| | Detail of Fee Submitted | 38700.0,<br>2025-09-04, |
| | The proposed proprietary name / brand name | **Prosyl** |
| | Label Claim | Each mL contains: Dinoprost USP..... 5mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 2mL-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)As per requirement |
| | For generic drugs (me-too Status) | DPROST 0.5% Injection |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | The Facility of M/s. SJG Fazul e Ellahie, Karachi was found to be operating in compliance with the requirements of Good Manufacturing Practices. Detailed inspection report was also prepared on GMP Audit proforma separately. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

| | | |
|---|---|---|
| | Deferred for justification for need of applied pack size (2ml) as applied pack is not registered already. | |
| | **Decision** | |
| | **Deferred** | |
| 546 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Selmore Pharmaceuticals Limited** Plant: 36-KM Multan Road, Lahore: Head Office: SPL House No. 82, R-1 Johar Town **(000507)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U4R-PHG-55X7, 2025-10-27) |
| | Detail of Fee Submitted | 38700,<br>2025-10-08, |
| | The proposed proprietary name / brand name | **TULOSEL INJECTION 10ML** |
| | Label Claim | Each ml contains: Tulathromycin = 100mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore the medicine below 25degree centigrade, protect from light and moisture. |
| | For generic drugs (me-too Status) | Thrust Injection Reg. No. 122868 by M/s Elko Organization Pvt. Ltd. Karachi |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | M/s Selmore Pharmaceuticals (Pvt) Ltd. 36-Km, Multan Road, Lahore was operating at a satisfactory level of CMP compliance. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 547 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)** |
| | Application Form Dy. No / Tracking ID & date of submission | (156-P9A-5ZLG, 2025-10-03) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Arvon 50mg/ml Injection** |
| | Label Claim | Each ml contains: Buparvaquone.....50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10ml x 1's,20ml x 1's, 30ml x 1's,40ml x 1's ,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Attached as Annexure IV |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |

| | | |
|---|---|---|
| | **Approved** | |
| 548 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6ES-SB2-BDTH, 2025-10-04) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Fluven 50mg/ml Injection** |
| | Label Claim | Each ml contains: Flunixin as Meglumine.....50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10ml x 1's, 20ml x 1's, 50ml x 1's , 100ml x 1's-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Attached as Annexure IV |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 549 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7LD-2VS-7ADG, 2025-09-29) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Veecam 7.5mg/ml injection** |
| | Label Claim | Each ml contains: Meloxicam .....7.5mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10ml × 1's , 50ml × 1's, 100ml × 1's -De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Attached as Annexure IV |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 550 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (EYB-19N-YG81, 2025-10-01) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Nit -Vee 340mg/ml Injection** |
| | Label Claim | Each ml contains: Nitroxynil.....340mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10ml x 1's, 50ml x 1's , 100ml x 1's-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Attached as Annexure IV |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 551 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NYE-H4T-38UG, 2025-09-29) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Veecam 10mg/ml injection** |
| | Label Claim | Each ml contains: Meloxicam .....10mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10ml x 1's, 50ml x 1's , 100ml x 1's-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Attached as Annexure IV |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 552 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z7A-MEE-WBG6, 2025-09-29) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Veecam 20mg/ml injection** |
| | Label Claim | Each ml contains: Meloxicam .....20mg |
| | Reference to Finished product specifications | British Pharmacopeia |

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| | Proposed Pack Size | 10ml x 1's, 50ml x 1's , 100ml x 1's-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Attached as Annexure IV |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 553 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)** |
| | Application Form Dy. No / Tracking ID & date of submission | (X4P-5R9-YW6A, 2025-09-29) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Veeket 100mg/ml Injection** |
| | Label Claim | Each ml contains: Ketoprofen.....100mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10ml x 1's, 20ml x 1's, 30ml x 1's, 50ml x 1's , 1-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Attached as Annexure IV |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Valid |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 554 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1VE-EE8-DP9B, 2025-12-24) |
| | Detail of Fee Submitted | 97200,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **WAL MOX-C 20 POWDER** |
| | Label Claim | Each 100gm powder contains (As Per Innovator Spec.) Amoxicillin as trihydrate BP..... 20g Colistin sulphate BP ..... 80MIU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | AMOXITIN W/S POWDER (071062) ATTABAK PHARMA ISLAMABAD |

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|---|---|---|
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | D-Maarson Pharmaceuticals-PLOT # 17 ST#SS-2, NATIONAL INDUSTRIAL ZONE RAWAT, ISLAMABAD- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 555 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (34D-D9L-A48P, 2025-12-24) |
| | Detail of Fee Submitted | 97200,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **WAL MOX POWDER** |
| | Label Claim | Each 1000gm powder contains (BP) Amoxicillin (As trihydarte) BP..... 500g |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | RYMOX-50 W/S POWDER (069665) ZUMRAS PHARMA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | D-Maarson Pharmaceuticals-PLOT # 17 ST#SS-2, NATIONAL INDUSTRIAL ZONE RAWAT, ISLAMABAD- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 556 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3JJ-88E-Z9ZQ, 2025-12-24) |
| | Detail of Fee Submitted | 97200,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **WAL MOX-C 50 POWDER** |
| | Label Claim | Each 100gm powder contains (As Per Innovator Spec.) Amoxicillin as trihydrate ..... 50g Colistin sulphate ..... 50MIU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled |

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|---|---|---|
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | AMOX-C MAARSON W/S POWDER (071054) ATTABAK Pharma |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | D-Maarson Pharmaceuticals-PLOT # 17 ST#SS-2, NATIONAL INDUSTRIAL ZONE RAWAT, ISLAMABAD- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 557 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7R9-QPL-539Q, 2025-12-24) |
| | Detail of Fee Submitted | 97200,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **WAL PROFEN 40LAC DRY POWDER INJECTION** |
| | Label Claim | Each dry powder vial contains: (As per Innovator spec.) Penicillin G Procaine BP.....4, 000,000 IU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x 1's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | PP Cillin 4-M Injection (112338) ETERNA PHARMACEUTICALS |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | D-Maarson Pharmaceuticals-PLOT # 17 ST#SS-2, NATIONAL INDUSTRIAL ZONE RAWAT, ISLAMABAD- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 558 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EGJ-GRH-J6M2, 2025-12-24) |
| | Detail of Fee Submitted | 97200,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **STREPLIN 5g DRY POWDER INJECTION** |
| | Label Claim | Each dry powder vial contains: (As per Innovator spec.) Benzyl Penicillin |

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|---|---|---|
| | | BP.....500,000 IU Penicillin G Procaine USP.....15, 00,000 IU Streptomycin Sulphate BP..... 5g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1 x 1's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | Biopen 5 GM Injection (081718) SELMORE PHARMA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | D-Maarson Pharmaceuticals-PLOT # 17 ST#SS-2, NATIONAL INDUSTRIAL ZONE RAWAT, ISLAMABAD- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 559 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M3R-SJ5-W66R, 2025-08-19) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-18, |
| | The proposed proprietary name / brand name | **IVAZOLE ORAL SUSPENSION** |
| | Label Claim | Each 100ml contains (As Per Innovator Spec.) Triclabendazole ..... 12g Albendazole BP..... 10g Ivermectin BP..... 0.2g |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | THUNDER DRENCH STAR LAB LAHORE |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | At the time of inspection firm was operating according to GMP |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 560 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M7Q-R2L-BLH6, 2025-08-19) |

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| | Detail of Fee Submitted | 38700.0,<br>2025-08-18, |
| | The proposed proprietary name / brand name | **KAMISOLE 1.5% ORAL LIQUID** |
| | Label Claim | Each 100ml contains (BP) Levamisole HCl 1.5g |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | LEVANIL DRENCH (059113) BREEZE PHARMA ISLAMABAD |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | At the time of inspection firm was operating according to GMP |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 561 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QVQ-84M-EG2Q, 2025-12-24) |
| | Detail of Fee Submitted | 97200,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **MOX WAL LA INJECTION** |
| | Label Claim | Each ML contains: (BP Vet.) Amoxicillin as Trihydrate.....150mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | SYMOX LA INJECTION (058999) SYMMANS PHARMA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | D-Maarson Pharmaceuticals-PLOT # 17 ST#SS-2, NATIONAL INDUSTRIAL ZONE RAWAT, ISLAMABAD- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 562 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TEB-M8N-U3TG, 2025-12-24) |

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| | Detail of Fee Submitted | 97200,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **NAWA MOX-E POWDER** |
| | Label Claim | Each gm powder contains (As Per Innovator Spec.) Amoxicillin Trihydrate eq. to Amoxicillin BP..... 200mg Lincomycin HCl eq. to Lincomycin BP..... 88mg Spectinomycin Sulphate eq. to Spectinomycin BP ..... 88mg Vitamin E Acetate BP..... 30mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000g-De-Controlled,100g-De-Controlled,250g-De-Controlled,500g-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | MOX SEL E POWDER (122265) ARACHARD PHARMA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | D-Maarson Pharmaceuticals-PLOT # 17 ST#SS-2, NATIONAL INDUSTRIAL ZONE RAWAT, ISLAMABAD- |
| | GMP status of the firm | The Panel Recommends renewal of Drug Manufacturing License |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 563 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawal Pharmaceuticals** Plot No 11-A, Punjab Small Industrial Estate **(000735)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UZG-4WE-U6P1, 2025-08-19) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-18, |
| | The proposed proprietary name / brand name | **LOBEN ORAL SUSPENSION** |
| | Label Claim | Each 100ml contains (BP Vet Spec.) Albendazole BP ..... 2.5g |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 100ml-De-Controlled,1Lit-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 30°C |
| | For generic drugs (me-too Status) | ZOLE DM ORAL SUSPENSION (078271) D-MAARSON PHARMA RAWAT |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | At the time of inspection firm was operating according to GMP |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |

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| | **Approved** | |
| 564 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4AD-GMW-VEYL, 2025-11-25) |
| | Detail of Fee Submitted | 38700,<br>2025-11-19, |
| | The proposed proprietary name / brand name | **Doxy Nix 50 oral powder** |
| | Label Claim | Each 100gm contains: Doxycycline hyclate (USP) ----50gm . |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10KG-De-Controlled,1KG-De-Controlled,250gm-De-Controlled,25KG-De-Controlled,500GM-De-Controlled,5KG-De-Controlled |
| | Shelf Life (Unit) | 2 Year25C° |
| | For generic drugs (me-too Status) | Xedo-50 Oral Powder by A.K PHARMA Faisal abad |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 565 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4U5-16H-AW17, 2025-11-18) |
| | Detail of Fee Submitted | 38700,<br>2025-11-15, |
| | The proposed proprietary name / brand name | **L S B Inj 100ml** |
| | Label Claim | Each ml contains: Lincomycin (as HCL) BP 50 mg Spectinomycin (as HCL) USP 100 mg Benzyl alcohol BP 9mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ML-De-Controlled |
| | Shelf Life (Unit) | 2 Year25C° |
| | For generic drugs (me-too Status) | LUPINS INJ by leads pharma |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby |

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|---|---|---|
| | | issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 566 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (88E-U8J-VVGE, 2025-11-20) |
| | Detail of Fee Submitted | 38700,<br>2025-11-19, |
| | The proposed proprietary name / brand name | **NOWORM 50% Oral Powder** |
| | Label Claim | Each gm contains: LEVAMISOLE HCL BP. 500mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10kg-De-Controlled,1kg-De-Controlled,250gm-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year25C° |
| | For generic drugs (me-too Status) | Levasel 50 powder Reg 057008 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 567 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8AV-MNU-163Z, 2025-11-20) |
| | Detail of Fee Submitted | 38700,<br>2025-11-19, |
| | The proposed proprietary name / brand name | **L S NIX 50/100 injection** |
| | Label Claim | Each ml contains Lincomycin as hydrochloride) BP..... 50 mg Spectinomycin ( as sulphate tetrahydrate) EP..... 100 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ML-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25C° |

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|---|---|---|
| | For generic drugs (me-too Status) | Lincostin 150mg Injection Reg #122039 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 568 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HYV-87B-SP4M, 2025-11-20) |
| | Detail of Fee Submitted | 38700,<br>2025-11-19, |
| | The proposed proprietary name / brand name | **GENTANIX 10% injection** |
| | Label Claim | Each ml contains Gentamicin (as Sulphate) USP..... 100mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 100ML-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25C° |
| | For generic drugs (me-too Status) | GENTASEL-10 Injection Reg 034594 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 569 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N1V-QTM-UM2B, 2025-12-24) |
| | Detail of Fee Submitted | 38700,<br>2025-12-17, |
| | The proposed proprietary name / brand name | **Tylanix 10% (oral Powder)** |
| | Label Claim | Each kg contains Tylosin phosphate USP.....100gm, |
| | Reference to Finished product specifications | As per Innovators Specification |

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|---|---|---|
| | Proposed Pack Size | 10kg-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25C° |
| | For generic drugs (me-too Status) | Vety tylomix powder Reg 019936 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 570 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NEQ-JTY-E464, 2025-11-26) |
| | Detail of Fee Submitted | 38700,<br>2025-11-19, |
| | The proposed proprietary name / brand name | **FLUMEQ-C Oral Powder** |
| | Label Claim | Each GM contains Flumequine(EP.USP) ----------100mg Colistin sulphate(USP)----------0.5MIU |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10kg-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25C° |
| | For generic drugs (me-too Status) | Farmecol oral Powder M/S FARM AID GROUP(FAG PHARMACEUTICAL) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 571 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (QP9-QAB-1LPV, 2025-11-25) |
| | Detail of Fee Submitted | 38700,<br>2025-11-19, |
| | The proposed proprietary name / brand name | **TIAMONIX 45% Oral Powder** |
| | Label Claim | Each 100 gm contains TIAMULIN (as hydrogen fumarate) (EP.USP) ----------45gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10kg-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year25C° |
| | For generic drugs (me-too Status) | F-TYMO Powder by M/S Farm Aid Group Hattar,Haripur. |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 572 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R7G-Q88-T6TQ, 2025-12-24) |
| | Detail of Fee Submitted | 38700,<br>2025-12-17, |
| | The proposed proprietary name / brand name | **Tylotar nix100%** |
| | Label Claim | Each gm contains Tylosin tartrate USP..... 1000mg, |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10kg-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25C° |
| | For generic drugs (me-too Status) | Tylolina 100% powder |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

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|---|---|---|
| | **Decision** | |
| | **Approved** | |
| 573 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UW8-9WZ-MJBR, 2025-12-24) |
| | Detail of Fee Submitted | 38700,<br>2025-12-17, |
| | The proposed proprietary name / brand name | **EV Sel Solution for inj** |
| | Label Claim | Each ml contains Vitamin E (USP) 100 mg Sodium Selenite (BP) 0.5 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ML-De-Controlled,50ML-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25C° |
| | For generic drugs (me-too Status) | V-Sel inj reg #088141 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 574 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pharmonix Pharmaceuticals** Plot 28, Street SS-2, National Industrial Zone, Rawat **(000990)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y45-JWW-NA2T, 2025-12-30) |
| | Detail of Fee Submitted | 38700,<br>2025-12-17, |
| | The proposed proprietary name / brand name | **MV Sel injection** |
| | Label Claim | Each ml contains: sodium selenite.....0.5 mg α-tocopherol .....70 mg cyanocobalamin (vit. B12)...0.1 mg Vitamin B1 20mg adenosin-5'-monophosphoric acid.....5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ML-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)25C° |
| | For generic drugs (me-too Status) | selphos inj by selmore |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Accordingly, the Drug Manufacturing License No. 00990 by way of Formulation is hereby issued w.e.f 17-01-2024 subject to conditions in the Schedule B-I, B-II, B-III and provisions of |

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| | | rule 15, 16, 18 & 20 and provisions of the Drugs (Licensing, Registering |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 575 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **GHANI BROTHERS** 2ND FLOOR KARIMJEE BUILDING, NORTH NAPIER ROAD, OPP HBL BANK **(094)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2T3-HZB-NJ1J, 2025-12-30) |
| | Detail of Fee Submitted | 313500,<br>2025-12-15, |
| | The proposed proprietary name / brand name | **Oxylong 50mg Injection** |
| | Label Claim | Each ml contains: Oxytetracycline USP.....50mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 50ml vial per box-De-Controlled |
| | Shelf Life (Unit) | 3 Year(s)Keep tightly sealed and store in a cool, dark place. |
| | For generic drugs (me-too Status) | EMIVET-5 INJECTION BY ZAKFAS PHARAMCEUTICAL ( PVT) LTD, MULTAN |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | north china pharmaceutical group corporation veter-no 11, yangzi road, economic and techological development zone, shijiazhuang, hebei-China |
| | Name, address of Marketing Authorization Holder: | north china pharmaceutical group corporation veter, no 11, yangzi road, economic and techological development zone, shijiazhuang, hebei, China |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | Firm was asked to provide justification for In house specifications while Oxytetracycline injection is pharmacopeial product. Firm replied that "The limit of key items in the specification is established based on Veterinary Drug Quality Standards (2017 Edition) compendial monograph and meet the requirements of the current Pharmacopoeia.They provided Verification Report of Analytical Methods for Oxytetracycline Injection". | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for provision of pharmacopeial (USP) specifications. | |
| 576 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (A4U-2ZT-MVXY, 2025-06-26) |

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|---|---|---|
| | Detail of Fee Submitted | 37000.0,<br>2025-06-03, |
| | The proposed proprietary name / brand name | **PROLIUM-90 WATER SOLUBLE** |
| | Label Claim | Each 100G Contains: - Amprolium HCL..... 90 g |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1 KG-De-Controlled,100 G-De-Controlled,25 KG-De-Controlled,250 G-De-Controlled,5 KG-De-Controlled,500 G-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | AMPROMED ORAL POWDER 094405 by M/s ICI Pakistan |
| | Pharmacotherapeutic Group of (API) | Antiprotozoal |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 577 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BEH-9H7-9EPT, 2025-06-26) |
| | Detail of Fee Submitted | 37000.0,<br>2025-06-17, |
| | The proposed proprietary name / brand name | **OXYFEN INJECTION** |
| | Label Claim | EACH ML CONTAINS: -<br>OXYTETRACYCLINE HCL BP .....50MG<br>MEPYRAMINE MALEATE BP.....25MG |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | OXYFEN INJECTION by Attabak Pharmaceutical Industries |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC ANTIHISTAMINE |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | As per inspection conducted on 24.2.2021-25.2.2021 firm is operating at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 578 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L1Q-NRW-6M4T, 2025-06-26) |

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|---|---|---|
| | Detail of Fee Submitted | 37000.0,<br>2025-06-17, |
| | The proposed proprietary name / brand name | **OXYFEN INJECTION** |
| | Label Claim | Each mL Contains: - OXYTETRACYCLINE HCL BP.....50MG MEPYRAMINE MALEATE BP.....25MG |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | OXYFEN INJECTION by Attabak Pharmaceutical Industries |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC ANTIHISTAMINE |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | As per inspection conducted on 24.2.2021-25.2.2021 firm is operating at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 579 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L6D-U1V-N7R6, 2025-06-25) |
| | Detail of Fee Submitted | 37000.0,<br>2025-06-03, |
| | The proposed proprietary name / brand name | **GENTA PLUS INJECTION** |
| | Label Claim | Each mL Contains: - Gentamicin sulphate BP eq to gentamicin base.....30mg Sulphadimidine BP.....125mg Trimethoprim BP.....25mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50mL -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | Genta Plus Injection by M/s Vety Care Pharmaceutical |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | As per inspection conducted on 24.2.2021-25.2.2021 firm is operating at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 580 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Vetrox Pharmaceuticals** Chak No. 388-JB,12-KM Toba Jhang Road ,Near M-4 Interchange,Toba Tek Singh **(000940)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (LT4-WRH-L2MU, 2025-11-29) |
| | Detail of Fee Submitted | 38700,<br>2025-11-28, |
| | The proposed proprietary name / brand name | **Roxitrim ORAL SUSPENSION** |
| | Label Claim | Each liter contains Trimethoprim ..... 80mg Sulfadiazine ..... 400mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10 ml-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,20 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)• Store in a cool, dry, dark place (e.g. 15–30 °C) Protect from moisture and direct sunlight |
| | For generic drugs (me-too Status) | TRIBRISSEN Oral Suspension |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Good Compliance |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 581 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N1M-4PG-QND2, 2025-06-26) |
| | Detail of Fee Submitted | 37000.0,<br>2025-06-17, |
| | The proposed proprietary name / brand name | **KCND INJECTION** |
| | Label Claim | Each mL Contains: - Kanamycin Sulphate.....50mg Colistin Sulphate BP.....100000 IU Neomycin sulphate BP..... 50mg Dexamethasone -21- Phosphate Sodium Salt ....0.5 mg As per Innovator's Specifications |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | I-KENCY 100ML INJECTION by M/s International Pharma |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | As per inspection conducted on 24.2.2021-25.2.2021 firm is operating at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |

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| 582 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RX9-Y4S-7DLE, 2025-06-25) |
| | Detail of Fee Submitted | 37000.0,<br>2025-06-03, |
| | The proposed proprietary name / brand name | **GENTA PLUS INJECTION** |
| | Label Claim | Each mL Contains:- Gentamicin sulphate BP eq to gentamicin base.....30mg Sulphadimidine BP.....125mg Trimethoprim BP.....25mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |
| | For generic drugs (me-too Status) | Genta Plus Injection by M/s Vety Care Pharmaceutical |
| | Pharmacotherapeutic Group of (API) | ANTIBIOTIC |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | As per inspection conducted on 24.2.2021-25.2.2021 firm is operating at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 583 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Vetrox Pharmaceuticals** Chak No. 388-JB,12-KM Toba Jhang Road ,Near M-4 Interchange,Toba Tek Singh **(000940)** |
| | Application Form Dy. No / Tracking ID & date of submission | (S42-YWX-GE8H, 2025-11-29) |
| | Detail of Fee Submitted | 38700,<br>2025-11-27, |
| | The proposed proprietary name / brand name | **VETNOR ORAL SOLUTION** |
| | Label Claim | VETNOR Oral Solution Each 100ml Contain:- Norfloxacin ..... 20gm Aminophyllin ..... 8gm Guaiphenesin ..... 20gm 5. Dosage & Administration • Route: Oral, via drinking water o Dosage rate: Poultry: 1 ml into 2 liters of drinking water for 3-5 days for Veterinary use only |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10 ml-De-Controlled,100 ml-De-Controlled,1000 ml-De-Controlled,20 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)• Store in a cool, dry, dark place (e.g. 15–30 °C) Protect from moisture and direct sunlight |
| | For generic drugs (me-too Status) | NORFLOX P FORTE Oral Solution |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |

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| | GMP status of the firm | Good Compliance |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 584 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Vetrox Pharmaceuticals** Chak No. 388-JB,12-KM Toba Jhang Road ,Near M-4 Interchange,Toba Tek Singh **(000940)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VSY-2RT-MLWM, 2025-11-29) |
| | Detail of Fee Submitted | 38700,<br>2025-11-28, |
| | The proposed proprietary name / brand name | **OXYCURE ORAL POWDER** |
| | Label Claim | Each 1000gm Contains: Oxytetracycline HCL USP.....950gm (Product complies with USP Specs) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10 gm-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,20 gm-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)• Store in a cool, dry, dark place (e.g. 15–30 °C) Protect from moisture and direct sunlight |
| | For generic drugs (me-too Status) | OXYMIX Water Soluble Powder |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Good Compliance |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 585 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Mylab pvt ltd** Khanqah Sharif, Bahawalpur **(000747)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z6X-1AH-NH4H, 2025-06-26) |
| | Detail of Fee Submitted | 37000.0,<br>2025-06-17, |
| | The proposed proprietary name / brand name | **KCND INJECTION** |
| | Label Claim | Each mL Contains: - Kanamycin Sulphate .....50mg Colistin Sulphate .....100000 IU Neomycin sulphate..... 50mg Dexamethasone -21- Phosphate Sodium Salt ....0.5 mg As per Innovator’s Specifications |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store Below 30°C |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | I-KENCY 100ML INJECTION by M/s International Pharma |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | As per inspection conducted on 24.2.2021-25.2.2021 firm is operating at satisfactory level of GMP compliance. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 586 | Case Category | Routine (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 | (ZVV-N4W-PGTL, 2025-11-05) |
| | Detail of Fee Submitted | 75000,<br>2025-10-27, |
| | The proposed proprietary name / brand name | **SICCAMED +** |
| | Label Claim | Each Intramammary syringe contains: Cloxacillin (as Cloxacillin benzathine) ..... 600 mg Ampicillin (as Ampicillin trihydrate) .....300 mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 5.4g Intramammary Tube-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store at temperature among 15º to 30º C, in original package. Keep out from the reach of children. |
| | For generic drugs (me-too Status) | Not Manufacturing Locally |
| | Pharmacotherapeutic Group of (API) | Antibiotic |
| | Name, address of Manufacturing site: | AVE&VETMEDIC DOO Beograd-Bregalnička 32, Vršac, Belgrade-Serbia |
| | Name, address of Marketing Authorization Holder: | AVE&VETMEDIC DOO Beograd, Bregalnička 32, Vršac, Belgrade, Serbia |
| | Details of Certificates (CoPP/FSC/cGMP): | Firm submitted copy of GMP certificate issued by Republic Serbia Ministry of Agriculture, Forestry and Water Management Veterinary Department, Belgrad. |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 587 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Vetrox Pharmaceuticals** Chak No. 388-JB,12-KM Toba Jhang Road ,Near M-4 Interchange,Toba Tek Singh **(000940)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3DD-LXB-SXV7, 2025-11-29) |

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| | Detail of Fee Submitted | 38700,<br>2025-11-28, |
| | The proposed proprietary name / brand name | **TYLOFOR-50 WSP** |
| | Label Claim | Each gm contains Tylosin Tartrat BP.....500 gm |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 10 gm-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,20 gm-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)• Store in a cool, dry, dark place (e.g. 15–30 °C) Protect from moisture and direct sunlight |
| | For generic drugs (me-too Status) | TYLO-50 Water Soluble Powder |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Good Compliance |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 588 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Y65-7XH-8MJ2, 2025-10-16) |
| | Detail of Fee Submitted | 38700,<br>2025-10-10, |
| | The proposed proprietary name / brand name | **Nephstar Powder** |
| | Label Claim | Each gm contains: Hexamethylene Tetramine (Methenamine).....955mg Riboflavin (Vitamin B2).....10mg Calcium Pantothenate (Vitamin B5).....5mg Nicotinamide (Vitamin B3).....25mg (Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°C. |
| | For generic drugs (me-too Status) | Rinosel Powder Reg. # 049621 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |

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| | **Decision** | |
| | **Approved** | |
| 589 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XQJ-A7T-TX6D, 2025-09-19) |
| | Detail of Fee Submitted | 38700,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **Rasomycin-5 Injection** |
| | Label Claim | Each ml contains:- Oxytetracycline HCl BP.....50mg Lignocain HCl BP.....10mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | OxyJet-50 Injection Reg. # 111562 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 590 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WDJ-6HG-YR6E, 2025-09-19) |
| | Detail of Fee Submitted | 38700,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **Rasomycin-5 Injection** |
| | Label Claim | Each ml contains:- Oxytetracycline HCl BP.....50mg Lignocain HCl BP.....10mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | OxyJet-50 Injection Reg. # 111561 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the |

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| | | findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 591 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TJU-RJS-UWUG, 2025-09-16) |
| | Detail of Fee Submitted | 38700,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **Rasomycin LA Injection** |
| | Label Claim | Each ml contains:- Oxytetracycline HCl BP.....200mg Lignocain HCl BP.....20mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | Oxywim Injection Reg. # 088617 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 592 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (M8P-YA4-WB4E, 2025-09-16) |
| | Detail of Fee Submitted | 38700,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **Rasomycin-10 injection** |
| | Label Claim | Each ml contains:- Oxytetracycline HCl BP.....100mg Lignocain HCl BP.....20mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |

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| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | OxyJet-100 Injection Reg. # 111564 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 593 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MDU-V97-XER2, 2025-12-06) |
| | Detail of Fee Submitted | 38700,<br>2025-10-16, |
| | The proposed proprietary name / brand name | **Flumestar-C Powder** |
| | Label Claim | Each kg contains: Flumequine EP.....100gm Colistin sulfate BP..... .....400,000,000IU (Innovaotr's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)store below 30C. |
| | For generic drugs (me-too Status) | Flumetek-C Powder Reg. # 028540 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | inspection pennel recommended the renewal of dml and gmp. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 594 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MLS-X2Y-5GY6, 2025-09-19) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Neo-Oxy Plus Powder** |
| | Label Claim | Each 1000gm contains; Oxytetracycline HCl BP.....300gm Neomycin sulphate BP.....250gm Colistin sulphate BP.....500MIU (Innovator's Specification |

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| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | Oxyneoriq Water Soluble Powder Reg. # 073952 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 595 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PXY-BNV-LLXU, 2025-12-10) |
| | Detail of Fee Submitted | 38700,<br>2025-10-16, |
| | The proposed proprietary name / brand name | **Primzine Powder** |
| | Label Claim | Each 100 gm contains: Trimethoprim BP..... 4g Sulphadiazine BP..... 20g Guaiphenesin BP.....20g Ammonium Chloride BP.....8g (Innovaotr's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm,100gm,250gm,500gm,1kg,2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25o C, Keep away from heat, moisture & children. |
| | For generic drugs (me-too Status) | Cotrizyn Plus Oral Powder Reg. # 033239 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | inspection pennel recommended the renewal of dml and gmp. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 596 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MXH-XE4-1QB3, 2025-12-13) |
| | Detail of Fee Submitted | 38700,<br>2025-11-12, |

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| | The proposed proprietary name / brand name | **Fos-Star Powder** |
| | Label Claim | Each gm contains:- Fosfomycin Calcium BP..... .....200mg Tylosin (as tartrate) BP..... 50mg Fructose 1,6 Diphosphate BP..... 180mg Sodium Phosphate BP ..... 150mg Magnesium Phosphate BP ..... 100mg Sodium Chloride .....qs 1000mg (Innovaotr's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25o C, Keep away from heat, moisture & children. |
| | For generic drugs (me-too Status) | FOS-T Oral Powder Reg. # 119962 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | inspection pennel recommended the renewal of dml and gmp. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 597 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1PZ-TLU-NBMN, 2025-12-12) |
| | Detail of Fee Submitted | 38700,<br>2025-10-16, |
| | The proposed proprietary name / brand name | **Sulphavit Plus Powder** |
| | Label Claim | Each 1000 gm contains: Sulphaquinoxaline Sodium BP....200g Sulphadimidine Sodium BP.....82.5g Diaveridine.....50g Vitamin A. .....2.5MIU Vitamin E .....5g Vitamin K3..... 5g (Innovaotr's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm,100gm,250gm,500gm,1kg,2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25o C, Keep away from heat, moisture & children. |
| | For generic drugs (me-too Status) | Coxi- Quake Water Soluble Powder Reg. # 035017 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | inspection pennel recommended the renewal of dml and gmp. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |

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| | **Approved** | |
| 598 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2XL-TUN-XZHA, 2025-09-16) |
| | Detail of Fee Submitted | 38700,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **Rasomycin LA Injection** |
| | Label Claim | Each ml contains:- Oxytetracycline HCl BP.....200mg Lignocain HCl BP.....20mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | Oxywim Injection Reg. # 088617 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 599 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1MX-13E-VNDW, 2025-11-20) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **FASFO-25 POWDER** |
| | Label Claim | Each gm contains:- Fosfomycin Calcium BP - 250mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10000gm-De-Controlled,1000gm-De-Controlled,100gm-De-Controlled,25000gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | Fosmium Powder of Leads Pharma (Reg#118659) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |

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| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 600 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1SS-SLM-65JT, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **Alba Poul-5 Oral Drench** |
| | Label Claim | Each 100ml contains: Albendazole USP- 5 gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,2500ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | Albanil Suspension of Farm Aid Group (Reg # 035199) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 601 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3NQ-W6X-4TZ4, 2025-11-24) |

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| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **POUL NOR-20 ORAL LIQUID** |
| | Label Claim | EACH 100 ml CONTAINS:- NORFLOXACIN BP - 20gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | FLOXIN 20% OR ALINA COMBINE (REG # 046512) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 602 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VGB-6EB-T1HM, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **Poul Amp-50** |
| | Label Claim | Each 100gm contains:- Amprolium HCl USP-50gm |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1000gm-De-Controlled,100gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | Roxaprol-50 Water Soluble Powder |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. |

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| | | ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 603 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (W7V-V6W-U4DT, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **POUL DAEK-51 ORAL LIQUID** |
| | Label Claim | Each 1000ml contains:- Vitamin A - 30000000 IU Vitamin D3 - 1000000 IU, Vitamin E - 5000 mg, Vitamin K3 - 6000mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10000ml-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,25000ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 YearAT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | Adekbar of Baariq Pharmaceuticals (Reg#073950) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 604 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XA6-NJ3-GGM4, 2025-11-24) |

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| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **TRY FEVER ORAL DRENCH** |
| | Label Claim | Each 1000ml contains:- Febendazole - 5.0gm, Triclabendazole BP- 5.0gm, Ivermectin BP- 1.0gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10000ml-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,25000ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | Iverzole-F Suspension of Alina Combine (Reg # 052337) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 605 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YMN-R2D-67NZ, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **LE KHOR ORAL DRENCH** |
| | Label Claim | Each ml contains:- Levamisole HCl BP- 37.5mg, Triclabendazole BP- 50mg, Cobalt Sulphate - 1.67mg, Sodium Selenite BP- 0.035mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | TRIBEX DRENCH OF EVERGREEN PHARMA (REG # 073989) |
| | Pharmacotherapeutic Group of (API) | |

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| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 606 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (42E-D37-GESZ, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **POUL NAG SUPER ORAL SOLUTION** |
| | Label Claim | Each 100 ml contains:- Norfloxacin BP - 20gm, Guaiphensin BP- 20gm, Aminophylline BP - 8gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | NOR + AG SOLUTION OF BIOGEN PHARMA (REG # 058968) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 607 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (5A3-SV1-WHY9, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **POUL FENDAZOL ORAL DRENCH** |
| | Label Claim | Each ml contains:- Oxfendazole BP- 22.65mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | OXASEL DRENCH OF SELMORE PHARMACEUTICALS (REG#071084) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 608 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9MU-QSQ-RLYS, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **OXYSOLE ORAL DRENCH** |
| | Label Claim | Each 100ml contains:- Levamisole HCl BP- 1.5gm, Oxyclozanide BP- 3.0gm, Cobalt Sulphate - 0.382gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | Vital Cure Oral Drench of Prix Pharmaceuticals (Reg#063690) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |

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| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 609 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ANE-TDS-DH3J, 2025-11-21) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **COOX SEL ORAL DRENCH** |
| | Label Claim | Each ml contains:- Oxfendazole BP- 22.65mg, Cobalt - 1.67 mg, Selenium BP- 0.50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,150ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,450ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | WANTOX PLUS ORAL DRENCH OF BREEZE PHARMACEUTICALS (REG#059110) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 610 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (DJ7-GX7-XJWM, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **POUL FLOX-60 WATER SOLUBLE POWDER** |
| | Label Claim | Each gm contains:- Florfenicol - 300mg, Oxyteracycline HCl-BP 300mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10000gm-De-Controlled,1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,20gm-De-Controlled,25000gm-De-Controlled,2500gm-De-Controlled,250gm-De-Controlled,5000gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | CYCLOFLOX-60 WATER SOLUBLE POWDER OF BIORISE PHARMACEUTICALS (REG#111216) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 611 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZB9-MW4-89HL, 2025-11-24) |
| | Detail of Fee Submitted | 38700,<br>2025-11-20, |
| | The proposed proprietary name / brand name | **BENTEL SUSPENSION** |
| | Label Claim | EACH 100ml CONTAINS:- ALBENDAZOLE USP ... 10 gm , COLSANTEL BP.....- 2gm |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1000ml-De-Controlled,100ml-De-Controlled,2500ml-De-Controlled,450ml-De-Controlled,500ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)AT ROOM TEMPERATURE |
| | For generic drugs (me-too Status) | BOXER 10% SUSPENSION OF LEADS PHARMA (REG # 028523) |
| | Pharmacotherapeutic Group of (API) | |

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| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 612 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (35H-GDE-4ZE6, 2025-09-19) |
| | Detail of Fee Submitted | 38700,<br>2025-09-12, |
| | The proposed proprietary name / brand name | **Flofenic Plus Powder** |
| | Label Claim | Each gram contains: Neomycin Sulphate USP.....150mg<br>Florfenicol.....100mg<br>Oxytetracycline HCl BP.....300mg<br>(Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | Floron oral powder Reg. # 106665 Grand Pharma (Private) Limited |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 613 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3GY-4S5-1R95, 2025-12-12) |
| | Detail of Fee Submitted | 38700,<br>2025-10-16, |

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| | The proposed proprietary name / brand name | **Sulphavit Powder** |
| | Label Claim | Each kg contains: Sulphaquinoxaline Sodium USP .....200000 mg Sulphadimidine Sodium BP.....82500mg Diaverdine. .....40000mg Vitamin A..... .... . 2800000IU Vitamin K3.....2000mg (Innovaotr's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm,100gm,250gm,500gm,1kg,2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25o C, Keep away from heat, moisture & children. |
| | For generic drugs (me-too Status) | Koxidia Oral Powder Reg. # 031483 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | inspection pennel recommended the renewal of dml and gmp. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 614 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ETN-LYH-69XP, 2025-10-15) |
| | Detail of Fee Submitted | 38700,<br>2025-10-10, |
| | The proposed proprietary name / brand name | **Lincostar Powder** |
| | Label Claim | Each 100gm contains: Colistin Sulfate BP.....4.21mg (eq. to 80MIU) Lincomycin hydrochloride USP.....10mg (Innovator's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | Colisco Water Soluble Powder Reg. # 112169 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |

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| 615 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GYR-JAR-3PSG, 2025-10-16) |
| | Detail of Fee Submitted | 38700,<br>2025-10-10, |
| | The proposed proprietary name / brand name | **Lincostar Plus Powder** |
| | Label Claim | Each gm contains: Lincomycin as hydrochloride USP.....100mg Colistin Sulphate BP.....800000IU (Innovaotr's Specification) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50gm, 100gm, 250gm, 500gm, 1kg, 2kg,3kg,5kg-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | Tinocin Powder Reg. # 103974 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 616 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J83-EB2-U5DX, 2025-09-16) |
| | Detail of Fee Submitted | 38700,<br>2025-09-03, |
| | The proposed proprietary name / brand name | **Rasomycin-10 Injection** |
| | Label Claim | Each ml contains:- Oxytetracycline HCl BP.....100mg Lignocain HCl BP.....20mg (Innovator's Specifications) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 50ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. |
| | For generic drugs (me-too Status) | OxyJet-100 Injection Reg. # 111563 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the panel verified a maintained facility in respect of Drug |

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| | | Manufacturing License (DML) and conformance of requirements of DML as per D |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 617 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MXT-ELQ-9ZEB, 2025-11-26) |
| | Detail of Fee Submitted | 38700,<br>2025-11-25, |
| | The proposed proprietary name / brand name | **Cefur-RTU Injection 10ml** |
| | Label Claim | Each ml contains: Ceftiofur (as Hydrochloride) USP.....50mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 10ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 25 |
| | For generic drugs (me-too Status) | Ceftisel RTU Injection (Reg No. 115076) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | based on the stated observation their current GMP compliance level is rated as Good. |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 618 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Nawan Laboratories Pvt Ltd** Plot No 136-138 , Sector # 15 KIA **(000442)** |
| | Application Form Dy. No / Tracking ID & date of submission | (TS7-9D6-Q3A4, 2025-07-26) |
| | Detail of Fee Submitted | 37000.0,<br>2025-07-24, |
| | The proposed proprietary name / brand name | **Benzastrep Injection** |
| | Label Claim | Each ml Contains: Benzathine Penicillin G USP..... 100,000 IU Procaine Penicillin G USP..... 150,000 IU Dihydrostreptomycin Sulphate USP eq.to Dihydrostreptomycin..... ..... 200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)below 25 |
| | For generic drugs (me-too Status) | BPS-LA Injection (Reg # 080951) |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | based on the stated observation their current GMP compliance level is rated as Good. |

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| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 619 | Case Category | New License (Sara Mehreen) |
| | Name, address of Applicant. | **GAMMA PHARMACEUTICAL (PVT) LTD.** PLOT#N-28/III S.I.T.E, KOTRI SINDH. **(001016)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UD2-3DP-1ULU, 2025-11-26) |
| | Detail of Fee Submitted | 38700,<br>2025-11-17, |
| | The proposed proprietary name / brand name | **G-Vironil 10% Powder** |
| | Label Claim | Each gm Contains: Amantadine HCL USP.....100mg |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1 Kg-De-Controlled,100 Gm-De-Controlled,5 Kg-De-Controlled,500 Gm-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°C. Protect from light & moisture. |
| | For generic drugs (me-too Status) | Virodine Powder by M/s Selmore Pharmaceutical Pvt Ltd |
| | Pharmacotherapeutic Group of (API) | Antiviral |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | Recommendations of inspection: As per instructions contained in DRAP Islamabad Letter No.F.2-1/22-Lic, dated 29-07-2025, M/s. Gamma Pharmaceutical (Pvt) Ltd, Plot No.N-28/III SITE Kotri Sindh was visited & inspected in detail on 06th August 2025, by t |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The firm was requested to provide a reference for the finished product specifications. In response, the firm stated that the finished product specifications are in accordance with the USP monograph. However, upon evaluation, it was found that the USP does not provide specifications for Amantadine Oral Powder. The firm was informed of this discrepancy and was asked for three times to revise the specifications as innovator specifications and to submit the required pre-registration variation fee. In response to the final query regarding submission of the pre-registration fee, the firm claimed compliance with BP specifications; however, the BP also does not provide specifications for Amantadine Oral Powder. Moreover, applicant mentioned POULTRY as target species. Submitted for consideration of the Board, please. | |
| | **Decision** | |
| | **Rejected** | |
| 620 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **POULVET PHARMACEUTICAL (PVT) LTD** 0.5-KM HEAD RANGO WEST CANAL, 25-KM LAHORE ROAD MULTAN **(000970)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1YZ-BN9-DU73, 2025-01-14) |
| | Detail of Fee Submitted | 37000.0,<br>2024-12-17, |

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| | The proposed proprietary name / brand name | **Hepa Poul Oral Solution** |
| | Label Claim | Each 100ml contains L-Carnitine - 50mg Vitamin B6 - 50mg Vitamin B12 - 1.5mg Nicotinamide - 15mg Calcium Pantothenate - 100mg Sorbitol - 10gm Dl Methionine - 1000mg L-arginine - 300mg L Citruline - 200mg L-Glycine - 200mg L-Aspartic Acid - 150mg L-Lysine - 100mg L-Glutamic Acid - 150mg L-Ornithine- 200mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 100ml, 250ml, 500ml,-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Do not store above 30°C. Protect from direct sun light. |
| | For generic drugs (me-too Status) | Crdisol Oral Solution of RAS Pharma (Reg#106724) |
| | Pharmacotherapeutic Group of (API) | Multivitamins & Amino Acids |
| | Name, address of Manufacturing site: | -- |
| | GMP status of the firm | INSPECTION WAS CONDUCTED ON DATED 09-09-2024 BY THE PANEL OF INSPECTORS MR. FAISAL SHAHZAD, ADDITIONAL DIRECTOR,DRAP, LAHORE AND MR. ABDUL RASHID SHAIKH FEDERAL INSPECTOR OF DRUG,DRAP,LAHORE THE PANEL WAS OF OPINION THAT M/s. POULVET PHARMACEUTICALS (PVT) |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm has changed formulation and submitted pre-registration variation fee. Submitted for consideration of the Board, please. | |
| | **Decision** | |
| | **Approved** | |
| 621 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T72-B7B-1J1E, 2024-10-09) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-19, |
| | The proposed proprietary name / brand name | **Solopate Ointment 1mg/g (0.1%)** |
| | Label Claim | Each gram of Ointment contains: Methylprednisolone aceponate.....1mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x15g-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30C |
| | For generic drugs (me-too Status) | Brand Name: Advocort Registration holder: Atco Laboratories Limited |
| | Pharmacotherapeutic Group of (API) | Corticosteroids Corticosteroids |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Name: Bayer AG. Address: Ernst-Schering-Straße 14 59192 Bergkamen, Germany. |
| | Detail of stability batches of drug product | 3 Batches Size 250 Tubes |
| | Documents for the procurement of API with approval from DRAP | Loan from obs invoice num 4634842302743 13.03.23 |

| | | |
|---|---|---|
| | (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Reference product: Supriad 1mg/g Ointment) , |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | TGA approved |
| | GMP status of the firm | Certificate no 3.7/2018-add.dir (QA-LT-I) 11-11-22 |
| | Evidence of approval of manufacturing facility | No F.1-16/2016-Lic(vol-I) dated 12-06-2017 mentioning cream section |
| | **Evaluation Remarks** | |
| | Applicant stated that "Our system is not 21 CFR Compliant". The authenticity & integrity of submitted data can not be verified. Submitted for consideration of the Board, please. | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of audit trail, system log and 21st CFR compliance status. | |
| 622 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **OBS Pharma (Pvt) Ltd** 108 Kotlakhpat Industrial Estate, Lahore 54760 Pakistan **(000243)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MJD-1RV-UZ2B, 2024-10-08) |
| | Detail of Fee Submitted | 75000.0, 18000.0<br>2024-09-03, 2024-09-13 |
| | The proposed proprietary name / brand name | **Advantan Milk 0.1%** |
| | Label Claim | Each ml contains: Methylprednisolone Aceponate ..... 1 mg (0.1%) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 20gm-As per SRO |
| | Shelf Life (Unit) | 2 YearStore Below 30 degree |
| | For generic drugs (me-too Status) | Advacort Lotion 0.1% |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | SERAPH PHARMACEUTICAL.-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan.- |
| | Name & address of API manufacturer | Bayer AG. Address: Ernst-Schering-Straße 14 59192 Bergkamen, Germany. |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Italian Medicine Agency (AIFA) Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Applicant stated that "Our system is not 21 CFR Compliant". The authenticity & integrity of submitted data can not be verified. Submitted for consideration of the Board, please. | |

| | | |
|---|---|---|
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of audit trail, system log and 21st CFR compliance status. | |
| 623 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LXJ-MMZ-93M6, 2024-07-09) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-05, |
| | The proposed proprietary name / brand name | **Neubet-N Ointment** |
| | Label Claim | Each gram of Ointment contains : Betamethasone (as Betamethasone Valerate)...1.0mg (0.1% w/w) & Neomycin Sulfate....5.0mg (0.5%w/w) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 20 gm-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25° C |
| | For generic drugs (me-too Status) | Betnovate-N Ointment |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | MAHIMA LIFE SCIENCES PRIVATE LIMITED,Sichuan Long March Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | Betamethasone valerate/Neomycin sulfate 1 mg/5 mg/g Ointment |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 624 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)** |
| | Application Form Dy. No / Tracking ID & date of submission | (G4Y-4PY-91PS, 2024-07-16) |
| | Detail of Fee Submitted | 30000.0,<br>2024-06-05, |
| | The proposed proprietary name / brand name | **Neubet-N Cream** |
| | Label Claim | Each gram of cream contains: Betarnethasone (as Betamethason Valerate)..... 1.Omg (0.1% w/w Neornycin Sulphale 5.0mg (0.5% w/w) |

| | | |
|---|---|---|
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 20gm Tube -As per SRO |
| | Shelf Life (Unit) | 2 YearStore between 15 - 30°C in a dry place, protect from light |
| | For generic drugs (me-too Status) | Avialable |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | Betamethasone valerate/Neomycin sulphate 1 mg/5 mg/g Cream |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 625 | Case Category | Routine (Sara Mehreen) |
| | Name, address of Applicant. | **Pine Pharmaceuticals** Plot No, 40, S-4, Rawat Industrial Estate, Islamabad **(000955)** |
| | Application Form Dy. No / Tracking ID & date of submission | (NDQ-NG6-JJ49, 2024-08-16) |
| | Detail of Fee Submitted | 75000.0, 2024-07-29, |
| | The proposed proprietary name / brand name | **Baclopin 10mg tablet** |
| | Label Claim | Each Tablet Contains; Baclofen ..... 10mg (USP Spec's) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Yearbelow 30 º C |
| | For generic drugs (me-too Status) | Baclin 10mg Tablet,Genome Pharmaceuticals (Pvt.) Ltd., |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Solaris Life Sciences (Pvt.) Ltd,-Plot No. 8, Street No. S-1, RCCI, Industrial Estate, Rawat-PAKISTAN- |
| | Name & address of API manufacturer | M/S:panchsheel organic Ltd, B6-B7,sector-c,sanwer road,industrial estate,indore |
| | 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 | Lioresal 10mg Tablet,Novartis Ireland Limited,Vista Building Elm Park Merrion Road, Ballsbridge Dublin 4 Ireland |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | Firm replied that "The same product's CTD is approved in DRB (M-357) (Minutes Copy Attached) of M/s Solaris Life Sciences through PRVC Tracking ID: PWM-ME8-GL9X, as per DRAP guideline/ decision the Cross-reference product do not require any further data". | |
| | **Decision** | |
| | **Approved** | |
| 626 | Case Category | New Section (Shahrukh Ali) |
| | Name, address of Applicant. | **A H PHARMACEUTICALS (PVT) LIMITED** 865-A, SMALL INDUSTRIAL ESTATE, SARGODHA ROAD **(000630)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1LL-USZ-JU93, 2026-02-04) |
| | Detail of Fee Submitted | 38700,<br>2025-10-13, |
| | The proposed proprietary name / brand name | **FESASON-G Cream** |
| | Label Claim | Each gram contains: Betamethasone Dipropionate (USP) 0.64mg eq to Betamethasone 0.5mg; Gentamicin Sulphate (USP) 1.7mg eq to Gentamicin 1mg |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | AS PER SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)STORE BELOW 25 DEGREE |
| | For generic drugs (me-too Status) | PROCORT-G CREAM BY SAFFRON PHARMACEUTICALS PVT LTD. |
| | Pharmacotherapeutic Group of (API) | Betamethasone Dipropionate: Synthetic Glucocorticoid Corticosteroid. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | API FROM ANHU PHARMA INDIA,API FROM FUAN PHARMACEUTICAL GROUP YANTAI JUSTWARE PHARMACEUTICAL CO. LTD. |
| | Detail of stability batches of drug product | Data of 03 batches at long-term and accelerated conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | ATTACHED |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | ATTACHED |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 03 batches at long-term and accelerated conditions |
| | The status in reference regulatory authorities | Merck Sharp & Dohme (AGES) Diprogenta AUSTRIA |
| | GMP status of the firm | Provided |
| | Evidence of approval of manufacturing facility | DML; Additional Section Approval for Cream/Ointment Section (General) (New) dated |

| | | |
|---|---|---|
| | | 28.03.2025 |
| | **Evaluation Remarks** | |
| | Firm was asked to submit Drug substance stability data as per zone IV_A conditions, Firm submitted the same Zone II-A data and changed the conditions on it. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application considering that the firm has submitted exactly same stability studies of zone II-A in query to submit data as per conditions of Zone IV, by changing conditions from zone II-A to IVA only in stability study protocol raising concerns regarding the authenticity and originality of the submitted data. | |
| 627 | Case Category | New Section (Shahrukh Ali) |
| | Name, address of Applicant. | **Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J7B-S9S-9VM2, 2025-09-17) |
| | Detail of Fee Submitted | 38700.0,<br>2025-08-19, |
| | The proposed proprietary name / brand name | **Neuhyzon 500mg Powder for Injection** |
| | Label Claim | Each vial contains: Hydrocortisone sodium succinate equivalent to Hydrocortisone.....500mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's/As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Before reconstitution do not store above 25°C. After reconstitution the product may be stored at 2°C-8°C (in a refrigerator) for up to 24 hours. |
| | For generic drugs (me-too Status) | Hyzonate Injection 500mg (Reg # 019227) by Amson Vaccines & Pharma |
| | Pharmacotherapeutic Group of (API) | SYMBIOTEC PHARMALAB PRIVATE LIMITED |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches having batch size of 250 vials each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has also submitted clearance certificate issued dated 19-02-2025 specifying 1kg Hydrocortisone sodium succinate. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | P.E is performed against Hyzonate 500mg Injection manufactured by Amson Vaccines & Pharma |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability studies for batch #HSS12038 ,HSS12065 & HSS12067 were conducted as per Zone IVa conditions |
| | The status in reference regulatory authorities | US FDA Approved SOLU CORTEF marketed by PHARMACIA AND UPJOHN |
| | GMP status of the firm | Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of grant of additional section dated 16-04-2025 specifying Dry Powder Injection Section (Steroid). |
| | **Evaluation Remarks** | |

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|---|---|---|
| | Dear Sir, With reference to Tracking ID :J7B-S9S-9VM2, we would like to submit that an application for the same molecule, strength, and brand (Neuhyzon 500 mg Injection) has already been approved under Tracking ID 2J6-7LN-BMV6 in the 358th meeting. We kindly request the withdrawal of application submitted vide tracking ID: J7B-S9S-9VM2. Best Regards | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application considering that the firm has submitted request of withdrawal for said application. | |
| 628 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2S6-P4J-84LL, 2024-12-02) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-31, |
| | The proposed proprietary name / brand name | **Clobetasol Propionate Cream 0.05%w/w** |
| | Label Claim | Label Claim: Each gram of cream contains: Clobetasol Propionate.... 0.05% w/w USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store at 25C |
| | For generic drugs (me-too Status) | Dermovate Cream by GSK |
| | Pharmacotherapeutic Group of (API) | D07AD01 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Three batches having 200 tubes |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | E-2543/2020-DRAP dated: 14-02-2020 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Dermovate Cream GlaxoSmithKline |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | Dermovate Cream by GSK UK (EMC) |
| | GMP status of the firm | 145/2025-DRAP(AD-5053118354) dated 02.09.25 |
| | Evidence of approval of manufacturing facility | No. F.1-3/2003-LIC dated 4 -07-2020 mentioning skin ointment section |
| | **Evaluation Remarks** | |
| | "The application is complete as per codal formalities for consideration by the Registration Board" | |
| | **Decision** | |
| | **Approved** | |
| 629 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RHX-LNM-TPVJ, 2024-11-14) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-31, |

| | | |
|---|---|---|
| | The proposed proprietary name / brand name | **Clobetasol Propionate ointment 0.05%w/w** |
| | Label Claim | Label Claim: Each gram of Ointment contains: Clobetasol Propionate.... 0.05% w/w (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's -As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store at 25C |
| | For generic drugs (me-too Status) | Dermovate ointment by GSK |
| | Pharmacotherapeutic Group of (API) | Corticosteroid D07AD01 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Three batches having 200 tubes |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | E-2543/2020-DRAP dated: 14-02-2020 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Dermovate Cream GlaxoSmithKline |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | Dermovate ointment by GSK UK (EMC) |
| | GMP status of the firm | 145/2025-DRAP(AD-5053118354) dated 02.09.25 |
| | Evidence of approval of manufacturing facility | No. F.1-3/2003-LIC dated 4 -07-2020 mentioning skin ointment section |
| | **Evaluation Remarks** | |
| | "The application is complete as per codal formalities for consideration by the Registration Board" | |
| | **Decision** | |
| | **Approved** | |
| 630 | Case Category | Export Facilitation (Shahrukh Ali) |
| | Name, address of Applicant. | **Indus Pharma (Pvt.) Ltd.** Plot No 26,27,63,64,65,66 & 67 Sector 27, Korangi Industrial Area, Karachi. **(000124)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PZD-TY5-41TX, 2025-09-30) |
| | Detail of Fee Submitted | 75000.0, 2025-05-06, |
| | The proposed proprietary name / brand name | **Indogol Junior** |
| | Label Claim | Each sachet contain: Macrogol 3350----------6.563g Sodium chloride----------0.1754g Sodium hydrogen carbonate-----0.0893g Potassium chloride----------0.0251g On Reconstitution in 62.5ml of water , each sachet provides. Sodium----------65mmol/L Chloride----------53mmol/L Bicarbonate----------17mmol/L Potassium----------5.4mmol/L |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 6, 8, 10, 20, 30, 40-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C. Protect from heat, light & moisture. Store reconstituted solution in refrigerator (2°C to 8°C). |
| | For generic drugs (me-too Status) | N/A |

| | | |
|---|---|---|
| | Pharmacotherapeutic Group of (API) | Osmotic laxative |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Hub Pak Salt Refinery C186-194, C2O6, HITE, Hub, Balochistan, Pakistan,Huzhou Zhanwang Pharmaceutical Co., Ltd, West Development Area Rd, Linghu, Huzhou, Zhejiang, P.R. China(China),JIANGSU QINFEN PHARMACEUTICAL CO, LTD, SANKONJQIAO INDUSTRIAL ZONE , NANTONG ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE JIANGSU PROVINCE(China),TATA CHEMICALS EUROPE LTD MOND HOUSE, WINNINGTON LANE, NORTHWICH CHESHIRE, CW84DT, UNITED KINGDOM |
| | Detail of stability batches of drug product | (TR-1/ESC 6.9g, TR-2/ESC 6.9g, TR-3/ESC 6.9g) refer to Section 3.2.P.8 |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | PEG (E-671182885683), Potassium Chloride (E-1341182884135) |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Refer to Module 3 Section 3.2.P.2.2.1 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Long Term (30°C ±2°C, 65% RH ± 5%) & Accelerated (40°C ± 2°C, 75% RH ±5% RH) |
| | The status in reference regulatory authorities | Movicol® Pediatric Plain 6.9 g powder for oral solution Manufactured by Norgine Pharmaceuticals Limited, New Road, Hengoed,Mid Glamorgan, CF82 8SJ, U.K., MHRA |
| | GMP status of the firm | Certificate No. 11/2024-DRAP (K) |
| | Evidence of approval of manufacturing facility | DML No. 000124 |
| | **Evaluation Remarks** | |
| | Firm was asked to submit Testing of Diethylene Glycol (DEG) & Ethylene Glycol (EG) at Central Drug Laboratory, Karachi, firm has responded that this notification was issued on 21-oct-22 and testing was already done by applicant and they will perform said test on commercial batches before marketing the product | |
| | **Decision** | |
| | **Approved** | |
| 631 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Pacific Pharmaceuticals Ltd.** Plot No.384, Sundar Industrial Estate, Raiwind Road, Lahore **(000902)** |
| | Application Form Dy. No / Tracking ID & date of submission | (JZN-95V-GDSD, 2024-04-30) |
| | Detail of Fee Submitted | 30000.0, 2024-04-02, |
| | The proposed proprietary name / brand name | **Mannitol IV Infusion 20% w/v** |
| | Label Claim | Each 100ml contains Mannitol .....20g |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 500ml-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 30°C |
| | For generic drugs (me-too Status) | Medisol Mannitol 20% w/v by Medipak Limited |
| | Pharmacotherapeutic Group of (API) | |

| | | |
|---|---|---|
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Merck KGaA Frankfurter Str. 250, 64293 Darmstadt, Germany |
| | 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 | MANNITOL- mannitol injection, solution by B. Braun Medical Inc. RRA-USFDA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | 3.2. P.8.3 •Documents for procurement of API, clearance certificate with approval from DRAP by loan giver shall be submitted. Despite multiple attempts, the loan giver(M/S Martin Dow) has not been willing to share the requested documents, citing that the data is quite old and the team has been changed. Additionally, we would like to inform you that we have already imported the same material at our premises, but the submitted data is based on the loan material. | |
| | **Decision** | |
| | **Approved**<br><br>Approved subject to loan verification as firm has submitted that loan giver is not willing to submit clearance documnents | |
| 632 | Case Category | Contract Manufacturing (Shahrukh Ali) |
| | Name, address of Applicant. | **Wenovo Pharmaceuticals** Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi. **(000790)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EPH-WLH-NG4B, 2024-08-27) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-24, |
| | The proposed proprietary name / brand name | **FODIC 2% CREAM** |
| | Label Claim | Each gm Contains: Fusidic acid (BP).....20mg (2% w/w) (Product complies BP Specs) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)20-25C |
| | For generic drugs (me-too Status) | Ucid 2% Cream Reg # 081566 Ciba Pharmaceuticals |
| | Pharmacotherapeutic Group of (API) | Antibiotic for Topical use (ATC code: D06AX01) |
| | Name, address of Manufacturing site: | M/s Winbrains Research Laboratories-PLOT #69/1, BLOCK B, PHASE-I&II, INDUSTRIAL ESTATE, HATTAR.- |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches Batch Size 200 tubes |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | 224/2021 21.10.21 |

| | | |
|---|---|---|
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | fudic cream M/s shaigan |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | MHRA Approved |
| | GMP status of the firm | Certificate no 41/2023-dRAP-k dated 23-06-23 |
| | Evidence of approval of manufacturing facility | No F.3-7/2007-Lic dated 11-04-17 mentioning cream section |
| | **Evaluation Remarks** | |
| | In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. | |
| | **Decision** | |
| | **Approved** | |
| 633 | Case Category | New Section (Shahrukh Ali) |
| | Name, address of Applicant. | **BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T53-U4E-S9EN, 2026-05-18) |
| | Detail of Fee Submitted | 38700,<br>2026-01-20, |
| | The proposed proprietary name / brand name | **Bemdo EZ 180mg + 10mg Tablets** |
| | Label Claim | Each film coated tablet contains: Bempedoic Acid .....180mg Ezetimibe.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's, 14's, 10's, 20's, 28's, 30's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Protect from heat sunlight and moisture. Store below 30ºC |
| | For generic drugs (me-too Status) | BMP-E 180mg +10mg Tablets of Hilton Pharma (Pvt.) Ltd |
| | Pharmacotherapeutic Group of (API) | C10BA10 Combination of various lipid modifying agent bempedoic acid and ezetimibe |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Metrochem API Pvt Ltd (Unit IV) Plot No. 34 B, 40B & 60B, J.N Pharma city, Thanam (V), Parawada (M), Anakapalli District-531 021 Andhra Pradesh, India. ,Zhejiang Tianyu Pharmaceutical Co., Ltd. 15, Donghai 5" Avenue, Zhejiang Provincial Chemical and Medical Raw Materials Base Linhai Zone, Taizhou City. |
| | Detail of stability batches of drug product | 3 Batches Size 1000 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | RO-AF4675 dated 24.12.24 DIL_C-2B 3897 dated 24.12.24 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Bempeget-EZ M/s getz |

| | | |
|---|---|---|
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | Nexlizet (Bempedoic acid and Ezetimibe ) Tablets by Esperion Therapeutics,Inc. US-FDA |
| | GMP status of the firm | Certificate No: 0115-24/2024-DRAP(K) Valid till 25-04-2027 |
| | Evidence of approval of manufacturing facility | Valid DML No. 000707 and section approval dated 29 January 2024. |
| | **Evaluation Remarks** | |
| | "The application is complete as per codal formalities for consideration by the Registration Board" | |
| | **Decision** | |
| | **Approved** | |
| 634 | Case Category | New Section (Shahrukh Ali) |
| | Name, address of Applicant. | **BOSCH PHARMACEUTICALS (PVT) LTD** PLOT NO. 209, SECTOR 23, KORANGI INDUSTRIAL AREA **(000707)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PPB-H2W-3GPV, 2026-06-02) |
| | Detail of Fee Submitted | 38700, 2025-12-24, |
| | The proposed proprietary name / brand name | **Bemdo 180mg Tablets** |
| | Label Claim | Each film coated tablet contains: Bempedoic acid ..... 180mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 7's, 10's, 14's, 20's, 28's, 30's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store below 30°C |
| | For generic drugs (me-too Status) | Bempics Tablets 180mg - Searle Company Limited |
| | Pharmacotherapeutic Group of (API) | C10AX - Other Lipid Modifying Agent |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Metrochem API Private Limited |
| | Detail of stability batches of drug product | 3 Batches Size 1000 tablets |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | RO-AF4675 dated 24.12.24 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Bempeget-EZ M/s getz |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | Nexletol 180mg Tablets - Esperion Therapeutics, Inc. USFDA |
| | GMP status of the firm | 115-24 /2024-DRAP(K) the, 07.08.2024 |
| | Evidence of approval of manufacturing facility | No. F.2-19/2006-Lic dated 24 .03. 2026 mentioning Tablet (General). |
| | **Evaluation Remarks** | |
| | "The application is complete as per codal formalities for consideration by the Registration Board" | |
| | **Decision** | |
| | **Approved** | |
| 635 | Case Category | Contract Manufacturing (Shahrukh Ali) |

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| | Name, address of Applicant. | **Focus & Rulz Pharmaceuticals (Pvt) Ltd** 44 - Industrial Triangle, Kahuta Road **(000628)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YBM-UJU-ZXA2, 2024-08-28) |
| | Detail of Fee Submitted | 75000.0,<br>2024-04-29, |
| | The proposed proprietary name / brand name | **Cefoplus Injection 2g** |
| | Label Claim | Each vial contains: Sulbactam sodium eq, to sulbactam.....1000mg Cefoperazone sodium eq, to Cefoperazone .....1000mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 25°C. |
| | For generic drugs (me-too Status) | 2sum 2g injection |
| | Pharmacotherapeutic Group of (API) | antibiotics |
| | Name, address of Manufacturing site: | Bio-Labs Pvt. Ltd-Plot #145, Industrial Triangle,Kahuta Road,Islamabad- |
| | Name & address of API manufacturer | Suzhou Dawnrays No.22 Tianling Road, Wuzhong Economic Development District, Suzhou, Jiangsu China |
| | Detail of stability batches of drug product | commercial batches |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | registered product |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | 2sum 2g injection |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | iv-A |
| | The status in reference regulatory authorities | Sulperazone 2g for I.V Injection |
| | GMP status of the firm | F.3-1912019-Addl. Dir. (QA & LT-I)77 28 December,2023 |
| | Evidence of approval of manufacturing facility | No. F.1-12/98-LIC dated 24 -03-2007 |
| | **Evaluation Remarks** | |
| | The instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F | |
| | **Decision** | |
| | **Approved** | |
| 636 | Case Category | Contract Manufacturing (Shahrukh Ali) |
| | Name, address of Applicant. | **Focus & Rulz Pharmaceuticals (Pvt) Ltd** 44 - Industrial Triangle, Kahuta Road **(000628)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LRY-VS1-NMJS, 2024-08-27) |
| | Detail of Fee Submitted | 75000.0,<br>2024-04-29, |
| | The proposed proprietary name / brand name | **Cefoplus Injection 1g** |
| | Label Claim | Each vial contains: Sulbactam sodium eq, to sulbactam.....500mg Cefoperazone sodium eq, to Cefoperazone .....500mg |

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|---|---|---|
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 YearDo not store above 25°C |
| | For generic drugs (me-too Status) | 2sum 1g injection |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Bio-Labs Pvt. Ltd-Plot #145, Industrial Triangle,Kahuta Road,Islamabad- |
| | Name & address of API manufacturer | Suzhou Dawnrays Pharmaceuticals co,LTD |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | Sulperazon I.V Injection |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F | |
| | **Decision** | |
| | **Approved** | |
| 637 | Case Category | Contract Manufacturing (Shahrukh Ali) |
| | Name, address of Applicant. | **De-Mont Research Laboratories (Pvt.) Ltd.** 20 Km, Lahore-Sharikpur Road, Sheikhupura **(000844)** |
| | Application Form Dy. No / Tracking ID & date of submission | (5UX-MB9-LMPL, 2024-08-31) |
| | Detail of Fee Submitted | 75000.0,<br>2024-06-27, |
| | The proposed proprietary name / brand name | **Fumont 2% cream** |
| | Label Claim | Each gm Contains: Fusidic acid (BP).....20mg (2% w/w) (Product complies BP Specs) |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)store below 30 degree centigrade |
| | For generic drugs (me-too Status) | Ucid 2% Cream (Ciba Pharmaceuticals) |
| | Pharmacotherapeutic Group of (API) | Antibiotic for Topical use (ATC code: D06AX01) |
| | Name, address of Manufacturing site: | Winbrains Research Laboratories-Plot No. 69/1, Block B, Phase-I&II, Industrial Estate, Hattar- |
| | Name & address of API manufacturer | FUSIDIC ACID NORTH CHINA PHARMACEUTICAL HUASHENG CO., LTD. NO. 8, YANGZI ROAD, SHIJIAZHUANG ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, CHINA |

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| | Detail of stability batches of drug product | 3 batches Batch Size 200 tubes |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | 224/2021 21.10.21 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | fudic cream M/s shaigan |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | MHRA |
| | GMP status of the firm | Certificate no 41/2023-dRAP-k dated 23-06-23 |
| | Evidence of approval of manufacturing facility | No F.3-7/2007-Lic dated 11-04-17 mentioning cream section |
| | **Evaluation Remarks** | |
| | The instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LRA) Rules, 1976 is also needed as part of module-1 of Form 5F | |
| | **Decision** | |
| | **Approved** | |
| 638 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Pacific Pharmaceutical Ltd** 30 km Multan Road Lahore **(000295)** |
| | Application Form Dy. No / Tracking ID & date of submission | (E1X-PVE-ZE9S, 2024-07-11) |
| | Detail of Fee Submitted | 30000.0, 2024-05-20, |
| | The proposed proprietary name / brand name | **Mefenamic Acid 500mg Tablet** |
| | Label Claim | Each film coated Tablet contains: Mefenamic acid.....500mg |
| | Reference to Finished product specifications | British Pharmacopeia |
| | Proposed Pack Size | 200s or 20s-As per SRO |
| | Shelf Life (Unit) | 3 Year(s)below 30°C |
| | For generic drugs (me-too Status) | Ponstan forte 500mg Tablet |
| | Pharmacotherapeutic Group of (API) | Analgesic |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | ALKA LABORATORIES PVT LTD B 1124 Phase III RIICO Industrial Area Bhiwadi 301019 District Alwar Raj India |
| | Detail of stability batches of drug product | 25 packs 3 batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | E-3193782059183 Date of issue: 28-10-2022 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Mefenamic acid 500mg by Chemidex Pharma Ltd. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | Mefenamic acid 500mg Tablet by Chemidex Pharma Limited |
| | GMP status of the firm | 180/2023-DRAP(AD-11901169456) 24.10.23 |

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| | Evidence of approval of manufacturing facility | No. F.1-9/89-LIC dated 30 -06-2015 mentioning tablet section |
| | **Evaluation Remarks** | |
| | Justify the release of mefenamic acid more than 85% in acidic media at pH 1.2 within 10 minutes moreover reason for not specifying the method for dissolution in 3.2.5.1 and not performing dissolution in batch analysis and why the method of dissolution specified in USP for capsules was not considered during in house method development. Firm has submitted revised CDP report | |
| | **Decision** | |
| | **Deferred**<br><br>The case for submission of scientific justification for new dissolution release profile. | |
| 639 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WP8-5PU-LHBW, 2024-10-09) |
| | Detail of Fee Submitted | 37000.0,<br>2024-09-19, |
| | The proposed proprietary name / brand name | **Solopate Cream 1mg/g (0.1%)** |
| | Label Claim | Each gram of Cream contains:<br>Methylprednisolone aceponate.....1mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x15g-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30C |
| | For generic drugs (me-too Status) | Brand Name: Advacort Registration holder: Atco Laboratories Limited |
| | Pharmacotherapeutic Group of (API) | Corticosteroids |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Name: Bayer AG. Address: Ernst-Schering-Straße 14 59192 Bergkamen, Germany. |
| | Detail of stability batches of drug product | 3 Batches Size 250 Tubes |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Loan from obs invoice num 4634842302743 13.03.23 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Reference product: Supriad 1mg/g Ointment) , |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | TGA approved |
| | GMP status of the firm | Certificate no 3.7/2018-add.dir (QA-LT-I) 11-11-22 |
| | Evidence of approval of manufacturing facility | No F.1-16/2016-Lic(vol-I) dated 12-06-2017 mentioning cream section |
| | **Evaluation Remarks** | |
| | verification of loan from M/s Bayer pharmaceutical | |
| | **Decision** | |
| | **Deferred**<br><br>Deferred for submission of audit trail, system log and 21st CFR compliance status. | |
| 640 | Case Category | New Section (Shahrukh Ali) |

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| | Name, address of Applicant. | **Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3BP-HN8-EHYG, 2026-02-20) |
| | Detail of Fee Submitted | 38700,<br>2025-09-26, |
| | The proposed proprietary name / brand name | **Neu-Medrol 40mg/ml Injection** |
| | Label Claim | Each ml contains: Methylprednisolone acetate .....40mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1's/As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore between 15-30 degree celsius |
| | For generic drugs (me-too Status) | Depo-Medrol Injection (Reg# 000606) by Pfizer Pakistan Limited |
| | Pharmacotherapeutic Group of (API) | SYMBIOTEC PHARMALAB PRIVATE LIMITED |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Stability studies for Batch # MPAiSB1-25,MPAiSB2-25 & MPAiSB3-25 were conducted as per Zone-IVa conditions |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate having computerized no. E-ROAC7EF4 stating import of 400gm of Methylprednisolone acetate |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | P.E is performed against Depo-Medrol Injection manufactured by Pfizer Pakistan Limited |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability studies for Batch # MPAy18001,MPAy18002 & MPA18003 were conducted as per Zone-IVa conditions. |
| | The status in reference regulatory authorities | US FDA Approved DEPO-MEDROL marketed by PFIZER |
| | GMP status of the firm | GMP has been issued vide Ref No.145/2025-DRAP(AD-5053118354) Dated 02-09-2025 valid for three years from the date of inspection |
| | Evidence of approval of manufacturing facility | CLB has granted Liquid Injectable (Ampoule/Respule)(BFS)(Steroid) vide letter No.F. 1-3/2003-Lic(Vol-III) dated April 16th, 2025 |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved** | |
| 641 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Cunningham Pharmaceuticals (Pvt.) Ltd.** Plot No. 81 - Sunder Industrial Estate, Raiwind Road, Lahore- Pakistan **(000840)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZBH-QHD-MQT6, 2024-07-30) |
| | Detail of Fee Submitted | 30000.0,<br>2024-04-22, |
| | The proposed proprietary name / brand name | **Phyto-K Injection 10 mg/ml** |
| | Label Claim | Each ml contains: Phytomenadione.....10 mg/ml. |
| | Reference to Finished product specifications | United States Pharmacopeia |

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| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Temp 40°C ±2°C and Humidity 75% ±5% ,Temp 30°C ±2°C and Humidity 65% ±5% |
| | For generic drugs (me-too Status) | K-Lot® Injection is Approved in DRAP. |
| | Pharmacotherapeutic Group of (API) | Vitamin |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s Anhui Wanhe Pharmaceutical Co., Ltd |
| | Detail of stability batches of drug product | 2000 ampoules 3 batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | E 7426942842753 21.11.23 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | K-Lot inj Manufactured by M/s Gt Pharma |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | VITAMIN K1 Injection is Approved in USFDA |
| | GMP status of the firm | No F.64/2025-DRAP (AD-3747954777) dated 07-03-2025 |
| | Evidence of approval of manufacturing facility | No F.1-75/2011-Lic dated 13-june-2016 mentioning Liq Inj SVP section |
| | **Evaluation Remarks** | |
| | 3.2.p.8.3 submit complete evidence of audit trail and digital data logger report | Firm has submitted same chromatogram throughout stability and changed parameters retention time and |
| | 3.2.P.5.3 Submit complete studies of Validation of the Analytical Procedure along with performance calculation and chromatograms. Attached lineraity reports are from internet in Japanese language justification required. | Firm has submitted revised report |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same chromatogram spectra throughout stability data performed by the drug product manufacturer, along with its registration application | |
| 642 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Hiranis Pharmaceuticals Pvt. Ltd.** E-145-149, North Western Industrial Zone, Port Qasim, Karachi-75020, Pakistan **(000785)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GHM-E9J-Z8D4, 2024-11-05) |
| | Detail of Fee Submitted | 37000.0,<br>2024-10-28, |
| | The proposed proprietary name / brand name | **HYCOS 1%w/w CREAM** |
| | Label Claim | Each gram contains: Hydrocortisone.....10mg (1%w/w) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10g & 20g-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 30OC at a dry place, protect from light and heat. |
| | For generic drugs (me-too Status) | Hydrocort Cream, Reg. No. 067250, M/s Atco Laboratories Ltd |

| | | |
|---|---|---|
| | Pharmacotherapeutic Group of (API) | Corticosteroid for Topical use |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | M/s. Tianjin Tianyao Pharmaceuticals Co., Ltd. |
| | Detail of stability batches of drug product | 3 batches Batch Size 500 tubes |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate 5047980808956 14.04.23 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | HYDROCORTISONE CREAM Pinewood Laboratories |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | HYDROCORTISONE 1.0% w/w CREAM; Pharmasol Limited North Way, Walworth Industrial Estate, Andover, SP10 5AZ, UK., MHRA Approved |
| | GMP status of the firm | GMP certificate issued on the basis of inspection conducted on 14-12-2023 is submitted. |
| | Evidence of approval of manufacturing facility | Tablet (Steroid) Section is approved as per Letter No. F.1-33/2009-Lic dated 07-02-2014. |
| | **Evaluation Remarks** | |
| | Submitted pictorial evidence B. No is different from claimed batch number previously submitted. Justify? firm submitted that " we identified that the batch number contained a typographical error and was inadvertently reported incorrectly. We respectfully request that the later-submitted report be accepted in place of the previous version. | |
| | **Decision** | |
| | **Rejected**<br><br>The Registration Board rejected the application on the basis of submission of incorrect batch number of reference in CDP vis-a-vis submitted data. So the authenticity of data is compromised. | |
| 643 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L34-TXB-8DBH, 2024-09-10) |
| | Detail of Fee Submitted | 30000.0,<br>2024-08-13, |
| | The proposed proprietary name / brand name | **Clomecit 50mg Tablets** |
| | Label Claim | Each tablet contains: Clomiphene Citrate .....50mg (USP Specifications) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30ºC |
| | For generic drugs (me-too Status) | Cerophene 50mg tablets, Manufacturer: Hilton Pharmaceuticals (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Ovulation stimulants (Selective Estrogen Receptor Modulator, ATC code: G03GB02). |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 batches 1500 tablets each |
| | Documents for the procurement of API with approval from DRAP | loan from M/s neutro pharma |

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|---|---|---|
| | (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Cerophene 50mg Tablets m/s Hilton |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | Clomiphene citrate, Company: Cosette pharma, (NDA): 075528 (USFDA Approved) |
| | GMP status of the firm | DML issued 17.01.2024 |
| | Evidence of approval of manufacturing facility | DML issued 17.01.2024 |
| | **Evaluation Remarks** | |
| | loan from M/s neutro pharma | |
| | **Decision** | |
| | **Approved**<br><br>Approved. Subject to verification of loan documents | |
| 644 | Case Category | New License (Shahrukh Ali) |
| | Name, address of Applicant. | **Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MHR-1X5-7NDU, 2026-02-17) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-06-16, 2025-10-13 |
| | The proposed proprietary name / brand name | **Levecetam Tablet 500mg** |
| | Label Claim | Each tablet contain Levetricetam.....500mg USP Specs |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10's-De-Controlled |
| | Shelf Life (Unit) | 2 Year30C+- |
| | For generic drugs (me-too Status) | Lerace Tablet 500mg (Hilton Pharma) |
| | Pharmacotherapeutic Group of (API) | Anti-Epilepsy |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | EMMENNAR PHARMA PVT LTD |
| | Detail of stability batches of drug product | 2 batches (ST-01 and ST-02 ) 6 month stability studies) submitted both Accelerated and Real time studies |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | EMMENNAR PHARMA PVT LTD<br>ADDRESS:PLOT #15 JAWAHARLAL NHRU PHARMA CITY TADI (V) PARAWADA (M)VISAKHAPATNAM District-531 091 A.P INDIA. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Lerace tablet 500mg (Hilton Pharm) via Levecetam tablet 500mg |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 36 Month Accelerated and Real time studies Submitted |
| | The status in reference regulatory authorities | USFDA approved |
| | GMP status of the firm | ACTIVE ( W.E.F 26/08/2024) DML # 0009961 |
| | Evidence of approval of manufacturing facility | TABLET (GENERAL) |
| | **Evaluation Remarks** | |
| | Firm submitted the same pharmaceutical equivalence data and stability data of drug product as submitted by another firm along with their registration application. | |

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| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and stability data of drug product that had been submitted by another firm, along with its registration application. | |
| 645 | Case Category | New License (Shahrukh Ali) |
| | Name, address of Applicant. | **Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BZ7-PTX-ZQV4, 2026-02-17) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-06-16, 2025-10-13 |
| | The proposed proprietary name / brand name | **Levecetam Tablet 250mg** |
| | Label Claim | Each tablet Contains: Levetricetam .....250mg USP Specs |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO -De-Controlled |
| | Shelf Life (Unit) | 2 Year30C+- |
| | For generic drugs (me-too Status) | Lerace Tablet 250mg (Hilton Pharma) |
| | Pharmacotherapeutic Group of (API) | Anti-Epilepsy |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | EMMENNAR PHARMA PVT LTD |
| | Detail of stability batches of drug product | 2 batches (ST-01 and ST-02 ) 6 month stability studies) submitted both Accelerated and Real time studies |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | EMMENNAR PHARMA PVT LTD<br>ADDRESS:PLOT #15 JAWAHARLAL NHRU PHARMA CITY TADI (V) PARAWADA (M)VISAKHAPATNAM District-531 091 A.P INDIA. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Lerace tablet 250mg (Hilton Pharm) via Levecetam tablet |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 36 Month Accelerated and Real time studies Submitted |
| | The status in reference regulatory authorities | USFDA |
| | GMP status of the firm | ACTIVE ( W.E.F 26/08/2024) DML # 0009961 |
| | Evidence of approval of manufacturing facility | TABLET (GENERAL) |
| | **Evaluation Remarks** | |
| | Firm submitted the same pharmaceutical equivalence data and stability data of drug product as submitted by another firm along with their registration application. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and stability data of drug product that had been submitted by another firm, along with its registration application. | |

| | | |
|---|---|---|
| 646 | Case Category | New License (Shahrukh Ali) |
| | Name, address of Applicant. | **Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WB5-EZ9-3USQ, 2026-04-06) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-06-16, 2025-10-13 |
| | The proposed proprietary name / brand name | **Nexito Tablet 10mg** |
| | Label Claim | Each Tablets Contains: Escitalopram Oxalate as (Escitalopram).....10mg USP Specs |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO -De-Controlled |
| | Shelf Life (Unit) | 2 Year30C+- |
| | For generic drugs (me-too Status) | CIpralex 10mg Tablets (Lundbeck pharmaceutical) |
| | Pharmacotherapeutic Group of (API) | selective serotonin reuptake inhibitors (SSRIs). |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | SHODHANA LABORTORIES PVT LTD |
| | Detail of stability batches of drug product | 2 batches (ST-01 and ST-02 ) 6 month stability studies) submitted both Accelerated and Real time studies |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | SHODHANA LABORTORIES PVT LTD PLOT # 24,25,&26 Phase-I &II Village Quthbulllapur mandal,Medchal Malkajiri District Oincode 500055 TalaganaIndia |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Nexito 10mg tablet (Tovida Pharmaceuticals) via Cipralex 10mg tablet (Lundbeck pharmaceuticals) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 36 Month Accelerated and Real time studies Submitted |
| | The status in reference regulatory authorities | USFDA Approved (ESCITALOPRAM 10mg TABLET ) by ACCORD HEALTHCARE LIMITED |
| | GMP status of the firm | ACTIVE ( W.E.F 26/08/2024) DML # 0009961 |
| | Evidence of approval of manufacturing facility | TABLET (GENERAL) |
| | **Evaluation Remarks** | |
| | Firm submitted the same pharmaceutical equivalence data and stability data of drug product as submitted by another firm along with their registration application. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and stability data of drug product that had been submitted by another firm, along with its registration application. | |
| 647 | Case Category | New License (Shahrukh Ali) |
| | Name, address of Applicant. | **Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)** |

| | | |
|---|---|---|
| | Application Form Dy. No / Tracking ID & date of submission | (S62-HEN-B1HL, 2026-04-06) |
| | Detail of Fee Submitted | 37000, 1700<br>2025-06-16, 2025-10-13 |
| | The proposed proprietary name / brand name | **Nexito Tablet 20mg** |
| | Label Claim | Each Tablets Contains; Escitalopram Oxalate ..... eq, to Escitalopram.....20mg USP Specs |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO -De-Controlled |
| | Shelf Life (Unit) | 2 Year30C+- |
| | For generic drugs (me-too Status) | CIpralex 20mg Tablets (Lundbeck pharmaceutical) |
| | Pharmacotherapeutic Group of (API) | selective serotonin reuptake inhibitors (SSRIs). |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | SHODHANA LABORTORIES PVT LTD |
| | Detail of stability batches of drug product | 2 batches (ST-01 and ST-02 ) 6 month stability studies) submitted both Accelerated and Real time studies |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | SHODHANA LABORTORIES PVT LTD PLOT # 24,25,&26 Phase-I &II Village Quthbulllapur mandal,Medchal Malkajiri District Oincode 500055 TalaganaIndia |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Nexito 20mg tablet (Tovida Pharmaceuticals) via Cipralex 20mg tablet (Lundbeck pharmaceuticals) |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | 36 Month Accelerated and Real time studies Submitted |
| | The status in reference regulatory authorities | USFDA approved (Escitalopram 20mg Tablets (ACCORD HEALTHCARE LIMITED UK Approved) |
| | GMP status of the firm | ACTIVE ( W.E.F 26/08/2024) DML # 0009961 |
| | Evidence of approval of manufacturing facility | TABLET (GENERAL) |
| | **Evaluation Remarks** | |
| | Firm submitted the same pharmaceutical equivalence data and stability data of drug product as submitted by another firm along with their registration application. | |
| | **Decision** | |
| | **Rejected**<br><br>Registration Board decided to reject the instant application, considering that the firm had submitted the exact same assay verification report of the drug substance performed by the drug product manufacturer, pharmaceutical equivalence data, comparative dissolution profile report, assay validation report of the drug product, and stability data of drug product that had been submitted by another firm, along with its registration application. | |
| 648 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **SHAWAN PHARMACEUTICALS** PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT **(000627)** |
| | Application Form Dy. No / Tracking ID & date of submission | (REU-Z8G-HG46, 2024-08-20) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-15, |
| | The proposed proprietary name / brand name | **Shaxone 2gram injection** |

| | | |
|---|---|---|
| | Label Claim | Each vial contains: Sterile Powder of Ceftriaxone Sodium USP eq. to Ceftriaxone.....2g. |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)room temperature |
| | For generic drugs (me-too Status) | Oxidil 2gram IV injection Reg. No.086609 |
| | Pharmacotherapeutic Group of (API) | Antibiotics |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Sinopharm Weiqida Pharmaceutical Co., Ltd. |
| | Detail of stability batches of drug product | 1400 vials 3 batches |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | E-3991684803167 06.1.23 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Oxidil 2g injection M/s sammi |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| | The status in reference regulatory authorities | MHRA / (USFDA Approved). |
| | GMP status of the firm | No F.3-43/2019 add.dir(Qa-Lt-I) dated 06-12-2022 |
| | Evidence of approval of manufacturing facility | No F.1-59/2005-Lic (Vol-I)dated 03-09 -2021 mentioning dry powder injection cephalosporin section |
| | **Evaluation Remarks** | |
| | 3.2.P.5.1 You have adopted specs for ceftriaxone injection instead of ceftriaxone for injection justification required as the former is for solution. 3.2.P.8.3 Stability studies are performed using chromatographic conditions for ceftriaxone injection instead of ceftriaxone for injection as the product is powder form | The analytical specifications and test methods of Ceftriaxone Injection were inadvertently adopted instead of those for Ceftriaxone for Injection, as both products require reconstitution prior to analysis and testing. Appropriate corrective actions have been initiated to align/revise the specifications and ensure that only the pharmacopoeia requirements specifically applicable to Ceftriaxone for Injection are used in future documentation and testing activities. |
| | **Decision** | |
| | **Deferred**<br><br>The board deferred the stability data and directed the firm to submit product development data according to Specifications for "Ceftriaxone for injection". | |
| 649 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (6VW-GDB-76XW, 2024-08-21) |
| | Detail of Fee Submitted | 75000.0,<br>2024-07-22, |
| | The proposed proprietary name / brand name | **BMD-EZ Tablet** |
| | Label Claim | Each Film Coated Tablet contains: Bempedoic Acid .....180MG Ezetimibe (USP) .....10MG (Product Complies Innovator’s Specs) |

| | | |
|---|---|---|
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | USFDA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | 3.2.P.5.1 SPECIFICATION OF DRUG PRODUCT: Water content (KF) and microbial purity tests neither have been performed nor included under finished product specification. Firm has Revised Finished product Specs however same tests have not been performed in batch analysis, fee for revision of specs is not submitted | |
| | **Decision** | |
| | **Approved**<br><br>Subject to submission of applicable fee for revision of specification's as per innovator | |
| 650 | Case Category | Routine (Shahrukh Ali) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4PE-PZS-G2N4, 2024-05-23) |
| | Detail of Fee Submitted | 30000.0,<br>2024-05-10, |
| | The proposed proprietary name / brand name | **Fomit 40mg Tablet** |
| | Label Claim | Each Film Coated Tablet contains:<br>Famotidine.....40mg (Product complies USP Specs) |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store below 25°c |
| | For generic drugs (me-too Status) | Acicon Tablet 40mg by M/s Barrett Hodgson Pakistan (Pvt.) Ltd |
| | Pharmacotherapeutic Group of (API) | Antiulcerative |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | 3 Batches Size 1200 tablets |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form -6 00/98/2022-DRAPCPS/505 dated 04.02.22 |

| | |
|---|---|
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Famot Tablets Shaigan Pharmaceuticals (Pvt.) Ltd. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | IV-A |
| The status in reference regulatory authorities | USFDA Approved |
| GMP status of the firm | 10/2024-DRAP AD 9071257570 dated 22.01.24 |
| Evidence of approval of manufacturing facility | No F.3-2/2006--Lic(vol-I) dated 11-06-2024 mentioning tablet section |
| **Evaluation Remarks** | |
| 3.2.P.2.2.1 Pharmaceutical equivalence: i. Submit pictorial evidence of reference product showing manufacturer's name, batch number etc. ii. Submit complete CDP studies in all 3 medias along with performance calculations and audit trail. | Firm has submitted a pack which is prescribed to a patient as pack outer carton has indications for patient with marker "1 rozana khali pait" |
| 3.2.P.5.1 SPECIFICATION OF DRUG PRODUCT: Submitted dissolution method is spectrophotometric method as USP monograph given spectrophotometric as well as chromatographic method of dissolution. | The dissolution test performed on spectrophotometric method as USP monograph given spectrophotometric as well as chromatographic method of dissolution. Firm has opted for inferior method |
| 3.2.P.8.3 Submitted Chromatograms don't show flow rate, wavelength. Mentioned injection size is not as per USP. Justify | Flow rate and wavelength is not showing on chromatogram because software does not have option for showing this data. Inj. size is 20µl instead of 50µl as it is going out of the detection limit in HPLC. |
| Submit evidence of CFR 21 compliance | Not submitted |
| **Decision** | |
| **Rejected**<br><br>The Board rejected as the firm did not satisfactorily submitted evidence regarding 21 CRF compliance and omission of flow rate, wavelength in the submitted chromatograms. | |

# Drug Regulatory Authority of Pakistan

## (Pharmaceutical Evaluation & Registration Division)

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## Registration Board 360 Meeting Additional/Supplementary Minutes:

| Sr. No | Title | Description |
|---|---|---|
| 1 | Case Category | Contract Manufacturing (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PTT-XE1-6V38, 2025-04-10) |
| | Detail of Fee Submitted | 93000.0,<br>2025-03-05, |
| | The proposed proprietary name / brand name | **AtheraVance Capsules 0.5g** |
| | Label Claim | Each Soft Gel Capsule contains 0.5g of Icosapentate Ethyl |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per DPC-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Not Available |
| | Pharmacotherapeutic Group of (API) | Antilipemic or lipid regulating agents |
| | Name, address of Manufacturing site: | Martin Dow Marker Limited-F-126, S.I.T.E., Karachi Pakistan- |
| | Name & address of API manufacturer | Shandong Xinhua Pharmaceutical Co., Ltd. Address: Hutian Chemical Industrial Zone, Zibo, Shandong, P. R. China |
| | Detail of stability batches of drug product | 3 batches having batch size of 10,000 capsule each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of form 6 dated 04-01-2024 specifying 102kg Icosapent Ethyl. Firm has submitted copy of goods declaration, airway bill, commercial invoice, packing list, form 3, form 7 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against Vascepa 0.5gm Capsules by M/s Amarin Pharmaceuticals Ireland Ltd. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per zone II |
| | The status in reference regulatory authorities | Vascepa (Icosapentate Ethyl) Capsule 0.5g USFDA Approved. |
| | GMP status of the firm | Martin Dow Marker Limited., Karachi Firm has submitted copy of cGMP certificate of the firm based on inspection dated 19-04-2024. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of regularization of sections dated 27-05-2021 specifying Soft Gelatin Capsule. |
| | **Evaluation Remarks** | |
| | Deferred in 359th meeting of RB Marked in category of new molecule | |
| | Shortcomings | Firm's Response |

| | |
|---|---|
| Stability study data of API as per Zone IV conditions till claimed shelf life | Firm has submitted stability study data of API as per zone IV-A till 24th months |
| Justification for not using tocopherol in applied formulation compared innovator's formulation | In the attached API Certificate of Analysis (Annexure II), it is evident that alpha-tocopherol is present as a constituent of the Icosapentate Ethyl API and it is used as an antioxidant. Therefore, it is not incorporated as a separate excipient in the finished product AtheraVance Capsules. The quantity of tocopherol associated with the Icosapentate Ethyl API is adequately controlled and tested through GC method as part of the API specifications which is reflected in the attached document, thereby ensuring the intended quality, stability, and performance of the finished product. |
| Results of accuracy test analytical method validation report | Accuracy test has been performed by standard addition method. Test report and chromatograms have been attached |
| Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation | Since there is no Risk Assessment and Risk Mitigation Review data available for the innovator Vascepa Capsules in USFDA, we have prepared the RMP from Pharmacological Review Report for the innovator Vascepa Capsules approved by USFDA. |
| Fee for revision of specifications. | Firm has submitted Rs. 9400/- for revision of specifications on deposit slip#869388551642 |
| Comparative table of the applied specifications and analytical methods versus the corresponding JP specifications and analytical methods. | Firm has only submitted a table and no comparison of analytical method and specification has been made. We have also revised FP specifications and method of analysis as per the JP pharmacopeia. |
| Scientific justification for the stability of applied formulation, considering that the innovator productrecommends storage at 20°C–25°C (with permitted excursions to 15°C–30°C), the applied product isunstable under accelerated conditions as per submitted data, and stability studies have been conductedat 25°C ± 2°C/60% ± 5% RH (long-term) and 30°C ± 2°C/65% ± 5% RH conditions. | The stability of the applied formulation has been established in accordance with ICH Q1A(R2). We performed long term stability studies at 25°C ± 2°C/60% ± 5% RH and accelerated at 40°C ± 2°C/75% ± 5% RH but due to unsatisfactory results at 6-month interval of accelerated stability study, we conducted intermediate stability studies at 30°C ± 2°C/65% ± 5% RH as per ICH Q1A(R2) guidelines. Consider this justification that innovator product recommends storage condition 20°C-25°C (with permitted excursions to 15°C30°C) that is as per USP for 24 hour |

**Decision**

**Rejected**

The Board was apprised that:

1. The applicant has developed the applied product without using Tocopherol in its formulation as used by the innovator's product. Tocopherol exhibits anti-oxidant properties contributing to the stability of the product.
2. The applied product shows unsatisfactory results at $6^{th}$ month time point at accelerated conditions as informed by the firm. The firm could not provide any justification for out of

specs results.

After detailed deliberation, the Registration Board decided to reject the application.

| | | |
|---|---|---|
| 2 | Case Category | Contract Manufacturing (Dr. Farhad Ullah) |
| | Name, address of Applicant. | **Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)** |
| | Application Form Dy. No / Tracking ID & date of submission | (7HV-TS8-AJAW, 2025-05-29) |
| | Detail of Fee Submitted | 93000.0,<br>2025-03-05, |
| | The proposed proprietary name / brand name | **Atheravance Capsule 1g** |
| | Label Claim | Each Soft Gel Capsule contains 1g of Icosapentate Ethyl |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per DPC-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Below 30°C |
| | For generic drugs (me-too Status) | Not Available |
| | Pharmacotherapeutic Group of (API) | Antilipemic or lipid regulating agents |
| | Name, address of Manufacturing site: | Martin Dow Marker Limited-F-126, S.I.T.E., Karachi Pakistan- |
| | Name & address of API manufacturer | Shandong Xinhua Pharmaceutical Co., Ltd. Address: Hutian Chemical Industrial Zone, Zibo, Shandong, P. R. China |
| | Detail of stability batches of drug product | 3 batches having batch size of 10,000 capsule each |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Firm has submitted copy of form 6 dated 04-01-2024 specifying 102kg Icosapent Ethyl. Firm has submitted copy of goods declaration, airway bill, commercial invoice, pacing list, form 3, form 7 |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | PE studies performed against Vascepa 1gm Capsules by M/s Amarin Pharmaceuticals Ireland Ltd. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Firm has submitted stability study data of 3 batches of drug substance as per zone II |
| | The status in reference regulatory authorities | Vascepa (Icosapentate Ethyl) Capsule 1g USFDA Approved. |
| | GMP status of the firm | Martin Dow Marker Limited., Karachi Firm has submitted copy of cGMP certificate of the firm based on inspection dated 19-04-2024. |
| | Evidence of approval of manufacturing facility | Firm has submitted copy of letter of regularization of sections dated 27-05-2021 specifying Soft Gelatin Capsule. |
| | **Evaluation Remarks** | |
| | Deferred in 359th meeting of RB Marked in category of new molecule | |

| Shortcomings | Firm's Response |
|---|---|
| Stability study data of API as per Zone IV conditions till claimed shelf life | Firm has submitted stability study data of API as per zone IV-A till 24th months |
| Justification for not using tocopherol in applied formulation compared innovator's formulation | In the attached API Certificate of Analysis (Annexure II), it is evident that alpha-tocopherol is present as a constituent of the Icosapentate Ethyl API and it is used as an antioxidant. Therefore, it is not incorporated as a separate excipient in the finished product AtheraVance Capsules. The quantity of tocopherol associated with the Icosapentate Ethyl API is adequately |

| | |
|---|---|
| | controlled and tested through GC method as part of the API specifications which is reflected in the attached document, thereby ensuring the intended quality, stability, and performance of the finished product. |
| Results of accuracy test analytical method validation report | Accuracy test has been performed by standard addition method. Test report and chromatograms have been attached |
| Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation | Since there is no Risk Assessment and Risk Mitigation Review data available for the innovator Vascepa Capsules in USFDA, we have prepared the RMP from Pharmacological Review Report for the innovator Vascepa Capsules approved by USFDA. |
| Fee for revision of specifications. | Firm has submitted Rs. 9400/- for revision of specifications on deposit slip#6477561560 |
| Comparative table of the applied specifications and analytical methods versus the corresponding JP specifications and analytical methods. | Firm has only submitted a table and no comparison of analytical method and specification has been made. We have also revised FP specifications and method of analysis as per the JP pharmacopeia. |
| Scientific justification for the stability of applied formulation, considering that the innovator productrecommends storage at 20°C–25°C (with permitted excursions to 15°C–30°C), the applied product isunstable under accelerated conditions as per submitted data, and stability studies have been conductedat 25°C ± 2°C/60% ± 5% RH (long-term) and 30°C ± 2°C/65% ± 5% RH conditions. | The stability of the applied formulation has been established in accordance with ICH Q1A(R2). We performed long term stability studies at 25°C ± 2°C/60% ± 5% RH and accelerated at 40°C ± 2°C/75% ± 5% RH but due to unsatisfactory results at 6-month interval of accelerated stability study, we conducted intermediate stability studies at 30°C ± 2°C/65% ± 5% RH as per ICH Q1A(R2) guidelines. Consider this justification that innovator product recommends storage condition 20°C-25°C (with permitted excursions to 15°C30°C) that is as per USP for 24 hour |

**Decision**

**Rejected**

The Board was apprised that:

1. The applicant has developed the applied product without using Tocopherol in its formulation as used by the innovator's product. Tocopherol exhibits anti-oxidant properties contributing to the stability of the product.
2. The applied product shows unsatisfactory results at $6^{th}$ month time point at accelerated conditions as informed by the firm. The firm could not provide any justification for out of specs results.

After detailed deliberation, the Registration Board decided to reject the application.

## Item No. III Division of Quality Assurance & Laboratory Testing

| S. No. | CASE TITLE |
|---|---|
| 1. | **Manufacture And Sale of Substandard, Spurious and Misbranded Products By M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha** |
| 2. | **Manufacture And Sale of Substandard and Misbranded Carefen Suspension Batch No. Cn-037, Reg No. 066500 And Spurious and Misbranded Carenol Ammonium Chloride Cough Syrup, Batch No. Cl-036, Reg No. 026907 Manufactured By M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha** |
| 3. | **Substandard Teczone Forte Injection Batch No. 02, Reg No. 045516 Manufactured By M/s SPL Pharmaceuticals Pvt. Ltd, Hattar** |
| 4. | **Manufacture And Sale of Substandard Ciprozat 500mg Tablet Reg No. 031221 Batch No. 2421 Manufactured By M/S Hizat Pharmaceutical Industry Peshawar** |
| 5. | **RESEMBLANCE OF COLOUR SCHEME, DESIGN AND ARTISTIC WORK AND PACKAGING** |
| 6. | **SUBSTANDARD GENTAMYCIN EAR DROPS MANUFACTURED BY M/S. AMROS PHARMA KARACHI – QCB ISLAMABAD CASE.** |
| 7. | **M/S ALKEMY PHARMACEUTICAL (PVT) LTD, HYDERABAD** |
| 8. | **MANUFACTURE AND SALE 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** |
| 9. | **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)** |
| 10. | **SUBSTANDARD MAVERICK 500MG INJ., REG. NO. 065444 BATCH NO 250901, AND WAFIN INJ. (WATER FOR INJECTION) REG. NO. 066643 BATCH NO. 250101 MANUFACTURED BY M/S CREST PHARMACEUTICALS, ISLAMABAD DML NO.000694** |
| 11. | **MANUFACTURE AND SALE OF SUB-STANDARD INJECTION CARA-DOBA 5ML (DOBUTAMINE 250MG/5ML) AND INJ A-CARE (ATRACURIUM) 50MG/5ML MANUFACTURED BY M/S. CARAWAY PHARMACEUTICALS PLOT NO. 12 STREET NO. N-3 NATIONAL INDUSTRIAL ZONE (RCCI) RAWAT, ISLAMABAD DML NO. 000629)** |

**CASE NO. 01: <u>MANUFACTURE AND SALE OF SUBSTANDARD, SPURIOUS AND MISBRANDED PRODUCTS BY M/S WELL CARE PHARMACEUTICALS PVT LTD., A/7 P.S.I.E SARGODHA</u>**

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

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

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

| | | | | | | |
|---|---|---|---|---|---|---|
| Syrup Histacare 450ml<br><br>Each 5ml contains:<br><br>Chlorpheniramine maleate…..2mg | M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha | 066498 | HE-036 | 09-2024 | 09-2026 | ***"Spurious"*** **on the basis of Assay of Chlorpheniramine maleate**<br>**Assay:**<br>Stated: 2mg/5ml<br>Determined:0.00mg/5ml (UV-Visible Spectroscopy)<br>**Percentage:**<br>0.00% (Does Not Comply)<br>Limit:<br>90.0-110.0% |
| Suspension Carefen 90ml<br><br>(Each 5ml contains: Ibuprofen 100mg) | M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha | 066500 | CN-035 | 09-2024 | 09-2026 | ***"Spurious"*** **on the basis of assay of Ibuprofen**<br>**Assay:**<br>Stated:<br>100mg/5ml (USP-2024)<br>**Determined:**<br>0.00 mg/ 5ml (HPLC)<br>**Percentage:**<br>0.0% (Does Not Comply)<br>Limit:<br>90.0-110.0%<br><br>***"Misbranded"*** on the basis of Manufacturing specifications are not mentioned, neither on the label nor on the unite carton of the sample |
| Syrup Wellfer 60ml | M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha | 066496 | WR-020 | | | ***Noncompliance regarding the provision method of Analysis to DTL, Rawalpindi*** |

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

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

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

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

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

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

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

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

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

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

8. In compliance to Registration Board decision, Division of QA&LT issued notice of personal hearing to appear before the Board, vide office letter No F. No.03-26/2026-QALT (360-RB) dated 29th June 2026 under Section 42 of the Drug Act 1976.

9. **Proceedings and Decision of 360th meeting of Registration Board**

**Division of QA & LT presented the case before the Registration Board. Mr. Malik Saeed Akhtar Managing Director of M/s Well Care Pharmaceuticals Pvt Lt., Sargodha along with Legal counsel Muhammad Sarfaraz Sajid appeared before Board. They inform that the matter is in the court of law.**

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

***i. Registration of the following products of M/s Well Care Pharmaceuticals Pvt. Ltd., Sargodha, shall remain suspended under Section 42 of the Drugs Act, 1976, and rules framed thereunder.***

| ***S. No*** | ***Product*** | ***Reg. No*** | ***S. No*** | ***Product*** | ***Reg. No*** |
|---|---|---|---|---|---|
| ***i.*** | ***Suspension Paracare 450ml*** | ***024998*** | ***iv.*** | ***Suspension Carefen*** | ***066500*** |

| | | | | | |
|---|---|---|---|---|---|
| | | | | ***90ml*** | |
| ***ii.*** | ***Syrup Carenol Ammonium Chloride Cough*** | ***026907*** | ***v.*** | ***Syrup Wellfer 60ml*** | ***066496*** |
| ***iii.*** | ***Syrup Histacare 450ml*** | ***066498*** | | | |

*ii. The applicant shall submit complete record pertaining to the court cases in the instant case.*

*iii. The Board shall take a final decision after reviewing all record related to the court cases.*

**CASE NO. 2: MANUFACTURE AND SALE OF SUBSTANDARD AND MISBRANDED CAREFEN SUSPENSION BATCH NO. CN-037, REG NO. 066500 AND SPURIOUS AND MISBRANDED CARENOL AMMONIUM CHLORIDE COUGH SYRUP, BATCH NO. CL-036, REG NO. 026907 MANUFACTURED BY M/S WELL CARE PHARMACEUTICALS PVT LTD., A/7 P.S.I.E SARGODHA**

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

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

| **Name of Drug** | **Manufactured by** | **Reg. No** | **Batch No** | **Mfg. Date** | **Exp. Date** | **DTL Test Report Details** |
|---|---|---|---|---|---|---|
| Suspension Carefen 90ml<br><br>(Each 5ml contains: Ibuprofen 100mg) | M/S Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha | 066500 | CN-037 | 11-2024 | 10-2026 | ***"Substandard"*** **on the basis of assay of Ibuprofen**<br>**Assay:**<br>Stated: 100mg/5ml (USP-2024)<br>**Determined:**<br>23.139 mg/ 5ml (HPLC)<br>**Percentage:**<br>23.14% (DOES NOT COMPLY)<br>Limit:<br>90.0-110.0%<br><br>***"Misbranded"*** on the basis of Product specifications are not mentioned, neither on the label nor on the unite carton of the sample |
| Syrup Carenol | M/s Well Care | 026907 | CL- | 08- | 08- | ***"Spurious"*** **on the** |

| | | | | | | |
|---|---|---|---|---|---|---|
| Ammonium Chloride Cough Each 5ml contains: Ammonium Chloride….125mg Sodium Citrate…. 55mg Chlorpheniramine maleate…..2.5mg | Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha | | 036 | 2024 | 2026 | **basis of** Chlorpheniramine maleate **Assay:** Stated: 2.5mg/5ml **Determined:** 0.000 mg/ 5ml (U\|V Spectrophotometer) **Percentage:** 00% (DOES NOT COMPLY) Limit: 95.0-105.0% ***Misbranded*"** on the basis of Product specifications are not mentioned, neither on the label nor on the unite carton of the sample |

3. The case was presented by the Provincial Quality Control Board in its 293rd meeting. The Board after perusal of case record and scrutiny of DTL report observed that sample of Suspension Carefen 90ml Batch No. CN-037 was declared ***Substandard and Misbranded*** and sample of Syrup Carenol Ammonium Chloride Cough Batch No. CL-036 was declared Spurious and Misbranded by DTL, Rawalpindi and the Licensed Manufacturer M/s Well Care Pharmaceuticals Pvt Ltd., A/7 P.S.I.E Sargodha committed the offense of Manufacturing and sale of *Substandard*, *Spurious* and *Misbranded* drug.

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

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

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

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

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

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

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

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

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

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

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

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

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

8. Accordingly, the matter is placed before Registration Board

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

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

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

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

| *S. No* | *Product* | *Reg. No* | *S. No* | *Product* | *Reg. No* |
|---|---|---|---|---|---|
| *i.* | *Suspension Carefen 90ml* | *066500* | *ii.* | *Syrup Carenol Ammonium Chloride Cough* | *026907* |

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

10. In compliance to Registration Board decision Division of QA&LT issued notice of personal hearing to appear before the Board, vide office letter No F. No.03-26/2026-QALT (360-RB) dated 29th June 2026 under Section 42 of the Drug Act 1976.

11. **Proceedings and Decision of 360th meeting of Registration Board**

**Division of QA & LT presented the case before the Registration Board. Mr. Malik Saeed Akhtar Managing Director of M/s Well Care Pharmaceuticals Pvt Lt., Sargodha along with Legal counsel Muhammad Sarfaraz Sajid appeared before Board. They inform that the matter is in the court of law.**

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

***i. Registration of the following products of M/s Well Care Pharmaceuticals Pvt. Ltd., Sargodha, shall remain suspended under Section 42 of the Drugs Act, 1976, and rules framed thereunder.***

| *S. No* | *Product* | *Reg. No* | *S. No* | *Product* | *Reg. No* |
|---|---|---|---|---|---|
| ***i.*** | ***Suspension Carefen 90ml*** | ***066500*** | ***ii.*** | ***Syrup Carenol Ammonium Chloride Cough*** | ***026907*** |

***i. The applicant shall submit record pertaining to the court cases in the instant case.***

***ii. The Board shall take a final decision after reviewing all record related to the court cases.***

**Case No.3: <u>SUBSTANDARD TECZONE FORTE INJECTION BATCH NO. 02, REG NO. 045516 MANUFACTURED BY M/S SPL PHARMACEUTICALS PVT. LTD, HATTAR</u>**

The Federal Inspector of Drugs, DRAP, Peshawar (Mr. Adnan Shahidullah) visited the premises of M/s SPL Pharmaceuticals Pvt. Ltd, Hattar on 23rd September 2025 and took samples of the Teczone Forte Injection 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-10-25-000098 dated 26th January 2026 declared the batch 028 of product Teczone Forte Injection manufactured by M/s SPL Pharmaceuticals Pvt. Ltd, Hattar 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** |
|---|---|---|---|---|---|---|
| Teczone Forte Injection<br><br>(Cefoperazone Sodium and Sulbactam Sodium) | M/s SPL Pharmaceuticals Pvt. Ltd, Hattar | 045516 | 02 | 09-2024 | 08-2026 | Sample has been declared as "Substandard" on pH: 4.3<br><br>Does not comply Limit: 4.5 to 6.5 |
| Sterile water for injection | Wuhan Grand Pharma Group Co, Ltd, China. | 043087 | 240578 | 05-2024 | 05-2027 | |

3. Federal Inspector of Drugs, DRAP, Peshawar, submitted the company's request of Appellate testing vide letter nil dated 24th February 2026, after receiving letter along with CDL report from FID, Lahore which was sent on 13th February ,2026

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

5. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F.03-06/2026-DD(QALT) dated 31st March 2026, requested the Federal Government Analyst CDL Karachi and M/s SPL Pharmaceuticals Pvt. Ltd, Hattar for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

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

**Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:**
Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with JP 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 SPL Pharmaceuticals Pvt. Ltd, Hattar:**
M/s SPL Pharmaceuticals Pvt. Ltd, Hattar, in their reply that the OOS result of pH 4.3 reported by DRAP is invalid for SPL's batch. In-house results and retain sample confirm pH, which complies with specification 4.5-6.5. Further the result is also within the pH 3.5-6.5 documented in the certificate of analysis for the batch.

**Technical evaluation**

- Firm submitted Certificate of analysis from two sources

i. Qilu Antibiotics Pharmaceuticals co., Ltd China of batch No.5132FJ81NE (pH 3.5 – 6.5)
ii. Shandong Ruiyng Pioneer Pharmaceutical co., Lt of batch no. 2410018003 (pH 3.5 – 6.5)

- Teczone 2g Injection Specification mentioned by SPL pharmaceuticals are USP Specifications, but it is not available in USP.

7. **Proceedings and Decision of 360th meeting of Registration Board**

***QA & LT Division presented the case before the Registration Board. The Board after considering facts of the case and thorough deliberation, decided to accede request of firm for appellate testing of Product Teczone Forte Injection (045516), Batch No. 02 manufactured by M/s SPL Pharmaceuticals Pvt. Ltd, Hattar, under Section 22 (5) of the Drugs Act, 1976. Registration Board further directed that the said sample be forwarded for appellate testing at the earliest, in view of its near expiry, without waiting for the formal approval of the meeting minutes.***

**Case No.4: MANUFACTURE AND SALE OF SUBSTANDARD CIPROZAT 500MG TABLET REG NO. 031221 BATCH NO. 2421 MANUFACTURED BY M/S HIZAT PHARMACEUTICAL INDUSTRY PESHAWAR**

The Federal Inspector of Drugs, DRAP, Peshawar (Mr. Shahid Nawaz) visited the premises of M/s Hizat Pharmaceutical Industry Peshawar on 18th November 2025 and took samples of the Ciprozat 500mg Tablet on Form-3 and sent to the Federal Government Analyst, CDL Karachi for test/analysis on Form-4.

2. Federal Government Analyst, CDL Karachi vide test report No. IP-12-25-000155 dated 17th February 2025, declared the batch 2421 of product Ciprozat 500mg Tablet manufactured by M/s Hizat Pharmaceutical Industry 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 |
|---|---|---|---|---|---|---|
| Ciprozat 500mg Tablet<br><br>(Ciprofloxacin : 500mg/tablet) | M/s Hizat Pharmaceutical Industry Peshawar | 031221 | 2421 | 04-2025 | 04-2028 | ***"Sub-Standard"*** on the basis of Dissolution<br>Stage 1: Does not comply<br><br>(Stage 2) : 74%<br>***Does not Comply***<br>Limit: Average of 12 NLT Q=80. Each unit should not be less than Q-15=65 |

3. Federal Inspector of Drugs, DRAP, Peshawar, submitted the company's request of Appellate testing vide letter No. HZ/HCl/03/26 dated 9th March, 2026 (after receiving letter along with CDL report from FID, Peshawar (which was sent on 3rd March, 2026)

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

5. In the light of above-mentioned decision of the Board, the division of QA&LT vide letter F.03-10/2026-DD(QALT) dated 2nd April, 2026, requested the Federal Government Analyst CDL Karachi and M/s Hizat Pharmaceutical Industry Peshawar for the submission of Out of specification (OOS) investigation as directed by the Registration Board.

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

**Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:**
Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with the USP 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 Hizat Pharmaceutical Industry Peshawar:**
M/s Hizat Pharmaceutical Industry Peshawar, in their reply that an OOS investigation was conducted on the retained samples of the subject batch in our Quality Control laboratory. The dissolution testing was carried out on 11-04-2026 under the following conditions Apparatus II (Paddle), Medium: 0.01N HCI 900ml, Temperature: 37°C RPM 50, Wavelength 277nm, Time: 30 minutes. The results obtained are as follows
Sample 1: 0.673 - 96.02%
Sample 2: 0.683 - 97.43%

Sample 3: 0.674 - 96.14%
Sample 4: 0.701-100.01%
Sample 5: 0.683 - 97.48%
Sample 6: 0.688 - 98.23%
Average: 97.55%
Limit: NLT 80% (Q)

Remarks: Complies Specifications

The OOS investigation results were found satisfactory. All six units complied with the dissolution specification, with an average dissolution of 97.55% against the limit of NLT 80% (Q). No out of Specification result was observed during retained sample testing.

**Scientific Justification for Appellate Testing:**
It is most respectfully submitted that the test report issued by CDL Karachi cites USP-NF 2025 as the reference standard. The USP General Chapter <711> on Dissolution prescribes a mandatory three-stage sequential testing protocol (S1, S2, and S3). The CDL has conducted testing only up to Stage 2 (S2) and has not proceeded to Stage 3 (S3), despite the S2 result not meeting the acceptance criteria. Under USP <711>, when S2 criteria are not met, testing must mandatorily proceed to Stage 3 (S3) before any final conclusion can be drawn. Declaring a product Substandard without completing Stage 3 (S3) of the prescribed protocol as required by the very reference standard cited in the CDL report-constitutes an incomplete and premature analytical conclusion.

**7. Proceedings and Decision of 360th meeting of Registration Board**

**Division of QA & LT presented the case before the Registration Board. The Board, after considering facts of the case, thoroughly deliberation and considering the OOS investigation, decided as follows:**

i. ***It was observed that stance of the firm that CDL has not proceeded for Stage 3 is not scientifically justifiable as during Stage 2 testing, one of their tablet is having test results of 53%, which renders product not to qualify for stage 3 testing (i.e Dissolution test of any tablet should not be lest than Q-15% while dissolution test of one tablet was 53%. Hence Registration Board did not accede request of the firm for appellate testing of Ciprozat 500mg Tablet (Ciprofloxacin Hcl) manufactured by M/s Hizat Pharmaceutical Industry Peshawar from Appellate Laboratory under section 22 (5) of the Drugs Act, 1976.***
ii. ***To issue show cause notice to M/s Hizat Pharmaceutical Industry 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.***

**Case No.5: RESEMBLANCE OF COLOUR SCHEME, DESIGN AND ARTISTIC WORK AND PACKAGING**

M/s Sami Pharmaceuticals (Pvt) Ltd submitted an application dated 21-04-2026, wherein they have stated the following:

*"It is respectfully submitted that product Esticef (Ceftrioxone sodium) 500mg IM and lg IM/IV Injections, under Regn. Nos. 087060 & 073339 respectively are being manufactured by M/s. Acumen Pharma Pvt. limited, Islamabad holding DML No. 000828; in this connection, we have to respectfully make the following submissions:*
*a. We have been manufacturing and marketing Ceftriaxone Sodium for the last several years under the brand name of OXIDIL range while M/s. Acumen Pharma Pvt. Limited, Islamabad Esticef (Ceftrioxone sodium) 500mg IM and lg IM/IV Injections are fresh registration granted to them vide Regn. Nos. 087060 & 073339 respectively; copies of our Registration Certificates alongwith renewal evidences are attached.*
*b. Printing style, font style, placement of matter and color scheme of the catch covers on Esticef (Ceftriaxone sodium) 500mg IM and lg IM/IV Injections which are manufactured by M/s. Acumen Pharma Pvt. Limited, Islamabad, are identical to our brand which clearly imitate our product being a clear violation of the undertaking submitted at the time of submission of registration application and*

*a deliberate attempt to encash our goodwill, which we have earned after long and hectic struggle in this field - one pack each of OXIDIL and Esticef are being sent for your kind comparison*

*c. Trade Mark:- OXIDIL has been registered with Trade Marks Registry, Government of Pakistan under the Trade Marks Act 1940 bearing Registration Nos. 444498 & 153709; copies of Registration and renewal certificates are respectfully enclosed for your kind perusal*

*d. Copyrights:- OXIOIL with colour scheme and design has been registered with Copyright Office, Government of Pakistan bearing Registration Nos. 24831-Copr, 36686-Copr, 36688-Copr, 36693-Copr & 36694-Copr; copies of Registration Certificates are respectfully enclosed for your kind perusal*

*In view of the above, it is requested that M/ s. Acumen Pharma Pvt. Limited, Islamabad be directed to stop manufacturing/marketing the product under this style, colour scheme forthwith and amend their packaging material as well.*

*We would be obliged if necessary direction/instructions in such regard are issued at the earliest"*

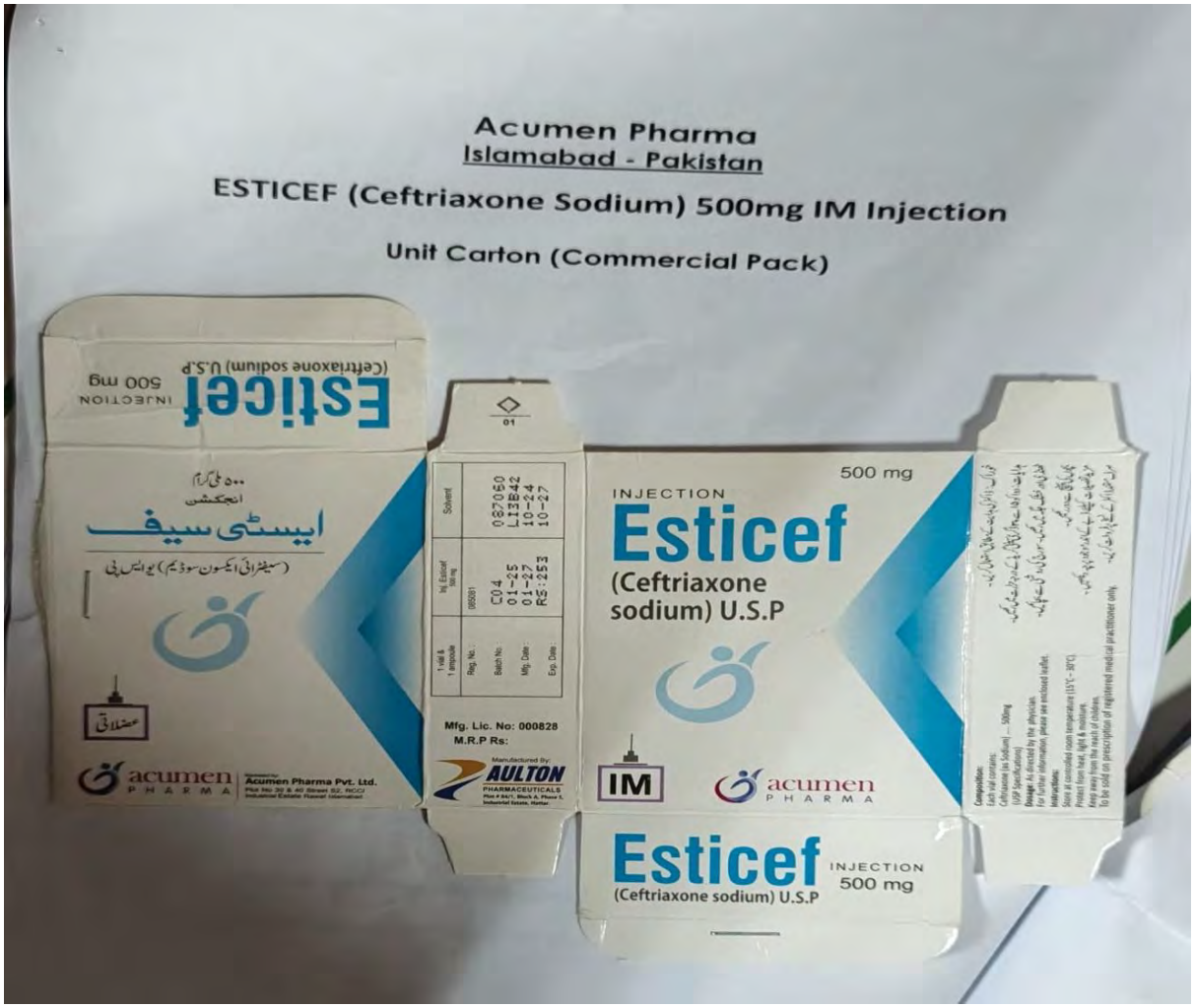
2. The firm has provided, commercial packs of above stated products as well as Inj. Qxidil 500mg & 1g for comparison purposes.

3. The firm has requested to restrain the aforementioned company from manufacturing, packaging, distributing, selling or offering for sale the said products.

## 4. Proceedings and Decision of 360th Meeting of Registration Board

The Division of QA & LT presented the subject case before the Registration Board. The Board examined the commercial packs of all strengths of both Oxidil and Esticef and decided as under:

**"*The Board after due consideration and deliberations of the case, observed resemblance in the design pattern, artistic work and color scheme of packaging of all strengths of Inj. Oxidil (Ceftrioxone sodium) manufactured by M/s Sami Pharmaceuticals (Pvt) Ltd Karachi, and Inj. Esticef (Ceftriaxone sodium), manufactured by M/s Aulton Pharmaceuticals, Hattar DML# 000828. The Board decided to direct the firm M/s Aulton Pharmaceuticals, Hattar to submit PRV within one month to PE&R Division for change in packaging, design, artwork, and color scheme of all registered strengths of Inj. Esticef (Ceftriaxone sodium) to ensure clear differentiation, under intimation to QA&LT Division.***


Acumen Pharma
Islamabad - Pakistan
ESTICEF (Ceftriaxone Sodium) 500mg IM Injection
Unit Carton (Commercial Pack)
Esticef
500 mg
INJECTION
(Ceftriaxone sodium) U.S.P
500 mg
INJECTION
Esticef
(Ceftriaxone sodium) U.S.P
IM
acumen
PHARMA
Mfg. Lic. No: 000828
M.R.P Rs:
AULTON
PHARMACEUTICALS
Esticef
INJECTION
500 mg
(Ceftriaxone sodium) U.S.P

SAMI Pharmaceuticals (Pvt) Limited
Karachi - Pakistan

OXIDIL (Ceftriaxone Sodium) 500mg IM Injection

Unit Carton (Commercial Pack)



SAMI Pharmaceuticals (Pvt) Limited

Karachi - Pakistan

**OXIDIL** (Ceftriaxone Sodium) **500mg IV Injection**

Unit Carton (Commercial Pack)

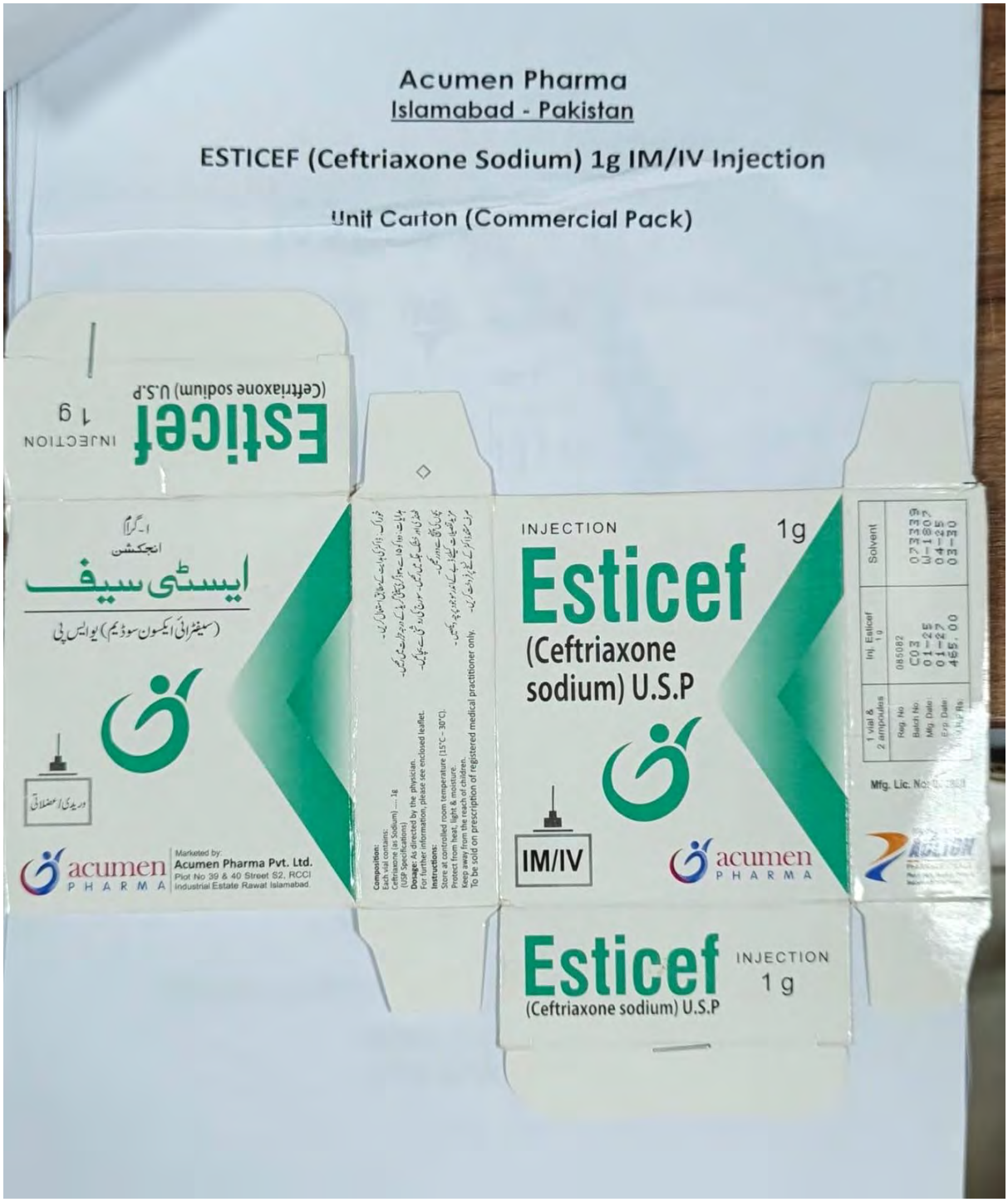


Acumen Pharma

Islamabad - Pakistan

ESTICEF (Ceftriaxone Sodium) 1g IM/IV Injection

Unit Carton (Commercial Pack)




SAMI Pharmaceuticals (Pvt) Limited
Karachi - Pakistan
OXIDIL (Ceftriaxone Sodium) 1g IV Injection
Unit Carton (Commercial Pack)
Oxidil
(Ceftriaxone) Sodium
1g IV Injection
USP Specs.
For intravenous use only
IV
Oxidil
(Ceftriaxone) Sodium
1g IV Injection
Each combination pack contains:
Vial:
Sterile Powder of Ceftriaxone Sodium USP equivalent to Ceftriaxone.....1g
Ampoule:
Sterile Water for Injection USP.....10ml
Direction for reconstitution:
Dissolve vial content by vigorous shaking using 10ml Sterile Water for Injection provided with the pack. Freshly reconstituted solution is recommended
Dosage:
As directed by the physician
Instructions:
For single use only, discard unused portion
Keep out of reach of children. Do not store over 30°C, and protect from heat, light and moisture
Improper storage may deteriorate the medicine
Only to be sold on prescription of a registered medical practitioner
Scan for Prescribing Information
Manufactured for:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, Off Hub River Road, S.I.T.E.
Karachi - Pakistan
ML No.090072 OR No.022422
GTIN: 08964001922476
by
Healthtek (Pvt.) Limited
Plot No. 14, Sector 19, Korangi Industrial Area, Karachi - Pakistan
ML No.090618
Oxidil
(Ceftriaxone) Sodium
1g IV Injection
USP Specs.
For intravenous use only
IV
آکسیڈل
(سیفٹرائی ایگزون) سوڈیم
Ampoule:
Water for Injection
(Sterile Water for Injection USP)


SAMI Pharmaceuticals (Pvt) Limited
Karachi - Pakistan
OXIDIL (Ceftriaxone Sodium) 250mg IV Injection
Unit Carton (Commercial Pack)
Oxidil®
(Ceftriaxone) Sodium
250mg IV Injection
USP Specs.
For intravenous use only
IV
SAMI
Oxidil®
(Ceftriaxone) Sodium
250mg IV Injection
Each combination pack contains:
Vial: Sterile Powder of Ceftriaxone Sodium USP equivalent to Ceftriaxone.....250mg
Ampoule: Sterile Water for Injection USP.....5ml
Direction for reconstitution:
Dissolve vial content by vigorous shaking using 5ml Sterile Water for Injection provided with the pack
Freshly reconstituted solution is recommended
Dosage: As directed by the physician
Instructions: For single use only, discard unused portion. Keep out of reach of children
Do not store over 30°C, and protect from heat, light and moisture
Improper storage may deteriorate the medicine
Only to be sold on prescription of a registered medical practitioner
Scan for Prescribing Information
Manufactured for:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, Off Hub River Road, S.I.T.E.
Karachi - Pakistan
ML No.000072 DR No.023393
GTIN: 08964001922445
by
Healthtek (Pvt.) Limited
Plot No. 14, Sector 18, Korangi Industrial Area, Karachi - Pakistan
ML No.000018
R#07/FAS
2000007415
Oxidil®
250mg IV Injection
Diluent
Free of Cost
B. No.:
MFG.:
EXP.:
M.R.P. Rs.:
Oxidil®
(Ceftriaxone) Sodium
250mg IV Injection
USP Specs.
For intravenous use only
IV
SAMI
2025
1 2 3 4 5 6
7 8 9 10 11
Ampoule:
Water for Injection
(Sterile Water for Injection USP)
Manufactured by:
Healthtek (Pvt.) Limited
Karachi - Pakistan
DR No.075484
06

**SAMI Pharmaceuticals (Pvt) Limited**
**Karachi - Pakistan**

**OXIDIL** (Ceftriaxone Sodium) **250mg IM Injection**

**Unit Carton (Commercial Pack)**



**Case No. 06: <u>SUBSTANDARD GENTAMYCIN EAR DROPS MANUFACTURED BY M/S. AMROS PHARMA KARACHI – QCB ISLAMABAD CASE.</u>**

1. Secretary Quality Control Board Islamabad vide letter vide F. No. 18(1)-QCB/ICT/2012/723 dated 22-02-2022 forwarded the case of manufacturing of Substandard Gentamycin 10ml Ear Drops Manufactured by M/s. Amros Pharmaceuticals Karachi. Brief facts of the case as under:

i. Inspector of Drugs Islamabad, during inspection of main store of DHO Office Islamabad drew samples of Gentamycin 10ml Ear drops B. No. EAM-011 manufactured by M/s. Amros Pharmaceuticals Karachi for the purpose of test/analysis.
ii. DTL Rawalpindi declared the said batch of Gentamycin Ear drops as "Substandard" on the basis of pH.
iii. M/s. Amros Pharmaceuticals Karachi requested to challenge the results of DTL test report in NIH Islamabad. The appellate laboratory, NIH Islamabad also declared the Gentamycin 10ml ear drops as of "substandard" quality on the basis of pH and volume.

2. In view of above-stated facts, Quality Control Board Islamabad in its 50th meeting held on 30-12-2021 decided as under:

*"The Board was briefed about the facts of the case as per record by Secretary. The Board was also informed that the nominated accused did not appear. The Board considered the facts available on record and after discussion decided to refer the case to Drug Registration Board for cancellation of drug registration of i.e. Ear Drops Gentamycin manufactured by M/s. Amros Pharmaceuticals Karachi after fulfilment of all legal/codal formalities in this regard."*

3. Secretary, Quality Control Board Islamabad in above-mentioned decision has requested the Registration Board for cancellation of Gentamycin 10ml Ear Drops, Reg. No. 019368 manufactured by M/s. Amros pharmaceuticals Karachi.

**Proceedings and Decision of 320th meeting:**

4. The case had been deferred due to paucity of time.

**Proceedings and Decision of 321st Meeting of Registration Board.**

5. Registration Board after discussion, considering the facts of the case decided:

*"To issue show cause notice to M/s. Amros pharmaceuticals Karachi for manufacturing and sale of substandard "Gentamycin 10ml Ear drops B. No. EAM-011" under clause (c) and (d) of sub section 11 of section 7 of the Drugs Act 1976 for suspension/cancellation/ prosecution in Drug Court of the subject cited drug and called them for personal hearing before Registration."*

6. In the light of decision of decision of Board, the accused were issued show cause notice vide letter F. No. 03-45/2022-QC(321-RB) dated 15-11-2022 with subsequent reminders on 06-01-2023 and 13-11-2023. However, no reply was received from the firm.

**Proceedings and Decision of 333rd Meeting of Registration Board:**

7. The matter was deliberated in depth and Board showed grave concerns regarding attitude of firm towards the matter at hand and decided as under:

i. *"Suspension of the Registration of Gentamycin Ear Drops (Registration No. 019368) manufactured by M/s. Amros Pharmaceuticals Karachi for six months and submission of product development data, root cause analysis along with CAPA.*

ii. *Product Specific Inspection shall be conducted by panel recommended by the Director QA&LT.*

iii. *The Board further decided to direct the DRAP office Karachi to not to accede with the request(s) of M/s. Amros Pharmaceuticals Karachi for clearance of Gentamycin API during the suspension period."*

8. Subsequently, the Division of QA&LT issued a letter vide No.F.03-12/2022-QC dated 27th October 2025 to constitute a panel to conduct Product Specific Inspection of M/s Amros Pharmaceuticals, Karachi and furnish the report to the Division of QA&LT.

9. Consequently, the following panel visited M/s Amros Pharmaceuticals, Karachi on 02-04-2026:

i. Mr. Abdul Rasool Sheikh, Additional Director, DRAP, Karachi
ii. Mr. Awais Ahmed, FID-II, DRAP, Karachi
iii. Mr. Abdul Waheed DD I&E, DRAP, Karachi

10. The panel submitted their inspection report which is being reproduced below:

"***Inspection Proceedings:***

*The panel reviewed, in-depth following areas/documents to identify the root cause of different batches of the above-mentioned substandard product:*

i. *Meeting/Discussion with Technical Staff*
ii. *Registration Letter*
iii. *Investigation Report*
iv. *Testing Methods of Finished and API*
v. *Lab Report of DTL and NIH*
vi. *Water System Qualification Report*
vii. *Method Validation 2023*
viii. *APQR of Gentamycin*
ix. *OOS SOP*
x. *SOP for Testing*
xi. *BMR*
xii. *BPR*
xiii. *Analyst qualification Record*
xiv. *COA of Raw Material*
xv. *COA of finish product*
xvi. *Calibration certificates of HPLC, dissolution apparatus, analytical balance*
xvii. *In Process Lab*
xviii. *Stability data*
xix. *Retained sample records*
xx. *Process validation reports*
xxi. *Cleaning validation*
xxii. *Analytical method validation*

*MEETING / DISCUSSION WITH TECHNICAL STAFF:-*

*Before start of the inspection, the technical persons were interviewed and the background of the matter in question was discussed. Firm's representative briefed the panel. Sample was declared substandard in pH initially by DTL Rawalpindi in 2018 and after declaration of substandard, firm challenged the sample in NIH and sample was also declared substandard by NIH in the same year i.e., 2018. Later on product was suspended for a period of six months w.e.f 27th Feb 2024 for 06 months and panel for PSI was constituted and conveyed on 27"' Oct 2025.*

*PROCEEDINGS OF THE INSPECTION:-*

*During record review, it was observed that product was tested as per USP specifications. COA of the Raw Material, finished product was reviewed. COAs of Initial sample test and repeat test were available where pH was within range, but complete testing record including raw data was not available with the firm, which could not be evaluated. Retention portion of the substandard batch was not available. Method validation and process validation were available. During visit of QC, it was verified that Quality Control Department was equipped with all the necessary equipment including HPLC, Dissolution Apparatus, FTIR, UV, Analytical Balances, pH meter, conductivity meter etc. During record review following observations were noted:*

- *Calibration Certificates of QC equipment were reviewed and found satisfactory.*
- *APQR of Gentamycin was reviewed.*
- *Method was validated in 2023.*
- *Media fill record was available and was being done as per defined SOP.*

*Furthermore, Firm has recently made many improvements including installation of Water system, installation of updated production machinery, addition of testing equipments, adding printers with equipments.*

*For verification of analyst competency and testing accuracy in pH, following samples of last available batches of gentamycin ear drops and two batches of other sample were tested and following results were observed (within range):-*

| *S.No.* | *Sample* | *Batch No.* | *Mfg. date & Expiry date* | *pH Range* | *Reading* |
|---|---|---|---|---|---|
| *1.* | *Gentamycin* | *EAM-189* | *10-23, 10-25* | *6.5-7.5* | *7.15* |
| *2.* | *Gentamycin* | *EAM-191* | *10-23, 10-25* | *6.5-7.5* | *7.14* |
| *3.* | *Benasol N* | *EAM-279* | *11-25, 11-27* | *6.0-8.0* | *7.35* |
| *4.* | *Benasol N* | *EAM-281* | *11-25, 11-27* | *6.0-8.0* | *7.52* |

*CONCLUSION & RECOMMENDATIONS: -*

*Keeping in view the above mentioned facts, non-availability of the raw data and some deviations in the method, Panel is of the opinion that firm may be directed to conduct product development by addressing the observations, adopting validated method and samples of first three batches may be sent to CDL for testing by Area FID. After declaration of standard results by the CDL, firm may be allowed to market the said product."*

11. Based on the conclusion of the panel in the PSI report, a show cause notice was issued to the firm, and they were also directed to appear before the Registration Board in its 360th Meeting to be held on 30-06-2026 vide letter No.F.03-26/2026-QALT-(RB-360) dated 22-06-2026.

12. Due to postponement of 360th meeting of the Registration Board, the new date i.e., 07-07-2026 was communicated to the firm vide letter No.F.03-26/2026-QALT-(RB-360) dated 29-06-2026

13. The firm had been called upon for Personal Hearing.

**14. Proceedings and Decision of 360th meeting of Registration Board**

**Division of QA & LT presented the case before the Registration Board. No one on behalf of firm appeared before the Board.**

**The Board, after considering the facts of the case, and thorough deliberations, noted with displeasure the repeated failure of the firm to reply to show cause notices issued by the QA&LT Division and to appear before the Board despite being given multiple chances, which is tantamount to willfully disobeying the lawful authority of the Registration Board; therefore, the Board decided as follows:**

***i. To cancel the Registration of Gentamycin Ear Drops (Registration No. 019368) manufactured by M/s. Amros Pharmaceuticals Karachi under Rule 24 (17) of the Drugs (L,R &A) Rules, 1976.***

***ii. To issue warning letter to the firm for not responding to the correspondences issued on behalf of the Board.***

**Case No. 7. M/S ALKEMY PHARMACEUTICAL (PVT) LTD, HYDERABAD**

**Background of the case:**

Dr. Abdur Rashid, Additional Director (QA&LT) along-with Syed Hakim Masood, Area FID, Karachi conducted inspection of the firm M/s Alkemy Pharmaceutical, Hyderabad on 16.11.2016 in connection to Quality Control letter dated 27.05.2016, wherein the firm was found in manufacturing and sale of sub-standard drug Azofin suspension, Kemycone suspension and to verify GMP compliance / production activities of the firm.

2. The panel noticed number of critical observations, which need urgent attention and rectification. The observations includes:-

i. No traceability of Raw Materials was available. No proper records were available. No thermometer and hygrometer were found for recording of temperature and humidity in the warehouse.

ii. Dispensing Areas needs renovation and additional calibrated weighing balance required.

iii. Old silverson mixers are rusted/old and required to be placed with new ones.

iv. Storage tanks required to be replaced with new ones.

v. Floor, walls and ceiling are cracked/old and needs overall, renovation required.

vi. The rodents and insects can enter from drainage in the production of syrup section and so requires better drainage system.

vii. Vessels need to be replaced.

viii. Liquid filling machine is old and rusty and must be replaced with semi-automatic filling machine with conveyor belt.

ix. Water System needs to be upgraded with new one.

x. Batch Manufacturing instructions were missing from batch manufacturing records.

xi. Iron racks are required to be placed in the warehouse. Iron and plastic pellets maybe further added in the warehouse and wooden pellets should be removed from the area.

xii. There are no racks in the finished goods store and medicines are placed on the floor. Few wooden pellets and plastic pellets are also seen in one room. There is a need that iron racks and plastic pellets maybe provided along with hygrometers to monitor the humidity of the finished goods store. Floor walls and ceiling needs renovation paint and up gradation.

xiii. Dust can enter from the open exhaust, therefore an exhaust is required.

xiv. There is overall need to upgrade the facility in the chemical and microbiological sections of the QC laboratory. No HPLC is available, so one HPLC may be provided.

xv. There is lacking of proper log book of the equipments, calibration, and validation of the analytical methods.

xvi. Viscometer is no more available to measure the viscosity of suspension.

xvii. In microbiological section, autoclave, colony counter and refrigerator are no more available. It is recommended to provide the same.

xviii. The qualified person in chemical and microbiological section needs training and has lack of latest knowledge. It is recommended that the technical personnel may be sent to Karachi for proper training.

xix. Qualified persons documents were submitted in 2013, but have not been approved by the concerned division.

xx. Packaging materials and labels are not properly stored and documented.

**The panel concluded that:-** The observations were discussed with the management and the management of the firm voluntarily stopped production in the liquid syrup section for maintenance and renovation. The panel recommended to issue a show cause notice for Liquid Section and personal hearing be given to the representative of the firm for cancellation and suspension of DML.

12. **Action taken by DRAP:** Accordingly show cause notice / suspension of production activities in liquid syrup section was issued to the firm on 09.01.2017.

13. **Reply by the firm:** The firm vide letter dated 17.01.2017 submitted reply, requested that the facility has been maintained and requested for the constitution of the panel to visit the firm and to provide opportunity for personal hearing.

**14. Proceedings of the 252nd Meeting of CLB**

The Board was informed by the Deputy Director (QA) that the samples of Azofin Suspension and Kemycone Suspension were declared as of substandard quality by the Central Drugs Laboratory, Karachi. Accordingly, the case was placed in 258th meeting of Registration Board held on 25th and 26th April, 2016. The Registration Board constituted panel of experts comprising of Dr. Abdur Rashid, Additional Director (QA&LT) and Syed Hakim Masood, Area FID to conduct PSI. The panel conducted inspection of the firm on 16.11.2016 and observed gross violations in Liquid Syrup Section. Accordingly, show cause notice / suspension of production activities in liquid syrup section was issued to the firm on 09.01.2017. The firm was served letter for personal hearing on 08.03.2017. Mr. Faraz Ahad Shaikh, Managing Director and Mr. Asif Najeeb Laghari, QC In-charge appeared before the Board. Managing Director inform the Board that they voluntarily stop the production in liquid section. He added that the observations noted by the panel have been rectified and they are ready for inspection. The Board inquired regarding availability of FTIR, Viscometer and Polarimeter in the Quality Control Lab. The QC In-charge replied in negative. The Board took serious notice of non-availability of most important equipments used for testing of liquid products, in QC Lab.

**Decision of the 252nd Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendations of the panel of experts in its report dated 16.11.2016, casual attitude of the firm towards GMP compliance in liquid syrup section, the Board decided to:-

i. *Suspend the Drug Manufacturing License of liquid syrup section of the firm M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd, Karachi, for a period of 03 months under section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (LR&A) Rules, 1976, from the date of issuance of decision of the 252nd meeting of CLB.*

*ii. Conduct panel cGMP inspection of the firm on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976, after submission of compliance report by the firm, by the following members:-*

- *Syed Muid Ahmad, Member CLB*
- *Dr. Abdur Rashid, Additional Director (QA&LT), Islamabad.*
- *Syed Hakim Masood, Area FID, Hyderabad / Karachi*

*iii. The Board also decided to direct the panel to submit brief report in tabulated form identifying the previous observations and the current status with clear and candid recommendations.*

*iv. The report shall be presented in the meeting of Central Licensing Board for perusal and approval.*

15. In compliance of the decision of CLB, QA&LT Division issued latter No.8-1/2017-QA) (M-252-CLB) dated 24" April 2017 for verification of the observations noted by the panel in PSI conducted on 16-11-2016. Accordingly, the panel conducted GMP inspection of the firm, on 26" July 2017. The Panel recommended for resumption of production in syrup section, which suggest PSI was already conducted and observations were verified in inspection of 26th July 2017 but PSI report was not available in record.

16. Therefore, the Director QA&LT Division constituted the following panel to conduct PSI of the firm M/s Alkemy Pharmaceutical Laboratories, Hyderabad vide letter F.No.13-45/2025-DD(QALT)-VI dated 08-01-2026:

i. Additional Director, DRAP, Karachi
ii. Area FID (Reporting & Coordinating Officer).
iii. DD (I&E)

17. The Panel visited the firm on 10-04-2026 and submitted the inspection report which is being reproduced below:

***"BACKGROUND & HISTORY***

*Alkemy Pharmaceuticals Laboratories Private Limited, site area Hyderabad, was visited on 10th April 2026 for Product specific inspection of Kemycone suspension containing (Aluminum Hydroxide, Magnesium Hydroxide and Semithicone) batch number 293." Kemycone suspension was declared substandard due to potency by the Central Drug Laboratory, DRAP Karachi vide No. Nil dated 11" Nov 2015. Firm challenged the CDL report and requested for Appellate testing. The appellate laboratory also declared the sample as substandard vide report 01-M/2016 dated 29" February 2016. Case was placed in CLB meeting held on 26h April 2016 and decided to suspend the registration for 06 months and conduct PSI by the panel and firm would recall the batch and area FID would supervise the destruction. During record evaluation, firm shown GMP inspection, conducted by the panel on 26" July 2017, in compliance to DRAP Islamabad &-1/2017-QA) (M-252-CLB) dated 24" April 2017 for verification of the observations noted by the panel in PSI conducted on 16-11-2016. The Panel recommended for resumption of production in syrup section (Report attached), which suggest PSI was already conducted and observations were verified in inspection of 26" July 2017 but PSI report was not available in record.*

***MEETING WITH THE MANAGEMENT AND TECHNICAL TEAM:***
*During discussion with the management of the company, Mr. Faraz Sheikh briefed the panel (copy attached) that they retested the retention sample and it was standard in retest results, as product was unstable in high temperature, they have not been paying the renewal fees of the registration since then, and they are not willing to continue the product (Letter attached).*

***PROCEEDINGS OF THE INSPECTION:***
*During visit, it was observed that some of the areas were under renovation for which firm had approved layout plan. Firm was granted new sections in new approved layout, Panel observed that almost work had been completed. During batch related record evaluation, it was observed that, sample was retested by the firm, but raw data related to retest was not available, however, original testing report was available at the site. BMR was available, and found no deviation from the approved method. Afterwards, QC facility was inspected where panel found firm had sufficient equipment for testing of the samples, including but not limited to HPLC, UV meter, pH meter, analytical balances, dissolution operators, disintegration operators, etc. were available. FTIR was out of order and out for repair. Work order was available and verified. Other equipments included oven, moisture analyzer, friability operators, stability chamber, hardness tester etc. were available. Furthermore, firm management informed that, in compliance to the CLB decision, they had initiated the recall but no return was reported, As batch was manufactured in July 2015 and recall was started on 27" May 2016, after lapse of almost 10 months, therefore no return was reported. because quantity was less i.e. total 4156 bottles.*

***CONCLUSION & RECOMMENDATION:***
*Keeping in view the above mentioned facts letter by the firm (copy attached) to withdraw the registration of the product it is concluded that, TORs of the PSI could not be verified on the basis of product discontinuation and registration of the product Kemycon suspension may kindly be cancelled."*

18. Based on the conclusion of the panel in the PSI report, a show cause notice was issued to the firm, and they were also directed to appear before the Registration Board in its 360th Meeting to be held on 30-06-2026 vide letter No.F.03-26/2026-QALT-(RB-360) dated 23-06-2026.

19. Due to postponement of 360th meeting of the Registration Board, the new date i.e., 07-07-2026 was communicated to the firm vide letter No.F.03-26/2026-QALT-(RB-360) dated 29-06-2026

20. The firm had been called upon for Personal Hearing, however, no one from the firm appeared before the Board.

## 21. Proceedings and Decision of 360th meeting of Registration Board

**Division of QA & LT presented the case and apprised the Registration Board that no request of the firm for cancellation of Registration of Kemycone suspension, as noted by the panel in inspection report, has been received in PE&R Division or QA&LT Division. No one on behalf of firm appeared before the Board.**

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

i. ***Verify the Registration status of both Azofin Suspension (Reg# 020860) and Kemycone Suspension (Reg# 025623). manufactured by M/s. Alkemy Pharmaceutical (Pvt) Ltd, Hyderabad.***
ii. ***Suspend the Registration of Azofin Suspension (Reg# 020860) and Kemycone Suspension (Reg# 025623). manufactured by M/s. Alkemy Pharmaceutical (Pvt) Ltd, Hyderabad till the next meeting of the Registration Board.***
iii. ***Direct the firm to submit their request for cancellation of Registration of both products in writing to the PE&R Division under intimation to the QA&LT Division, as per report of panel.***
iv. ***Call the firm for Personal Hearing in the next meeting of the Registration Board as a final chance to be heard in person.***

**CASE NO.8: MANUFACTURE AND SALE 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)<br><br>Batch No. 2599063 | 06/2025 | 05/2027 | Sterility<br><br>**Does not comply** | KQ-9-25-000125 dated 24th October 2025<br><br>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&LT 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&LT 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&LT is given as under:

**Summary of OOS investigation submitted by Central Drugs Laboratory, Karachi:**
Federal Government Analyst, CDL Karachi has submitted OOS investigation wherein it is informed that the sample is tested in accordance with the 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. The case was presented in 356$^{th}$ Meeting of the Registration Board

**Proceedings and Decision of 356th Meeting of Registration Board**

Representative of QA&LT 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 Board 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".*

16. Accordingly, decision of the Board was communicated to the firm and area FID vide letter No.F.03-17/2026-QALT(356-RB) dated 21-04-2026.

17. Reply of Show cause notice has not been received from the firm till date.

18. The firm has been directed to appear before the Board in its 360th meeting to be held on 30-06-2026 vide letter No.F.03-26/2026-QALT-(RB-360) dated 23-06-2026

19. Due to postponement of 360th meeting of the Registration Board, the new date i.e., 07-07-2026 was communicated to the firm vide letter No.F.03-26/2026-QALT-(RB-360) dated 29-06-2026

20. The firm had been called upon for Personal Hearing before the Board.

**21. <u>Proceedings and Decision of 360th meeting of Registration Board</u>**

**Division of QA & LT presented the case before the Board. Mr. Muhammad Rashid, Head of Quality Operations, and Mr. Aqeel Ahmad, Technical Director of M/s. Vetz Pharmaceuticals (Pvt.) Ltd., Plot # Q-1, S.I.T.E Kotri, Sindh appeared before Board. They apprised the Board that they have undertaken significant improvements of the facility and processes. They also informed that since all the manufactured stock of Melovetz Injection 50ml 10mg/1ml (Reg# 102021) was not marketed and the entire stock was destroyed in the presence of area FID and the report of the same was duly submitted by them to the Board. The Board, after considering the facts of the case, and thorough deliberations, decided as follows:**

***i. To conduct a comprehensive GMP inspection of the firm with particular focus on the Sterile Products Manufacturing Area by a panel of inspectors/experts to be nominated by the Director (QA/LT).***

***ii. To direct the area FID to carry out thorough sampling of all the registered sterile products manufactured by the firm.***

**iii.** ***To continue 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 under section 42 of the Drugs Act, 1976 and rules framed thereunder, till submission of satisfactory GMP report by the nominated panel and subsequent review of the same by the Registration Board.***

**CASE NO.9: <u>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)</u>**

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<br>(Each prolong release tablet contains: Glyceryl Trinitrate 2.6mg) | M/s Linta Pharmaceuticals, Plot No. 3, Street No. S-5, National Industrial Zone (RCCI), Rawat, Islamabad | 119607 | 25H261 | Substandard on the basis of Dissolution |
| 2 | Glitric Tablet 6.4mg<br>(Each prolong release tablet contains: Glyceryl Trinitrate 6.4mg) | | 119637 | 25H262 | Substandard on the basis of Dissolution |
| 3 | Betahist Tablet 16mg<br>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&LT, 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***<br>*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.*<br>*The panel inquired detailed information on the manufacturing process and control strategy for Glitric Tablets containing G**lyceryl 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 **Gltiric 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 - 001were 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 ≤ 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±0.5°C*

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

*Limits:*

| | |
|---|---|
| *1st hour* | *NMT 50%* |
| *4th hour* | *35-80%* |
| *8th 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 6.4mg*** *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% RH) not consistently monitored; dehumidifier not present.* | *Major* |
| *12* | *Cone mixer lid taped; dust collectors missing in compression rooms, could cause cross-contamination and particulate control issues.* | *Major* |
| *13* | *Stability chambers and QC instruments present but no validated methods for new equipment* | *Minor* |
| *14* | *Storage conditions for raw materials not clearly defined; alert/action limits not set.* | *Minor* |

| ***SUMMARY*** |
|---|
| *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.*<br><br>*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.* |
| ***CONCLUSION*** |
| *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* |
| ***RECOMMENDATION*** |
| *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 interpretation.** All analytical procedures must be revalidated using authenticated reference standards/validated working standards. Similar is the case of Betahistine tablet.*<br>*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.*<br>*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)*<br>*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)*<br>*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 Attached in Annexure 1* | *CAPA OPEN (till the sample arrives)* |
| *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 OBSERVATIOAL 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 annexure 3.* | *CAPA CLOSED. (05-02-2026)* |
| *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.

10. The case was presented in the 356th meeting of the Registration Board

**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."*

11. Accordingly, decision of the Board was communicated to the firm and area FID vide letter No.F.03-17/2026-QALT(356-RB) dated 21-04-2026, wherein the firm was directed to appear before the Board in its 358th Meeting to be held on 05-05-2026.

12. However, since the said meeting was rescheduled, therefore, the firm has been directed to appear before the Board in its 360th meeting to be held on 30-06-2026 vide letter No.F.03-26/2026-QALT-(RB-360) dated 23-06-2026.

13. Due to postponement of 360th meeting of the Registration Board, the new date i.e., 07-07-2026 was communicated to the firm vide letter No.F.03-26/2026-QALT-(RB-360) dated 29-06-2026

14. The firm had been called upon for Personal Hearing before the Board.

**15. <u>Proceedings and Decision of 360th meeting of Registration Board</u>**

**Division of QA & LT presented the case before the Board. Mr. Hashim Baig, Production Incharge, and Ms. Javeria, Quality Assurance Manager of M/s Linta Pharmaceuticals, Plot No. 3, Street No. S-5, National Industrial Zone (RCCI), Rawat appeared before Board. They apprised the Board that they have submitted CAPA of the deficiencies noted by the panel during their visit on 21-01-2026. On query raised by Board, representatives of the firm apprised that QCB of GB had not yet informed them regarding the fate of their request for appellate testing of their products. The Board, after considering the facts of the case, thorough deliberations, and considering that several CAPA points still remain open, decided as follows:**

i. ***To conduct a CAPA verification inspection of the firm by a panel of inspectors/experts to be nominated by the Director (QA/LT).***
ii. ***To continue Suspension of 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 under section 42 of the Drugs Act, 1976 and rules framed thereunder, till submission of satisfactory CAPA verification report by the nominated panel and subsequent review of the same by the Registration Board.***
iii. ***To direct the Firm to inform area FID to take sample from three commercial batches of Glitric Tablet 2.6mg (Reg# 119607), Glitric Tablet 6.4mg (Reg# 119637) & Betahist Tablet 16mg (Reg# 091595), after completion of manufacturing process validation studies for the purpose of test/analysis by CDL Karachi. The sale of the product shall be subject to the standard report by the Central Drugs Laboratory, Karachi and subsequent approval by the Registration Board.***

**CASE NO.10: <u>SUBSTANDARD MAVERICK 500MG INJ., REG. NO. 065444 BATCH NO 250901, AND WAFIN INJ. (WATER FOR INJECTION) REG. NO. 066643 BATCH NO.</u>**

**250101 MANUFACTURED BY M/S CREST PHARMACEUTICALS, ISLAMABAD DML NO.000694**

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

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

***"OBSERVATIONS:***

***Premises:***

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

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

***Change rooms:***

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

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

***Production Areas:***

***Front Block/Building:***

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

*Ms Farzana Safdar, who claimed to be the production pharmacist, was present at the premises. There was no other qualified person present. Neither Production incharge available. It appeared that manufacturing operations were halted in hurry and the workers left the production*

*areas. The sections were inspected. The HVAC system was not operational at the time of inspection. In the liquid injection ampoule section, the floor (epoxy painted) is covered with hard rough plastic sheet, probably to prevent the epoxy paint from getting damage. Status of equipment/machinery were not mentioned. The Calibration tag/slip affixed to Dry Heat Sterilizer, Model/ Sr. No. PK-02, has an expiry date of 03-12-2024.*

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

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

***Back side Block/Building:***

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

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

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

***Quality Control:***

*The firm has established a separate quality control laboratory. The quality control manager Ms. Annum Malik D/o Tariq Mehmood was not present. Two inexperienced pharmacists Ms Fatima and Ms Muqaddas, graduated in 2025 were present to supervise the quality control activities. No microbiologist was available. During discussion with the analysts, it became evident that they couldnot operate the HPLC system. The UV Visible Spectrophotometer is being used for analysis of*

*drug products. No calibration record of the quality control instruments was presented at the time of inspection. No record of area monitoring was available. Chemical and Biological indicators were not available. No evidence of use of indicators (biological and chemical) in the BMR of liquid injectable products was mentioned. Log book of Liquid Particle counter was available. Critical instruments such as Total Organic Carbon, FTIR, Air sampler, Particle counter were missing in the quality control laboratory. The stability chambers were without data loggers.*

***Quality Assurance:***

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

***HVAC and Water treatment system:***

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

***Technical personnel:***

*The firm lack sufficiently qualified competent technical personnel in production, quality control, microbiology and quality assurance department.*

***LIST OF DEFICIENCIES:***

| ***S.No*** | ***Deficiencies/Non-Compliance*** | ***Classification of Deficiency Guidance Document No. QALT/GL/CG/002 Effective Date: 30-03-2023*** | ***Reference (LRA Rules including Schedule B/ Decision of RB vide No.F.313-DRB/2021 (PE&R) dated 29.12.2021/ WHO TRS)*** |
|---|---|---|---|
| *1.* | *The air curtains were non-functional. No SOPs and cleaning record of change rooms or log books were available. No gowning protocols/SOPs were being observed as workers were found roaming in production corridor in street clothes. Change rooms were not maintained.* | *Critical* | *Schedule B-II: Premises & Personnel (Change Rooms, Protective Clothing, Hygiene WHO TRS 961 Annex 6* |
| *2.* | *Neither Production in-charge nor Quality Control In-charge were present at the premises at the time of inspection.* | *Major* | *Schedule B-II: Technical Staff & Supervision WHO TRS 961 Annex 3* |
| *3.* | *The HVAC system was not operational at the time of inspection.* | *Critical* | *B-II: Premises – Environmental Control / Air Handling WHO TRS 961 Annex 6* |
| *4.* | *In the liquid injection ampoule section, the floor (epoxy painted) is covered with hard rough plastic sheet, probably to prevent the epoxy paint from getting damage. The presence of plastic sheet will make difficult to qualify the sterile formulation and filling rooms for performing sterile operations.* | *Major* | *Schedule B-II: Premises – Cleanable Surfaces WHO TRS 961 Annex 6* |

| | | | |
|---|---|---|---|
| *5.* | *Status of equipment/machinery in production areas were not mentioned.* | *Major* | *Schedule B-II: Equipment Identification & Status Labelling*<br>*WHO TRS 961 Annex 3* |
| *6.* | *The Calibration tag/slip affixed to Dry Heat Sterilizer, Model/ Sr. No. PK-02, has an expiry date of 03-12-2024.* | *Critical* | *Schedule B-II: Equipment Calibration & Maintenance*<br>*WHO TRS 961 Annex 6* |
| *7.* | *Empty capsule shells were found in the hoppers, while capsule shell carton was also found in the section, indicating that capsule filling process was stopped intentionally. while no log book of capsule filling machine was available, neither batch manufacturing record was provided, for the in-process batch at the time of inspection.* | *Critical* | *Schedule B-II: Documentation & Batch Records*<br>*WHO TRS 961 Annex 3* |
| *8.* | *The in-process stocks of various products were found placed under uncontrolled storage conditions without bearing complete identification labels/status and without manufacturing record. Such as filled unlabeled vials in SS trays were found in the dry powder filling area, without any status. Cartons having blisters of Zanxy DS (Tizanidine) found placed in bottle blowing area without any label.Wafin (WFI) ampoules, Batch No. 250101 were found placed in de-cartoning/bottle blowing area in SS buckets. Empty capsule shells cartons for Capsule Sabizole 40mg were lying in dry powder suspension filling area.* | *Critical* | *Schedule B-II: Storage, Labeling & Status Control*<br><br>*WHO TRS 961 Annex 3* |
| *9.* | *Laminar flow cabinets were found installed in the dispending rooms of general and cephalosporin sections, instead of proper dispensing booth.* | *Major* | *Schedule B-II: Premises Design for Dispensing*<br>*WHO TRS 961 Annex 3* |
| *10.* | *The inner surfaces/side of the exhaust duct mounted above the coating pan was covered with powder/residue, from previously processed batches.* | *Major* | *Schedule B-II: Sanitation & Cleaning of Premises*<br>*WHO TRS 961 Annex 3* |
| *11.* | *Calibration tags/slips were either expired or were missing on various monitoring gauges of the machinery.* | *Major* | *Schedule B-II: Calibration of Instruments*<br>*WHO TRS 961 Annex 3* |
| *12.* | *In the tablet general section, various unlabeled drums having in-process powders and tablets are found stored without proper identifications tags/slips and batch manufacturing record. The HVAC in the areas was non-operational.* | *Critical* | *Schedule B-II: Environmental Control + In-process Control* |
| *13.* | *The quality control Incharge Ms. Annum Malik D/o Tariq Mehmood was not present. The firm has employed two inexperienced pharmacists Ms Fatima and Ms Muqaddas, both graduated in 2025 were present to supervise the quality control activities, who were unable to run the HPLC system.* | *Critical* | *Schedule B-II: Qualified QC Staff & Testing Facilities*<br>*WHO TRS 961 Annex 3* |
| *14.* | *No microbiologist available, while the firm has the injectable sections (Dry powder cephalosporin, liquid ampoule* | *Critical* | *Schedule B-II: Qualified Personnel for Sterile Products* |

| | | | |
|---|---|---|---|
| | *general and dry powder vial general sections.* | | |
| *15.* | *The UV Visible Spectrophotometer is being used for analysis of most of the products drug products through non-pharmacopoeial methods.* | *Major* | *Schedule B-II: Validated Test Methods*<br>*WHO TRS 961 Annex 6* |
| *16.* | *No calibration record of the quality control instruments was presented at the time of inspection.* | *Critical* | *Schedule B-II: Calibration & Maintenance of QC Instruments* |
| *17.* | *No record of area monitoring was available.* | *Critical* | *Schedule B-II: Environmental Monitoring Program*<br>*WHO TRS 961 Annex 6* |
| *18.* | *Chemical and Biological indicators were not available.* | *Critical* | *Schedule B-II: Sterilization Controls & Indicators*<br>*WHO TRS 961 Annex 6* |
| *19.* | *No evidence of use of indicators (biological and chemical) in the BMR of liquid injectable products was mentioned.* | *Critical* | *Schedule B-II: Batch Records – Sterilization Data* |
| *20.* | *Critical instruments such as Total Organic Carbon, FTIR, Air sampler, Particle counter were missing in the quality control laboratory.* | *Critical* | *Schedule B-II: Adequate QC Facilities & Environmental Monitoring* |
| *21.* | *The stability chambers were without data loggers.* | *Major* | *Schedule B-II: Stability Studies & Environmental Control* |
| *22.* | *The firm has not established a quality assurance department, as no Quality Assurance in-charge is employed to oversee the quality assurance activities.* | *Critical* | *Schedule B-II: Quality Assurance System*<br>*WHO TRS 961 Annex 3* |
| *23.* | *No record of cleaning validation studies, Annual product quality review, vendor qualification, self-inspection, analytical method validation and verification record, qualification of dry heath sterilizer and autoclave, vendor qualification etc were available.* | *Critical* | *Schedule B-II: Validation, Self-Inspection, Vendor Qualification, APQR*<br>*P*<br>*WHO TRS 961 Annex 3;* |
| *24.* | *Validation and qualification record for HVAC & Water Treatment System was not provided.* | *Critical* | *Schedule B-II: Qualification of Critical Utilities (HVAC, WTS)*<br>*WHO TRS 961 Annex 6* |

***Conclusion & Recommendation:***

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Out of Specs Investigation*

*• We analysed the retained samples of the 005 batches and found them within USP specs. Certificate of analysis is attached.*

*• Source water was analysed and found within specification. COA attached.*

*• Area was monitored for viable and non viable particles and found within specs.*

*Scientific Justification*

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

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

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

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

*Tests like identification, assay, physical appearance and pH are done in 1-2 hours, while sterility test takes two weeks. Federal Government Analyst did not perform the tests which take less time, as depicted from reports rather he preferred to go for the test which takes two weeks. Reports do not reflects how many plates have been inoculated with each medium? Whether the analyst compared it with positive or negative control? Did he repeat the test as described in USP? Growth promotion test requires minimum 20 samples for each media (Fluid Thioglycolate and Soyabean-Casein Digestive media) i.e, 40 sample for one test and 40 samples for repeat test as desired by USP. How many samples did he receive from the FID. Did he use 80 samples in sterility test? If yes, what about the other tests?*

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

***Equipment Validation***

*Certificates Attached.*

***Growth Promotion Test***

*Certificate of Analysis attached*

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

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

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

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

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

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

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

**Technical Evaluation of OOS Investigation:**

i. Both products were declared as sub-standard by CDL with respect to Sterility
ii. CDL performed the sterility test as per USP-NF 2026.
iii. The COAs provided in the BMRs of "Maverick 500mg Injection" Batch No. 250901 and "Wafin Injection (Water for Injection)" Batch No. 250101 respectively, do not mention with which official monograph do both products comply.
iv. The firm provided BMR of both "Maverick 500mg Injection" Batch No. 250901 and "Wafin Injection (Water for Injection)" Batch No. 250101.
v. The COA of Maverick 500mg (Ceftriaxone base) includes Assay, Foreign particle, pH, Pyrogen test, and Sterility test. However, according to the inspection report of the area FID, conducted on 28-01-2026, the firm does not have a microbiologist. The Quality Control In-Charge employed by the firm is daughter of the owner and was absent on the day of inspection. During the visit of FID, two analysts were present who were both fresh pharmacy graduates of 2025.
vi. The firm provided Growth Promotion Test (GPT) of Fluid Thioglycollate Medium (FTM) and Soybean–Casein Digest Medium conducted from 03-04-2026 to 17-04-2026 claimed to be performed in accordance with USP 2025 on retained samples whereas review of the GPT showed that the firm had not complied with USP 2025 Chapter <71>.
vii. The absence of Microbiologist further raises doubts concerning the availability of appropriate provisions such as ATCC strains for Area Monitoring and Quality Control Testing of the sterile products as well as BET kits as the COA only mentions that the product is pyrogen-free.
viii. The firm has failed to provide the validation or calibration certificates of the relevant equipment i.e., Autoclave and Dry Heat Sterilizer (DHS).
ix. The COA of bulk Purified Water and Bulk WFI provided by the firm states that it complies USP 35 specs whereas, in 2025 when bulk purified & bulk WFI were produced, USP 2025 i.e., USP 48 was in effect. Consequently, the firm was producing bulk purified & bulk WFI which was neither in compliance with official USP nor BP in terms of conductivity and TOC.
x. The firm released bulk purified for use without conducting microbial content & bulk WFI for use without conducting Bacterial Endotoxin Test (BET).
xi. The Sterilization technique being used to produce WFI (product) was membrane filtration followed by aseptic filling without a scientific rationale.
xii. The correct limit of conductivity in accordance with USP monograph for WFI is not mentioned on the COA of Wafin Injection (Water for Injection).
xiii. Media-fill trials have not been provided by the firm considering the fact that both substandard products were being aseptically manufactured.
xiv. CDL, Karachi has provided complete OOS investigation of both substandard products.

13. The case was presented in 359th meeting of the Registration Board.

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

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

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

14. Accordingly, the decision of the Registration Board was communicated to the firm vide letter No.F.03-29/2026-QALT(359-RB) dated 01-07-2026.

15. The firm had been called upon for Personal Hearing before the Board.

**16. Proceedings and Decision of 360th meeting of Registration Board**

**Division of QA & LT presented the case before the Board. Mr. Tariq Mehmood, CEO/Director, and Mr. Amar, Director of M/s. Crest Pharmaceuticals, Plot No. 43, Industrial Triangle, Kahuta Road, Islamabad appeared before Board. They apprised the Board that they**

**have hired the Microbiologist. The Board, after considering the facts of the case, thorough deliberations, and considering that the firm has not yet submitted CAPA of the deficiencies noted in the inspection report of the area FID , decided as follows:**

i. ***To direct the firm to submit a thorough Root Cause Analysis and CAPA of the deficiencies observed by the area FID in the inspection report conducted on 28-01-2026.***
ii. ***To Suspend the Registration of Maverick 500mg Injection (Reg# 065444) and Wafin Injection (Water for Injection) (Reg# 066643) manufactured by M/s. Crest Pharmaceuticals, Plot No. 43, Industrial Triangle, Kahuta Road, Islamabad under section 42 of the Drugs Act, 1976 and rules framed thereunder, till submission of satisfactory CAPA verification report by the nominated panel and subsequent review of the same by the Registration Board.***
iii. ***To conduct a CAPA verification inspection of the firm by a panel of inspectors/experts to be nominated by the Director (QA/LT) subsequent to submission of CAPA by the firm.***
iv. ***To direct the firm to inform area FID to take sample from three commercial batches of Maverick 500mg Injection (Reg# 065444) and Wafin Injection (Water for Injection) (Reg# 066643) after completion of manufacturing process validation studies for the purpose of test/analysis by CDL Karachi. The sale of the product shall be subject to the standard report by the Central Drugs Laboratory, Karachi and subsequent approval by the Registration Board.***

**Case No.11: MANUFACTURE AND SALE OF SUB-STANDARD INJECTION CARA-DOBA 5ML (DOBUTAMINE 250MG/5ML) AND INJ A-CARE (ATRACURIUM) 50MG/5ML MANUFACTURED BY M/S. CARAWAY PHARMACEUTICALS PLOT NO. 12 STREET NO. N-3 NATIONAL INDUSTRIAL ZONE (RCCI) RAWAT, ISLAMABAD DML NO. 000629)**

A Therapeutic Good Related Problem Report No. 2165 dated 02-12-2025, reported by Pharmacovigilance Officer, Services Hospital, Lahore, had been forwarded to Drug Regulatory Authority of Pakistan by the Director, Pharmacy & Pharmacovigilance, Directorate of Drugs Control, Punjab letter No. PPC/QI-2/2022 (P-III) dated 09-12-2025.

2. The said TGRP pertains to a product quality issue that is dark brown discoloration and crystallization observed in Inj. Cara-Doba (Dobutamine HCl 250mg/5ml), Batch Nos. 25E004 and 24J009 manufactured by M/s Caraway Pharmaceuticals, National Industrial Zone (RCCI), Rawat, Islamabad.

3. Drugs Testing Laboratory of Punjab also declared the above mentioned batches of Inj. Cara-Doba as of "Substandard" Quality details are reproduced below:

| Name of Product | Manufactured by | Reg. No. | Batch No. | DTL, Punjab Report |
|---|---|---|---|---|
| Inj. Cara-Doba (Dobutamine HCl 250mg/5ml) | M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI), Rawat, Islamabad | 054987 | 25E004 and 24J009 | **Batch 24J009** the sample has been declared Sub-Standard on the basis of Physical description and visible particulates **Batch 25E005** The color has been changed to Dark Brown with Crystallization (Sub-Standard on the basis of Physical description and visible particulates) |

4. The Director, Pharmacy & Pharmacovigilance, Directorate of Drugs Control, Punjab had desired that a detailed Product Specific Inspection of the firm M/s Caraway Pharmaceutical, may be conducted.

5. Consequently, DRAP Alert No. N$^{0}$I/S12-25-126 was issued on 30$^{th}$ December 2025. Additionally, as per directions of the Director, QA & LT Division, FID-I, Islamabad on 24-12-2025 and 31-12-2025 conducted the Product Specific Inspection of the firm M/s Caraway Pharmaceuticals, Rawat. The critical and major deficiencies noted during inspection are being reproduced below:

"***Critical observations/deficiencies:***

*1. Brown discoloration was observed in finished batch of Cara-Doba (Dobutamine HCl) injection; however, the firm failed to adequately assess, investigate and control this critical quality defect in a timely manner. This critical quality attribute may adversely affect the quality, safety and efficacy of the product.*

*2. Discrepancy was observed in the BMR of Inj. Cara-Doba 250mg/5ml, as the autoclaving time for terminal sterilization of filled ampoules was recorded as 02 hours, which differs from the validated and/or recommended sterilization cycle parameters (30 mints at 121 $^{0}$C). Furthermore, the batch manufacturing records did not contain recorded sterilization temperature. In the absence of complete and accurate sterilization cycle records, the firm is unable to demonstrate that filled ampoules of Dobutamine injection were not exposed to excessive thermal stress, which may have contributed to degradation and discoloration of the product. Moreover, the QA failed to effectively review the BMR, before release of drug product to the market.*

*3. It was observed that a single batch of Cara-Doba 250mg/5ml injection (24E004) was subjected to terminal sterilization in two separate autoclave loads due to limited autoclave capacity. However, the firm failed to provide adequate documented justification, risk assessment and validated controls to demonstrate that both sterilization cycles were equivalent and performed within validated parameters. The*

*firm was unable to demonstrate uniformity of sterilization conditions and thermal exposure across the entire batch. Variability in thermal exposure may have contributed to degradation and discoloration of the defective product.*

*4. The investigation (Customer Complaint Report) initiated for brown discoloration of Dobutamine injection was superficial and did not establish a scientifically justified root cause. The investigation failed to consider oxidation, formulation sensitivity and oxygen exposure during manufacturing.*

***Major Deficiencies/Observations:***

*1. The firm's stability studies did not sufficiently evaluate Photo-stability and oxidation-related degradation and stability data did not support the claimed shelf life. The firm failed to provide adequate evidence demonstrating that the container provides protection against light and oxygen ingress for Dobutamine injection throughout its shelf life.*

*2. It was observed that nitrogen gas used for purging during the manufacture of Dobutamine injection was not adequately controlled. The firm relied solely on the Certificate of Analysis (CoA) provided by the gas supplier/manufacturer without performing vendor qualification. Furthermore, no in-house testing of nitrogen gas quality was conducted and the firm lacked facilities and procedures for verification of critical quality attributes of nitrogen*

*gas prior to use. Resultantly, Oxygen content, moisture or impurities in nitrogen gas are not verified that may cause ineffective purging that directly increases the risk of oxidation of Dobutamine, leading to discoloration.*

*3. As per the firm's approved SOP for vendor qualification, qualification of API suppliers/manufacturers is required to be conducted on a documentation basis. However, during the inspection, the firm failed to provide complete vendor qualification data for the supplier/manufacturer of Dobutamine API. The firm was therefore unable to demonstrate that the API supplier had been appropriately evaluated and approved prior to use.*

*4. It was observed that the firm failed to present vendor qualification records and supporting data for the supplier/manufacturer of the primary packaging material (glass ampoules) used for Dobutamine injection. The firm was therefore unable to demonstrate that the ampoule supplier had been appropriately evaluated, approved and monitored in accordance with established procedures prior to use. Therefore, in the absence of documented qualification of the ampoule supplier, the firm cannot demonstrate that the primary packaging material is suitable for use with an oxidation-sensitive injectable product such as Dobutamine injection, which may have contributed to the observed discoloration.*

*5. It was observed that a silicone pipe/tubing was used for the transfer of Dobutamine injection solution from the manufacturing vessel to a Pyrex glass flask. However, the firm failed to provide documented evidence of qualification, material compatibility, extractables/leachables studies and cleaning validation for the silicone tubing used as product-contact equipment. The firm was therefore unable to demonstrate that the silicone transfer tubing was suitable for use with an oxidation-sensitive sterile injectable product. In the absence of qualification and compatibility studies for silicone transfer tubing, the firm cannot rule out the possibility of extractables or interaction with the product, which may have contributed to degradation and discoloration of Cara-Doba injection.*

***Conclusion & Recommendation**:*

*A Product Specific Inspection (PSI) was conducted following receipt of a critical quality complaint regarding brown discoloration in Inj. Cara-Doba (Dobutamine HCl), 250mg/5ml, Batch No. 24E004, a life-saving sterile injectable product. The inspection revealed multiple critical and major GMP deficiencies recorded above, that directly and indirectly impacting product quality, sterility assurance and chemical stability.*

*Based upon the recorded major and critical GMP deficiencies, it is recommended that the registration of the drug product Inj. Cara-Doba (Dobutamine HCl) 250mg/5ml, Registration No. 054987 of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI), Rawat, Islamabad, be **suspended** with immediate effect due to failure to ensure consistent quality, safety and efficacy of the product. The firm may be directed to conduct a comprehensive, scientifically justified investigation, implement effective CAPAs, reassess formulation, manufacturing controls, container integrity and stability studies."*

6. Consequently, A Show Cause and Personal Hearing Notice vide No.F.03-01/2026-DD(QALT)-VI dated 2nd January 2026 was issued to the firm they had failed to ensure consistent quality, safety and efficacy of the product and have violated section 23(1)(a)(v) of the Drug Act 1976, read with Schedule-II of the DRAP Act 2012 and the rules made there under 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.

7. The case Submitted for consideration in 353rd meeting of the Registration Board for Suspension of Registration.

**Proceedings and Decision of 353rd Meeting of Registration Board**

In compliance to the show cause notice and personal hearing letter issued, Mr. Umer Farooq Managing Director, Mr. Murad Head of Quality Operations and Mr. Noman Masood Incharge of Sterile Manufacturing area of M/s. Caraway Pharmaceuticals, Islamabad appeared before Board. They submitted before the Board that they had voluntarily initiated recall of their product after TGRP reported by Pharmacovigilance Officer, Services Hospital, Lahore on 02-12-2025, except the quantity that was part of Government supply which is being held at the institute from where the report had been initiated as per Punjab Government policy. Furthermore, the firm stated that the problem might have occurred during transportation in hot and humid months as the stock retained at the factory premises did not show discoloration or crystallization. The firm also added that they had taken several GMP upgradation measures and have undertaken CAPA but admitted that they did not arrive at a definitive Root Cause. It is pertinent to mention that the reply of the firm received in QA&LT did not have any supporting evidences but had rather provided only the statement reproduced above:

The Board after considering the facts of the case, to ensure availability of this life saving drug and after thorough deliberations decided as follows:

i. ***"To conduct PSI of the liquid sterile manufacturing facility of M/s Caraway Pharmaceuticals, Islamabad in light of report of FID-I, Islamabad including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT***
ii. ***The firm shall reduce the batch size, as per available capacity".***

8. The decision of the Registration Board was communicated to the firm vide letter F.No.03-02/2026-QALT(353-RB) dated 11-02-2026 wherein the director QA&LT had constituted the following panel for conducting PSI of the firm:

i.Mr. ZiaUllah Area Federal Inspector of Drugs, DRAP, Islamabad
ii.Mr. Malik Muhammad Asad, Deputy Director QA&LT, DRAP. Islamabad

9. The panel inspected the firm on 07-04-2026 and submitted the following report:

***"HISTORY:***

*1. Grant of DML No.000629 dated 19.06.2008 vide Licensing Division letter No.F.1-9/2004-Lic dated 20.06.2008.*
*2. Grant of additional section(s): Liquid Syrup (General) and Tablet Section (Psychotropic) approved vide letter No.F.1-9/2004-Lic (Vol-II) dated 04th July, 2022.*
*3. Renewal of DML: Renewal of Drug Manufacturing License granted on 04th July, 2022.*
*1.2 Brief History of Last Inspection:*

*a. Last inspection of the firm:*

*i. Conducted on 24-12-2025 & 31-12-2025 for the purpose of investigating a quality issue that is discoloration was observed in Inj. Cara-Doba (Dobutamine HCl 250mg/5ml), Batch No. 25E004 by Pharmacovigilance Officer, Services Hospital, Lahore (Therapeutic Good Related Problem Report No. 2165 dated 02-12-2025) and*

*forwarded/reported vide letter No. PPC/QI-2/2022 (P-III) dated 09-12-2025 by Director, Pharmacy & Pharmacovigilance, Directorate of Drugs Control, Punjab letter No. PPC/QI-2/2022 (P-III) dated 09-12-2025. Accordingly, The Product-Specific Inspection (PSI) of Inj. Cara-doba (Dobutamine HCl, 250mg/5ml), Batch No. 25E004 was initiated as per directions of the Director, QA & LT Division, DRAP, Islamabad.*

*ii. The panel of inspectors recommended as:*

*"Based upon the recorded major and critical GMP deficiencies, it is recommended that the registration of the drug product Inj. Cara-Doba (Dobutamine HCl) 250mg/5ml, registration No. 054987 of M/s Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI), Rawat, Islamabad, be suspended with immediate effect due to failure to ensure consistent quality, safety and efficacy of the product. The firm may be directed to conduct a comprehensive, scientifically justified investigation, implement effective CAPAs, reassess formulation, manufacturing controls, container integrity and stability studies".*

*iii. Action taken by the QA&LT and/or any other relevant Division (if any):*

*The case along with recommendations of area FID was presented before the Registration Board in its 353rd meeting. The Board after considering the facts of the case, to ensure availability of this life saving drug and after thorough deliberations decided as follows:*

*•"To conduct PSI of the liquid sterile manufacturing facility of M/s Caraway Pharmaceuticals, Islamabad in light of report of FID-I, Islamabad including verification of RCA and CAPA by panel of inspectors/experts to be nominated by Director QA/LT.*

*•The firm shall reduce the batch size, as per available capacity".*

*b. Brief description of the areas mentioned below (if any):*

*i. Status of last CAPA and actions taken by QA section:*

*CAPA submitted by the firm pursuance to the observations/recommendations made in the inspection report dated 24-12-2025 & 31-12-2025. The Director, QA & LT Division constituted panel for conduction of PSI including verification of RCA and CAPA as per decision of the Registration Board in its 353rd meeting.*

*ii. Major Changes undertaken by the firm since last inspection*

*•Reduction of batch size to align with autoclave capacity.*
*•Recording (digital) of sterilization cycle of autoclave.*
*•Purchase of oxygen sensor analyzer.*
*•Replacement of silicone pipe/tubing with a platinum-cured/medical grade silicon tube for transferring of solution to filling line.*
*•Retrospective Vendor qualification of glass ampoules supplier.*

*iii. Product Quality Defects/Out of Specifications Reported by National Quality Control Laboratories/ Drug Testing Laboratories and/or subsequent Appellate testing.*

*•Inj. Cara-Fer (Iron Sucrose) 100mg/5ml declared substandard by DTL, Rawalpindi vide TRA No. 01-74014540 dated 13th September, 2025. Several TGRPs reports associated with Inj. Cara-Fer (Iron Sucrose 100mg/5ml), Batch No. 24G001 were also reported by the Directorate of Drugs Control Punjab (DDCP)*
*•Brown discoloration in Inj. Cara-Doba (Dobutamine HCl 250mg/5ml), Batch No. 25E004 reported by Director, Pharmacy & Pharmacovigilance, Directorate of Drugs Control, while Batch No. 24J009 of the same product declared Sub-Standard, on the basis of Physical Description and Visible Particulates.*
*•Inj. Cara-Doba (Dobutamine HCl 250mg/5ml), Batch No. 25E004 was declared substandard by DTL Punjab, Lahore on the basis of physical description and visible particulate matter tests.*
*•Inj. Cara-Doba (Dobutamine HCl 250mg/5ml), Batch No. 26A037 was declared substandard by DTL Punjab, Bahawalpur on the basis of visible particulates in Injection and Assay Test.*

*iv. Other Regulatory Action taken by statutory Board (Registration Board, CLB, PQCB, Appellate Board etc) during the past one year.*

*v. Product Recall(s) (voluntary or regulatory):*

*A number of recalls (both voluntary and regulatory) were made.*

***1.2.1. List of Approved Sections***

*i. Tablet Section (General)*
*ii. Tablet Section (Antibiotic)*
*iii. Tablet (Psychotropic) Section*
*iv. Capsule Section (General)*
*v. Semisolids Cream/Ointment/Gel Section (General)*
*vi. Semisolids Cream/Ointment/Gel Section (Steroidal)*
*vii. Liquid Syrup (General)*
*viii. Oral Dry Powder Suspension (General) Section.*
*ix. Liquid Ampoule Section (Injectable).*
*x. Dry Powder for Injection (Cephalosporin) Section.*
*xi. Oral Dry Powder for Suspension (Cephalosporin) Section.*
*xii. Capsule (Cephalosporin) Section.*
*xiii. Lotion (Medicated)*

***2. OBSERVATIONS:***

*The proceedings/findings of inspection are recorded as follow:*
*Mr. Umar Farooq, Managing Director, Mr. Murad Ali, Quality Control Manager, Quality Assurance (Injectable sections), along with other technical personnel from production and quality control accompanied during inspection.*

*The details of observations and respective corrective and preventive actions performed by the firm are given as follow;*

***3. <u>RCA & CAPA DETAILS</u>***

| ***S.No*** | ***Deficiencies/Non-Compliance*** | ***Root Cause Analysis*** | ***Corrective and Preventive Action Plan*** | ***Evidence of compliance*** |
|---|---|---|---|---|
| *1.* | *Brown discoloration was observed in Inj. Cara-Doba (Dobutamine HCl) injection, Batch No. 25E004. However, the firm failed to adequately assess, investigate and control this critical quality defect in a timely manner. This may adversely affect the quality, safety and efficacy of the product.* | *Previous SOP (CP/QAD/SOP/004) for complaint was only limited to SMP/Deviation. SOP has been revised and risk assessment of valid complaint added in procedure to assess, investigate and control the critical quality defect in a timely manner.* | *i. SOP (CP/QAD/SOP/004) for complaint has been revised with addition of risk assessment of valid complaint and multi-disciplinary personnel involvement.*<br>*ii. issue stop-use alert for affected batch (and any confirmed impacted stock)*<br>*iii. Execute batch recall/ market withdrawal, notify distributer hospitals*<br>*iv Recall effectiveness check (document % recovered, customers contracted)*<br>*v. Quarantine remixing FG/WIP/Returns for affected batch*<br>*vi. Open deviation / complaint record, assign investigation number* | *i. Revised SOP of Complaint (CP/QAD/SOP/004) and Training*<br>*ii. Voluntarily Recall*<br>*iii. Stop Use notification*<br>*iv. Market Complaint*<br>*v. Recall effectives* |
| *2.* | ***a.*** *Discrepancy in BMR regarding terminal* | *a). The discrepancy in sterilization* | *i.Immediate reduction of batch size to align with* | *i. FO (Lethal) Study*<br>*ii. Assessment of Load to* |

| | | | | |
|---|---|---|---|---|
| | *sterilization time (02 hours recorded vs validated 30 minutes at 121°C) and absence of recorded sterilization temperature. QA failed to effectively review the BMR prior to batch release. Incomplete and inaccurate sterilization records prevent demonstration of process control. Excessive or uncontrolled thermal exposure may contribute to degradation and discoloration.*<br><br>***b.*** *A single batch was terminally sterilized in two separate autoclave loads without documented justification, risk assessment, or validation demonstrating equivalence of cycles. Lack of validated equivalence and uniform thermal exposure may result in product degradation and non-uniform quality across the batch.* | *temperature records was due to a documentation error within the Batch Manufacturing Record (BMR), likely arising from manual data entry or typographical mistakes. Actual autoclave cycle was correct (30 min at 121°C). It can be verified through autoclave log book and chemical indicators log book of microbiology.*<br>*b) in house and third party validation of autoclave and risk assessment were already executed prior to batch sterilization as per routine SOP. Data verification evidence also available in autoclave and microbiology log books. However, digital temperature recording of both loads through data logger and print outs was not available at that time* | *autoclave capacity (one batch–one sterilization cycle)*<br>*ii. Implementation of interim two-person verification of QA about exposure time and temperature*<br>*iii. Define and enforce standard autoclave pattern*<br>*iv. Print out of data log during sterilization period of autoclave*<br>*v. Validation of Autoclave* | *Load variability*<br>*iii. Revised BMR*<br>*iv. Training Record*<br>*v. Third Party Validation*<br>*vi. Autoclave Log Book.*<br>*vii. Autoclave Load Capacity*<br>*viii. Batch Scale down documentation (BMR)*<br>*ix. Risk assessment of Autoclave"*<br>*x. Process Validation of Cara-Doba inj (PVR/026/001* |
| *3.* | *Investigation of discoloration (Customer Complaint Report) was superficial and failed to establish a scientifically justified root cause, including evaluation of oxidation and oxygen exposure.*<br>*Inadequate investigation of a critical defect indicates failure of CAPA and Quality Risk Management systems, with continued risk to patient safety.* | *Initial investigation focused only on immediate observations and recall assessment and immediate containment of batch. all commercial supplied were successfully recalled and stop usage letter to public hospital was immediately delivered.*<br>*Oxidation and formulation sensitivity were subsequently ruled out by controlled studies showing no discoloration under* | *i. Re-investigation of the Complaint with Scientific Depth using FMEA framework as per PICs guidelines*<br>*ii.Risk Assessment for Oxidation-Prone Products*<br>*iii. Strengthening of Oxygen Control Measures*<br>*iv. Risk assessments about various factors that can affect the integrity of products were going on and risk factors highlighted during risk assessment exercise are mitigated.* | *i. Risk Assessment of Silicon Pipe*<br>*ii. Risk assessment Nitrogen Purging* |

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| | | *correct thermal conditions with same oxygen exposure.* | | |
| *4.* | *Dobutamine is light- and oxygen-sensitive. The firm's stability studies did not sufficiently evaluate photo-stability related degradation. The data did not support the claimed shelf life.* | *Photostability stability studies are not required since risk of photo sensitivity is already being minimized by usage of amber colour glass ampule.* | *i. Amber colored Ampoules are used*<br>*ii. Risk Assessment has been done to identify loop holes* | *i. Stability Studies protocol*<br>*ii. Risk assessment of Stability* |
| *5.* | *Nitrogen gas used for purging during manufacture was not adequatelycontrolled.*<br>*The firm relied solely on the supplier's Certificate of Analysis without vendor qualification or in-house testing. Oxygen content, moisture, or impurities in the gas were not verified, increasing the risk of oxidation* | *Vendor qualification program was limited to documents and COA, in house external verification was not conducted. Third party verification of Nitrogen purity from vendor was provided by vendor.*<br>*Retrospective testing of retained nitrogen samples confirmed purity met standards. No actual contamination — gap is procedural.* | *i. Oxygen sensor analyzer procured*<br>*ii. Nitrogen SOP has been updated*<br>*iii. vendor qualification and in house testing to be strengthened.* | *i. Oxygen sensor SOP (CP/QCD/SOP/078)*<br>*ii. Nitrogen Risk Assessment*<br>*iii. Oxygen Analyzer Report*<br>*iv. Testing Record of Oxygen Percentage in Nitrogen Gas Log Book and training of SOPs conducted* |
| *6.* | *The firm failed to provide complete vendor qualification data for the supplier of the dobutamine Active Pharmaceutical Ingredient (API), as required by its own SOP.* | *API quality verified by incoming testing all batches meet specifications. API lots are also cross verified by Primary USP reference standard.* | *Completion of Vendor Qualification for Dobutamine API Supplier*<br>*ii Risk Assessment of API Quality Impact*<br>*iii Strengthening of Vendor Qualification SOP Compliance* | *i. Vendor Risk Assessment*<br>*ii. Vendor Qualification* |
| *7.* | *The firm failed to present vendor qualification records for the supplier of the primary packaging material (glass ampoules). This failure means suitability for an oxidation-sensitive product cannot be demonstrated.* | *vendor qualification program was limited to documentary evidence only.*<br>*Ampules used for particular batch complied with USP type 1 specification based on internal testing.* | *i. Retrospective Vendor Qualification of Ampoule quality as per ISO 9187 Standards*<br>*ii. Physical phycial audit is made mandatory and SOP updated.* | *i. Vendor Risk Assessment*<br>*ii. Vendor Qualification.*<br>*iii. Physical verification conducted.*<br>*iv. ISO standard of Ampoule* |
| *8.* | *A silicone pipe/tubing was used for transferring the solution, but the firm failed to provide documented evidence of its qualification, material compatibility, extractable/leachable studies, or cleaning* | *i. Pharmaceutical-grade silicone tubing was used.*<br>*ii. Qualification tests were performed but not documented.*<br>*iii. No leachable can be produced due to usage of qualified inert silicon tube* | *i. Pharmaceutical-grade material (platinum-cured / medical grade) purchased.*<br>*ii. Vendor qualification done*<br>*iii. Non-reactive and inert material will be used.* | *i. Risk assessment of Silicon Tube*<br>*ii. Silicon Pip USE SOP (CP/PD/IPD/SOP/021) With Training*<br>*iii. IQ, OQ, PQ of Silicon Pipe* |

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| | *validation. The suitability of this product-contact equipment for a sensitive sterile injectable could not be demonstrated.* | *only.* | | |

***SUMMARY***

*During inspection, the panel thoroughly examined the RCA and CAPA undertaken by the firm regarding the quality defect (discoloration, crystallization/precipitation) observed in Inj. Cara-Doba (Dobutamine HCl). The comparison between previous observations and existing rectifications status are tabulated above. The relevant documentation was reviewed as well. In light of the observations made during the last PSI, the firm has made several improvements with documentary evidences, that could possibly affect the manufacturing, sterilization, stability, oxidation and quality of the finished product. These measures have been discussed in details in above sections. The firm informed that they intend to revise their current formulation of Inj. Cara-Doba (Dobutamine HCl) 250mg/5ml and formulation development/revision has been initiated and stability studies for the trial batches are under way. The firm intend to adopt the new formulation once the stability and relevant validations studies are successfully completed.*

***CONCLUSION & RECOMMENDATION***

*The firm has undertaken several measures to further improve the existing manufacturing and quality control facilities of their liquid ampoule drug products. Adequate facilities and control measures are in place as per GMP requirements for manufacturing of injectable ampoule preparations. However, based upon the RCA and CAPA regarding the product Inj. Cara-Doba (Dobutamine HCl), discussions made with the technical team of the firm, the in-process product development/formulation revision studies of the Inj. Cara-Doba (Dobutamine HCl), the substandard report (visible particulates/precipitates/aggregates) of a new batch of Inj. Cara-Doba (Dobutamine HCl), Batch No. 26A037 received from the DDC, Punjab as well as the written statement submitted by the firm regarding volunteer stoppage of production of Inj. Cara-Doba (Dobutamine HCl) till completion of product development, process validation and stability studies, it is concluded that since quality issues are being reported repeatedly for the product Inj. Cara-Doba (Dobutamine HCl), possibly due to unstable formulation, the firm need to complete the stability studies, process validation and submit the data for evaluation/verification by the Registration Board.*

*Therefore, based upon the above stated facts and volunteer stoppage of production by the firm, the firm may be directed not to resume the production of Inj. Cara-Doba (Dobutamine HCl) 250mg/5ml, registration No. 054987 till completion of formulation development, stability studies and validation studies and their subsequent verification through panel constituted by the Drug Registration Board.*"

10. Subsequently, the following communication was received from the office of the Director General Directorate of Drugs, Control Punjab, Lahore vide letter No.PPC/PPVC-1-1/2022(P-I) dated 04th June 2026:

*"With reference to this office's earlier communications bearing Nos, PPC/QI-2/2022(P-II) & PPC/Ql-2/2022(P-III), dated 11.08.2025 & 09.12.2025 respectively, and the decisions passed in the 18th Punjab PPVC meeting held on 22.04.2026 under the convenorship of the undersigned.*

*2. It is informed that the Provincial Pharmacovigilance Centre, Punjab, has received 02 Therapeutic Goods Related Problem Reports via Medicine Surveillance System from the Pharmacovigilance Officers, Services Hospital, Lahore & Ch. Pervaiz Elahi Institute of Cardiology, Multan; pertaining to a product quality issue i.e., discoloration observed in Inj. Cara-Doba (Dobutamine-HCl) 250 mg/5 mL, Batch No. 25E004 &24J009, manufactured by*

*M/s Caraway Pharmaceuticals. In view of the aforementioned quality concerns, this office had accordingly requested the DRAP for a Product Specific Inspection (PSI) of M/s Caraway Pharmaceuticals, Plot 12, St. N-3, National Industrial Zone (RCCI), Rawat, Islamabad.*
*3. Subsequently, the PSI was conducted on 24.12.2025 & 31.12.2025 during which the Federal*
*Inspector of Drugs-I (FID-I) noted critical deficiencies directly impacting Product quality, sterility assurance and chemical stability, and considering the nature of the product as a life-saving injectable. Consequently, a show cause notice had been issued to the firm M/s Caraway Pharmaceuticals by the QA&LT Division. DRAP Islamabad, before Suspension/Cancellation of registration of product Inj. Cara-Doba (Dobutamine HCI) 250mg/5ml, Registration No. 054987. The matter was subsequently placed before the 353rd Meeting of the Registration Board, DRAP which, after thorough deliberations and taking into account the drugs life-saving nature, resolved to; conduct the PSI of the liquid sterile manufacturing facility of M/s Caraway Pharmaceuticals, in light of the report of FID-I. Islamabad including verification of RCA and CAPA by the panel of inspectors/experts to be nominated by Director QA&LT, DRAP; and the firm shall reduce the batch size, as per available capacity.*
*4. The aforesaid decision of the Registration Board, DRAP was presented before the Punjab PPVC in its 18th Meeting. The Committee underscored that the product is critical in nature being a life-saving Injectable; and the matter is under purview of the Registration Board, DRAP; and took into account that at the same time, the product is inconsistently being produced by the firm that is continuously being distributed in health facilities and open markets. The Committee recommended that the said case must again be forwarded to the Registration Board, DR4P, with the proposal for suspension/cancellation of registration of the product Inj. Cara-Doba (Dobutamine) in view of the fact that, multiple batches (24J009,25E004, 26A034, 26A037 & 25J016 of Inj. Cara-Doba have been declared "substandard" by DTLs Punjab on the basis of physical and visible particles. The Committee also recommended to halt the production of the said product until dispensation of the decision of the Registration Board, DRAP. The DTL reports pertaining to the aforementioned batches had already been shared with DRAP via rartg@dra.gov.pk.*

*5. In view of the foregoing, it is deemed appropriate that immediate and appropriate regulatory action may be taken in the best public interest, and this office be apprised of any action taken or progress made on the subject case, for onward placement before the Punjab PPVC."*

11. Simultaneously, the Registration Board also received Recommendations from Secretary, Pharmacovigilance Risk Assessment Expert Committee (PRAEC) in the light of Decisions of its 6th meeting held on 31st December, 2025 which are being reproduced below:

*I. DOMESTIC CASES*

***i. Request for Review of Drug Formulation and Comparative Clinical Assessment of Inj A-Care (Atracurium) 50mg/5ml.***

***Decision:***

*The PRAEC deliberated on the matter at length. The Pharmacovigilance (PV) Focal Person from Punjab and the Director General, Directorate of Drug Control, Punjab, Mr. Muhammad Sohail, attended the meeting via Zoom and provided a detailed presentation of the case.*

*The Committee was informed that the complaint pertained to a lack of efficacy of the product. However, the referred case lacked essential information, including detailed adverse event reports (lack of efficacy) of the affected patients, which is necessary to establish causality. It was noted that the Individual Case Safety Reports (ICSRs) associated with this matter may be obtained by the Punjab Pharmacovigilance Centre for a comprehensive assessment of the case series.*

*The Committee further decided to refer the matter to the Registration Board for appropriate regulatory action to ascertain the efficacy of A-Care manufactured by M/s Caraway Pharmaceuticals,*

*and to prospectively consider similar issues related to other High Alert Medicines. Furthermore, the committee also recommended to the Registration Board to conduct Product Specific Inspection (PSI) of the firm, including its storage area.*

*Proceedings of 358th Meeting:*

*Mr. Abdul Mateen, Secretary PRAEC, DRAP attended the meeting and apprised the Board regarding background of the above-mentioned cases. During deliberation on 'Domestic Cases', the Board noted that the referred case lacks essential information which is necessary to establish causality and linkage with "Inj A-Care (Atracurium) 50mg/5ml" of M/s Caraway, Rawat. However, Director DTL, Bahawalpur (Member RB) highlighted that DTL Bahawalpur has received and declared a few samples as sub-standard of M/s Caraway, Rawat including drugs used in critical care. Therefore, keeping in view the recommendation received from PRAEC, a detailed inspection shall be conducted, specifically for injectable products of M/s Caraway Pharmaceuticals, Rawat.*

***Decision of 358th Meeting of the Board:***

**Registration Board has inter-alia decided as under:**

***i. With respect to Item No. I (i.e., Domestic Cases), a detailed inspection to the extent of 'Injectable products' of M/s. Caraway shall be conducted by a panel comprising of Director DTL, Bahawalpur and one member from, DRAP to be nominated by the Chairman, Registration Board.***

12. Consequently, the decision of the Board was communicated vide letter No. F.3-612026-Reg-l (M-358) dated 30-06-2026, wherein, the following panel was constituted by the Registration Board:

a. Mr. Asad Abrar, Director DTL, Bahawalpur.
b. Mr. Adil Saeed, DD PE&R Division DRAP, Islamabad

**13. Proceedings and Decision of 360th meeting of Registration Board**

**Division of QA & LT presented the case before the Board. The members of the Board were of the opinion that there should be an odd number of inspectors/experts in the panel. The Board, after considering the facts of the case, thorough deliberations, decided to reconstitute the following panel to conduct comprehensive GMP of sterile manufacturing area and testing facilities of M/s Caraway Pharmaceuticals, Islamabad:**

***i.*** **Mr. Ijaz Alvi, Director DTL, Rawalpindi.**
***ii.*** **Mr. Adil Saeed, Deputy Director PE&R Division DRAP, Islamabad**
***iii.*** **Mr. Hafiz Sanaullah Babar Deputy Director QA&LT Division DRAP, Islamabad**

**The panel shall conduct the inspection within one month w.e.f date of meeting of the Board. Mr. Sanaullah Babar shall coordinate the inspection. Matter shall be processed before finalization of minutes of the meeting.**

# Drug Regulatory Authority of Pakistan

## (Pharmaceutical Evaluation & Registration Division)

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## Registration Board 360 Meeting Minutes:

| Sr. No | Title | Description |
|---|---|---|
| 1 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WBB-MTM-BMME, 2026-06-22) |
| | Detail of Fee Submitted | 38700,<br>2026-05-20, |
| | The proposed proprietary name / brand name | **TIRZEE - 4 Solution for Injection 12.5mg/0.6mL in Multi-dose Pre-filled Pen** |
| | Label Claim | Each 0.6mL Pre-filled Pen contains: Tirzepatide ... 12.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Store in a refrigerator at 2°C-8°C. |
| | For generic drugs (me-too Status) | Mounjaro KwikPen (Tirzepatide) 12.5mg/0.6ml PFP by M/s Eli Lilly Pakistan (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | - |
| | Detail of stability batches of drug product | Stability data of 3 batches till 6 months at real time and accelerated conditions attached. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate No. RO-5E5585 dated 03-07-2025 for 900gm API is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative data with Mounjaro attached on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Real time and accelerated data of 3 batches attached. |
| | The status in reference regulatory authorities | Mounjaro KwikPen 12.5mg/0.6ml by M/s Eli Lilly and Company (USFDA Approved). |
| | GMP status of the firm | GMP certificate attached |
| | Evidence of approval of manufacturing facility | License and section approval attached. |
| | **Evaluation Remarks** | |
| | The application fulfils the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator’s specifications with following conditions: | |

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| | 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 2 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UB2-LLE-LGT6, 2026-06-22) |
| | Detail of Fee Submitted | 38700,<br>2026-05-20, |
| | The proposed proprietary name / brand name | **TIRZEE - 4 Solution for Injection 10mg/0.6mL in Multi-dose Pre-filled Pen** |
| | Label Claim | Each 0.6mL Pre-filled Pen contains: Tirzepatide ... 10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Store in a refrigerator at 2°C-8°C. |
| | For generic drugs (me-too Status) | Mounjaro KwikPen (Tirzepatide) 10mg/0.6ml PFP by M/s Eli Lilly Pakistan (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | - |
| | Detail of stability batches of drug product | Stability data of 3 batches till 6 months at real time and accelerated conditions attached. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate No. RO-5E5585 dated 03-07-2025 for 900gm API is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative data with Mounjaro attached on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Real time and accelerated data of 3 batches attached. |
| | The status in reference regulatory authorities | Mounjaro KwikPen 10mg/0.6ml by M/s Eli Lilly and Company (USFDA Approved). |
| | GMP status of the firm | GMP certificate attached |
| | Evidence of approval of manufacturing facility | License and section approval attached. |

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| | **Evaluation Remarks** | |
| | The application fulfils the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 3 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)** |
| | Application Form Dy. No / Tracking ID & date of submission | (SQ3-RSP-4TTH, 2026-06-22) |
| | Detail of Fee Submitted | 38700,<br>2026-05-20, |
| | The proposed proprietary name / brand name | **TIRZEE - 4 Solution for Injection 5mg/0.6mL in Multi-dose Pre-filled Pen** |
| | Label Claim | Each 0.6mL Pre-filled Pen contains: Tirzepatide ... 5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Store in a refrigerator at 2°C-8°C. |
| | For generic drugs (me-too Status) | Mounjaro KwikPen 5mg/0.6ml PFP manufactured by M/s Eli Lilly Pakistan (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | - |
| | Detail of stability batches of drug product | Stability data of 3 batches till 6 months at real time and accelerated conditions attached. |
| | Documents for the procurement of API with approval from DRAP | Clearance certificate No. RO-5E5585 dated 03-07-2025 for 900gm API is submitted. |

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| | (in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative data with Mounjaro attached on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Real time and accelerated data of 3 batches attached. |
| | The status in reference regulatory authorities | Mounjaro KwikPen 5mg/0.6ml by M/s Eli Lilly and Company (USFDA Approved). |
| | GMP status of the firm | GMP certificate attached |
| | Evidence of approval of manufacturing facility | License and section approval attached. |
| | **Evaluation Remarks** | |
| | The application fulfils the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 4 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RUW-YG9-NDGL, 2026-06-22) |
| | Detail of Fee Submitted | 38700,<br>2026-05-20, |
| | The proposed proprietary name / brand name | **TIRZEE - 4 Solution for Injection 7.5mg/0.6mL in Multi-dose Pre-filled Pen** |
| | Label Claim | Each 0.6mL Pre-filled Pen contains: Tirzepatide ... 7.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Store in a refrigerator at 2°C-8°C. |
| | For generic drugs (me-too Status) | TirzaTrim 7.5mg/0.6ml Multi-dose PFP by M/s Macter International Limited. |

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| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | - |
| | Detail of stability batches of drug product | Stability data of 3 batches till 6 months at real time and accelerated conditions attached. |
| | Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate No. RO-5E5585 dated 03-07-2025 for 900gm API is submitted. |
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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Real time and accelerated data of 3 batches attached. |
| | The status in reference regulatory authorities | Mounjaro KwikPen 7.5mg/0.6ml by M/s Eli Lilly and Company (USFDA Approved). |
| | GMP status of the firm | GMP certificate attached |
| | Evidence of approval of manufacturing facility | License and section approval attached. |
| | **Evaluation Remarks** | |
| | The application fulfils the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 5 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GSQ-5YN-6JE5, 2026-06-22) |
| | Detail of Fee Submitted | 38700,<br>2026-05-20, |

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| The proposed proprietary name / brand name | **TIRZEE - 4 Solution for Injection 15mg/0.6mL in Multi-dose Pre-filled Pen** |
| Label Claim | Each 0.6mL Pre-filled Pen contains: Tirzepatide ... 15mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 1's-De-Controlled |
| Shelf Life (Unit) | 24 Month(s)Store in a refrigerator at 2°C-8°C. |
| For generic drugs (me-too Status) | Mounjaro KwikPen (Tirzepatide) 15mg/0.6ml PFP by M/s Eli Lilly Pakistan (Pvt.) Ltd. |
| Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | - |
| Detail of stability batches of drug product | Stability data of 3 batches till 6 months at real time and accelerated conditions attached. |
| Documents for the procurement of API with approval from DRAP (in case of Import) | Clearance certificate No. RO-5E5585 dated 03-07-2025 for 900gm API is submitted. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative data with Mounjaro attached on finished product specification parameters. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Real time and accelerated data of 3 batches attached. |
| The status in reference regulatory authorities | Mounjaro KwikPen 15mg/0.6ml by M/s Eli Lilly and Company (USFDA Approved). |
| GMP status of the firm | GMP certificate attached |
| Evidence of approval of manufacturing facility | License and section approval attached. |
| **Evaluation Remarks** | |
| The application fulfils the prescribed codal formalities. | |
| **Decision** | |

**Approved**

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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| | 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 6 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3NX-R8M-W912, 2026-06-22) |
| | Detail of Fee Submitted | 38700,<br>2026-05-20, |
| | The proposed proprietary name / brand name | **Tirzee - 4 Solution for Injection 2.5mg/0.6mL in Multi-dose Pre-filled Pen** |
| | Label Claim | Each 0.6mL PFP contains: Tirzepatide....2.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)Store in a refrigerator at 2°C-8°C. |
| | For generic drugs (me-too Status) | Mounjaro KwikPen 2.5mg/0.6ml PFP manufactured by M/s Eli Lilly Pakistan (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | - |
| | Detail of stability batches of drug product | Stability data of 3 batches till 6 months at real time and accelerated conditions attached. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Clearance certificate No. RO-5E5585 dated 03-07-2025 for 900gm API is submitted. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative data with Mounjaro attached on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Real time and accelerated data of 3 batches attached. |
| | The status in reference regulatory authorities | Mounjaro KwikPen 2.5mg/0.6ml by M/s Eli Lilly and Company (USFDA Approved). |
| | GMP status of the firm | GMP certificate attached |
| | Evidence of approval of manufacturing facility | License and section approval attached. |
| | **Evaluation Remarks** | |
| | The application fulfils the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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 | |

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| | 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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 7 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)** |
| | Application Form Dy. No / Tracking ID & date of submission | (UU6-PD3-M93S, 2026-06-17) |
| | Detail of Fee Submitted | 38700,<br>2026-06-04, |
| | The proposed proprietary name / brand name | **Zephil Injection 7.5mg/0.5ml** |
| | Label Claim | Each 0.5ml PFS contains:<br>Trizepatide.....7.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's, 4's -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a refrigerator (2 ºC – 8 ºC). Do not freeze. |
| | For generic drugs (me-too Status) | Tirzee 7.5mg/0.5ml - Getz |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | - |
| | Detail of stability batches of drug product | Data of 3 batches is submitted till 6 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6, Batch certificate and Invoice (not DRAP attested) attached for 0.15 kg tirzepatide. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative studies performed with Mounjaro on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches submitted |
| | The status in reference regulatory authorities | Mounjaro USFDA approved |
| | GMP status of the firm | GMP certificate attached. |
| | Evidence of approval of manufacturing facility | DML and section approval letter attached. |
| | **Evaluation Remarks** | |
| | The application fulfills the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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 (Anam Saeed) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RM3-PBD-MWXZ, 2026-06-17) |
| | Detail of Fee Submitted | 38700,<br>2026-06-04, |
| | The proposed proprietary name / brand name | **Zephil Injection 12.5mg/0.5mL (Prefilled Pen Autoinjector)** |
| | Label Claim | Each 0.5mL PFS contains: Tirzepatide ..... 12.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled,4's-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at refrigerator conditions 2 - 8 °C. Do not Freeze |
| | For generic drugs (me-too Status) | Tirzee 12.5mg/0.5mL Prefilled pen autoinjector by Getz Pharma |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of 3 batches is submitted till 6 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6, Batch certificate and Invoice (not DRAP attested) attached for 0.15 kg tirzepatide. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative studies performed with Mounjaro on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches submitted |
| | The status in reference regulatory authorities | EMA approved - Mounjaro 12.5 mg solution for injection in pre-filled pen by Eli Lilly Italia S.p.A |
| | GMP status of the firm | GMP certificate attached. |
| | Evidence of approval of manufacturing facility | DML and section approval letter attached. |
| | **Evaluation Remarks** | |
| | The application fulfills the prescribed codal formalities. | |
| | **Decision** | |

**Approved**

Approved as per innovator's specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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

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| 9 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MN3-DTR-ME5P, 2026-06-17) |
| | Detail of Fee Submitted | 38700,<br>2026-06-04, |
| | The proposed proprietary name / brand name | **Zephil Injection 5mg/0.5mL (Prefilled Pen Autoinjector)** |
| | Label Claim | Each 0.5mL PFS contains: Tirzepatide ..... 5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1S-De-Controlled,4S-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in the original package in order to protect from Sunlight. Store in a refrigerator (2 ºC – 8 ºC). Do not freeze. |
| | For generic drugs (me-too Status) | GETZ PHARMA: TIRZEE |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of 3 batches is submitted till 6 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6, Batch certificate and Invoice (not DRAP attested) attached for 0.15 kg tirzepatide. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative studies performed with Mounjaro on finished product specification parameters. |

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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches submitted |
| | The status in reference regulatory authorities | Mounjaro Injection 5mg/0.5mL: Eli Lilly and Company, K.K, Japan. |
| | GMP status of the firm | GMP certificate attached. |
| | Evidence of approval of manufacturing facility | DML and section approval letter attached. |
| | **Evaluation Remarks** | |
| | The application fulfills the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 10 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LHR-EBG-7PH2, 2026-06-17) |
| | Detail of Fee Submitted | 38700,<br>2026-06-04, |
| | The proposed proprietary name / brand name | **Zephil Injection 15mg/0.5mL (Prefilled Pen Autoinjector)** |
| | Label Claim | Each 0.5mL PFS contains: Tirzepatide ..... 15mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-De-Controlled,4's -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in the original package in order to protect from Sunlight. Store in a refrigerator (2 ºC – 8 ºC). Do not freeze. |
| | For generic drugs (me-too Status) | GETZ PHARMA: TIRZEE |

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| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | |
| | Detail of stability batches of drug product | Data of 3 batches is submitted till 6 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6, Batch certificate and Invoice (not DRAP attested) attached for 0.15 kg tirzepatide. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative studies performed with Mounjaro on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches submitted |
| | The status in reference regulatory authorities | Mounjaro Injection 15mg/0.5mL: Eli Lilly and Company, K.K, Japan. |
| | GMP status of the firm | GMP certificate attached. |
| | Evidence of approval of manufacturing facility | DML and section approval letter attached. |
| | **Evaluation Remarks** | |
| | The application fulfills the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 11 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area **(000136)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EV9-ATE-8ZMS, 2026-06-17) |
| | Detail of Fee Submitted | 38700,<br>2026-06-04, |
| | The proposed proprietary name / brand name | **Zephil Injection 2.5mg/0.5ml** |

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| | Label Claim | Each 0.5ml PFS contains:<br>Trizepatide.....2.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's, -De-Controlled,4's -De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a refrigerator (2 ºC – 8 ºC). Do not freeze. |
| | For generic drugs (me-too Status) | Tirzee - Getz |
| | Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | - |
| | Detail of stability batches of drug product | Data of 3 batches is submitted till 6 months. |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6, Batch certificate and Invoice (not DRAP attested) attached for 0.15 kg tirzepatide. |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative studies performed with Mounjaro on finished product specification parameters. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches submitted |
| | The status in reference regulatory authorities | Refer to 1.5.9 RRA Reference |
| | GMP status of the firm | GMP certificate attached. |
| | Evidence of approval of manufacturing facility | DML and section approval letter attached. |
| | **Evaluation Remarks** | |
| | The application fulfills the prescribed codal formalities. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 12 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Hilton Pharma (Pvt) Limited.** Plot No. 13-14 & 43, Sector-15, Korangi Industrial Area |

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| | **(000136)** |
| Application Form Dy. No / Tracking ID & date of submission | (1Y6-3YY-RMGY, 2026-06-17) |
| Detail of Fee Submitted | 38700,<br>2026-06-04, |
| The proposed proprietary name / brand name | **Zephil Injection 10mg/0.5mL (Prefilled Pen Autoinjector)** |
| Label Claim | Each 0.5mL PFS contains: Tirzepatide ..... 10mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 1's-De-Controlled,4's-De-Controlled |
| Shelf Life (Unit) | 2 Year(s)Store in the original package in order to protect from Sunlight. Store in a refrigerator (2 ºC – 8 ºC). Do not freeze. |
| For generic drugs (me-too Status) | GETZ PHARMA: TIRZEE |
| Pharmacotherapeutic Group of (API) | Gastric inhibitory polypeptide (GIP) analog and a GLP-1 receptor agonist. ATC Code: A10BX16 |
| Name, address of Manufacturing site: | Self Manufacturing |
| Name & address of API manufacturer | |
| Detail of stability batches of drug product | Data of 3 batches is submitted till 6 months. |
| Documents for the procurement of API with approval from DRAP<br>(in case of Import) | Form 6, Batch certificate and Invoice (not DRAP attested) attached for 0.15 kg tirzepatide. |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | Comparative studies performed with Mounjaro on finished product specification parameters. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Data of 3 batches submitted |
| The status in reference regulatory authorities | Mounjaro Injection 10mg/0.5mL: Eli Lilly and Company, K.K, Japan. |
| GMP status of the firm | GMP certificate attached. |
| Evidence of approval of manufacturing facility | DML and section approval letter attached. |
| **Evaluation Remarks** | |
| The application fulfills the prescribed codal formalities. | |
| **Decision** | |

**Approved**

Approved as per innovator’s specifications with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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

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| 13 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z94-X2U-RR3S, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each Dose Contains 10mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |

**Evaluation Remarks**

The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board.

**Decision**

**Approved**

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

3. The firm shall install LC-MS facilities at their premises within six months, specifically for identifying and quantifying peptide-related impurities. Until the installation is complete, contract

testing must be carried out at any government drug testing laboratory or DRAP's licensed testing facility for each batch release and the reports shall be submitted in the relevant field office of DRAP.

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

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

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

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| 14 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (B1W-SX8-5B5H, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL)<br>Contains: Tirzepatide.....50mg (Each Dose Contains 12.5mg in 0.6ml solution)<br>(Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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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| 15 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ADS-3HY-5GX6, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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 | |

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| | 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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 16 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (56L-X1P-PYQJ, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....20mg (Each Dose Contains 5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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 | |

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| | 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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 17 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1YS-H1W-ZW1P, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 60mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 15mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration. | |

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| | 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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 18 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wnsfeild Pharmaceuticals** Plot No. 122, Phase-V, Block-A, Industrial Estate Hattar, KPK **(000610)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1A9-JD8-3QHA, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 7.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK.- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions: | |

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| | 1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 19 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA **(000751)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z61-5SY-L7RP, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 7.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of | |

RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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

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| 20 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA **(000751)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T5S-Q25-Q6TT, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved** | |

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| | The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 21 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA **(000751)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PY3-NZL-TYNQ, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 60mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 15mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |

**Approved**

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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

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| 22 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WAR-5JB-UJ9G, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-15, |
| | The proposed proprietary name / brand name | **MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. - |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |

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| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 23 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)** |
| | Application Form Dy. No / Tracking ID & date of submission | (RNY-MWA-3Y3Z, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-15, |
| | The proposed proprietary name / brand name | **MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....50mg (Each Dose Contains 12.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. - |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |

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| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 24 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MV7-RZ7-1MYR, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-15, |
| | The proposed proprietary name / brand name | **MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....20mg (Each Dose Contains 5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. - |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |

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| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 25 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)** |
| | Application Form Dy. No / Tracking ID & date of submission | (LQ1-1XS-J18G, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-15, |
| | The proposed proprietary name / brand name | **MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 7.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. - |
| | The status in reference regulatory authorities | EMA Approved |

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| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 26 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)** |
| | Application Form Dy. No / Tracking ID & date of submission | (J2M-2G2-812S, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-15, |
| | The proposed proprietary name / brand name | **MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each Dose Contains 10mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. - |

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| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 27 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)** |
| | Application Form Dy. No / Tracking ID & date of submission | (16S-TSQ-RZH4, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-15, |
| | The proposed proprietary name / brand name | **MIZTIDE 60mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 15mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As Per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | - |

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| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK. - |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 28 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA **(000751)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PD2-4NZ-E4ZD, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....20mg (Each Dose Contains 5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | N/A |

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| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 29 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA **(000751)** |
| | Application Form Dy. No / Tracking ID & date of submission | (8BG-HQY-1DPL, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each Dose Contains 10mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |

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|---|---|---|
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 30 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welwink Pharmaceuticals** G.T ROAD INDUSTRIAL ESTATE, GUJRANWALA **(000751)** |
| | Application Form Dy. No / Tracking ID & date of submission | (33T-SDD-L1MW, 2026-07-02) |
| | Detail of Fee Submitted | 97200,<br>2025-11-14, |
| | The proposed proprietary name / brand name | **MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....50mg (Each Dose Contains 12.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |

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|---|---|---|
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation is already approved in the name of proposed manufacturer in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 31 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QMS-5VY-ZZD2, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2025-11-17, |
| | The proposed proprietary name / brand name | **MIZTIDE 50mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 15mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |

| | | |
|---|---|---|
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.- |
| | The status in reference regulatory authorities | ema approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 32 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q3Q-E11-W1ZT, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2025-11-17, |
| | The proposed proprietary name / brand name | **MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each Dose Contains 10mg in 0.6ml solution) (Product complies Innovator's Specs) |

| | | |
|---|---|---|
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.- |
| | The status in reference regulatory authorities | ema approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 33 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L52-MMB-EYQH, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2025-11-17, |
| | The proposed proprietary name / brand name | **MIZTIDE 10mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |

| | | |
|---|---|---|
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.- |
| | The status in reference regulatory authorities | ema approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 34 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HR1-1YS-82LU, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2025-11-17, |

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|---|---|---|
| | The proposed proprietary name / brand name | **MIZTIDE 20mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....20mg (Each Dose Contains 5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.- |
| | The status in reference regulatory authorities | ema approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 35 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)** |
| | Application Form Dy. No / Tracking ID & date of submission | (4UR-6SL-N237, 2026-07-03) |

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| | Detail of Fee Submitted | 97200,<br>2025-11-17, |
| | The proposed proprietary name / brand name | **MIZTIDE 30mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 7.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.- |
| | The status in reference regulatory authorities | ema approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 36 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)** |

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| | Application Form Dy. No / Tracking ID & date of submission | (79J-EVA-VP27, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2025-11-17, |
| | The proposed proprietary name / brand name | **MIZTIDE 40mg/2.4ml Solution for Injection in Multi-Dose pre-filled pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....50mg (Each Dose Contains 12.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore below 25c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.- |
| | The status in reference regulatory authorities | ema approved |
| | Detail of previous approval | |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 37 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. |

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| | | **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YTN-PNN-GUHP, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Miztide 60mg/2.4ml Multidose Pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....60mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Miztide Injection, DRB 354 |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 38 | Case Category | Routine (Anam Saeed) |

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| Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| Application Form Dy. No / Tracking ID & date of submission | (VPP-14W-J6DW, 2026-07-03) |
| Detail of Fee Submitted | 97200,<br>2026-06-25, |
| The proposed proprietary name / brand name | **Miztide 40mg/2.4ml Multidose Pen** |
| Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....40mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | As per SRO-De-Controlled |
| Shelf Life (Unit) | 2 YearStore Below 25c |
| For generic drugs (me-too Status) | NA |
| Pharmacotherapeutic Group of (API) | |
| Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| The status in reference regulatory authorities | EMA Approved |
| Detail of previous approval | Miztide Injection, DRB 354 |

**Evaluation Remarks**

The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board.

**Decision**

**Approved**

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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

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| 39 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (V6E-58A-RXJX, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Miztide 20mg/2.4ml Multidose Pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....20mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Miztide Injection, DRB 354 |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |

**Approved**

The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:

1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.

2. The firm shall perform the following tests on the first two commercial batches using LC-MS, comparing the results with the reference product, and maintain records for review by the Registration Board, if desired so: a. Peptide mapping. b. Impurity profiling specifically peptide-related impurities. Under no circumstances, the registration holder shall release these batches into the market if the test results for both the test and reference products are not comparable as per above stated criteria and same shall immediately be reported to the Division of BE&R and QA &LT.

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

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

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

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

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| 40 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AJ1-821-7VE1, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Miztide 50mg/2.4ml Multidose Pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....50mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Miztide Injection, DRB 354 |
| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |

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| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 41 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (346-D1T-NY13, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Miztide 10mg/2.4ml Multidose Pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....10mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Miztide Injection, DRB 354 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 42 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XEX-BA5-51ZG, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Semvy 14mg Tablet** |
| | Label Claim | Each Tablet Contains:<br>SEMAGLUTIDE.....14mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | Semma 14mg Tablet |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Semma Tablet, DRB 340 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 340th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 43 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DTY-9AA-9V6G, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Semvy 7mg Tablet** |
| | Label Claim | Each Tablet Contains:<br>SEMAGLUTIDE.....7mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | Semma 3mg Tablet |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Semma Tablet, DRB 340 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 340th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 44 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ALG-SG8-X42H, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Semvy 3mg Tablet** |
| | Label Claim | Each Tablet Contains:<br>SEMAGLUTIDE.....3mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | Semma 3mg Tablet |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Semma Tablet, DRB 340 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 340th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 45 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (WG5-GN8-GNHY, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-27, |
| | The proposed proprietary name / brand name | **Terza 12.5mg Single Dose Prefilled Pen** |
| | Label Claim | Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....12.5mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | Tirzep by Weather Folds Pharma |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Terza, DRB 352 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 352nd meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 46 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VM2-QSB-863H, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-27, |
| | The proposed proprietary name / brand name | **Terza 10mg Single Dose Prefilled Pen** |
| | Label Claim | Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....10mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | Tirzep by Weather Folds Pharma |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Terza, DRB 352 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 352nd meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 47 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T77-TGG-AB5R, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-27, |
| | The proposed proprietary name / brand name | **Terza 15mg Single Dose Prefilled Pen** |
| | Label Claim | Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....15mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | Tirzep by Weather Folds Pharma |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Terza, DRB 352 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 352nd meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 48 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QMZ-L1D-6MQH, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-27, |
| | The proposed proprietary name / brand name | **Terza 7.5mg Single Dose Prefilled Pen** |
| | Label Claim | Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....7.5mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | Tirzep by Weather Folds Pharma |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Terza, DRB 352 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 352nd meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 49 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3VR-NPE-4QUX, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-27, |
| | The proposed proprietary name / brand name | **Terza 2.5mg Single Dose Prefilled Pen** |
| | Label Claim | Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....2.5mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | Tirzep by Weather Folds Pharma |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Terza, DRB 352 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 352nd meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 50 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BA1-9HL-7HT6, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-27, |
| | The proposed proprietary name / brand name | **Terza 5mg Single Dose Prefilled Pen** |
| | Label Claim | Each PRE-FILLED PEN (0.5mL) Contains: Tirzepatide.....5mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store at 2-8°c |
| | For generic drugs (me-too Status) | Tirzep by Weather Folds Pharma |
| | Pharmacotherapeutic Group of (API) | - |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Terza, DRB 352 |
| | **Evaluation Remarks** | |

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| | The applied formulation of proposed manufacturer is already approved in 352nd meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 51 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Wellesely Pharmaceuticals** Plot No. 30-A, Punjab Small Industrial Estate, Bahtar More. **(001029)** |
| | Application Form Dy. No / Tracking ID & date of submission | (QDY-XV1-4GLD, 2026-07-03) |
| | Detail of Fee Submitted | 97200,<br>2026-06-25, |
| | The proposed proprietary name / brand name | **Miztide 30mg/2.4ml Multidose Pen** |
| | Label Claim | Each Multi-Dose Pre-Filled Pen (2.4mL) Contains: Tirzepatide.....30mg (Each Dose Contains 2.5mg in 0.6ml solution) (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-De-Controlled |
| | Shelf Life (Unit) | 2 YearStore Below 25c |
| | For generic drugs (me-too Status) | NA |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Weather Folds Pharmaceuticals-Plot no. 69/2, Phase-II, Industrial Estate, Hattar- |
| | The status in reference regulatory authorities | EMA Approved |
| | Detail of previous approval | Miztide Injection, DRB 354 |

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| | **Evaluation Remarks** | |
| | The applied formulation of proposed manufacturer is already approved in 354th meeting of Registration Board. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s. Weather Folds Pharmaceuticals Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan subject to submission of RMP, Quality Agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 and a Declaration in the light of Notification F.No.1-2/2022- DMC dated 13th June, 2023, and with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 52 | Case Category | Priority As Per 257-M of RB (Anam Saeed) |
| | Name, address of Applicant. | **SIND MEDICAL STORES** 13-B, Block 6, PECHS, Shahrah e Faisal, **(450)** |
| | Application Form Dy. No / Tracking ID & date of submission | (MNW-26S-BP5Y, 2026-06-22) |
| | Detail of Fee Submitted | 313500,<br>2025-12-23, |
| | The proposed proprietary name / brand name | **Poliomyelitis Vaccine (Oral) Bivalent Type 1 and 3 - 20 Dose** |
| | Label Claim | Poliomyelitis Vaccine (oral) Bivalent Types 1 and 3 (bOPV): Each dose of 2 drops (0.1 mL) contains: Polio virus (Sabin) Type 1* ..... ≥ 10^6.0 CCID∨50 Polio virus (Sabin) Type 3* ..... ≥ 10^5.8 CCID∨50 * Grown on Vero cell Culture. CCID∨50: Cell Culture Infectious Dose 50 %. For the full list of excipients, see section 6.1. |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | Box of 50 Vials + Droppers-Controlled |
| | Shelf Life (Unit) | 2 Year(s)Store in a freezer (at or below –20°C). |
| | For generic drugs (me-too Status) | Kindly refer M-1, Pg.55-56. Bivalent Poliomyelitis Vaccine Type 1&3 Mfd by Panacea |

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| | | Biotech Ltd., India and registered in the name of AMSON Vaccine & Pharma, Islamabad. |
| | Pharmacotherapeutic Group of (API) | Viral Vaccines ATC code J07BF04 |
| | Name, address of Manufacturing site: | Serum Institute of India Pvt Ltd,-S. Nos. 203–205, 212, 223, 268–270 (H) & 104–110, 113–114, 168–170 (M), Hadapsar, Pune-411028, INDIA.-India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | N/A |
| | Name, address of Marketing Authorization Holder: | Serum Institute of India Pvt Ltd,, S. Nos. 203–205, 212, 223, 268–270 (H) & 104–110, 113–114, 168–170 (M), Hadapsar, Pune-411028, INDIA., India |
| | Details of Certificates (CoPP/FSC/cGMP): | Ministry of foreign affairs attested COPP submitted. |
| | Details of Authorization Letter : | N/A |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability submitted. |
| | The status in reference regulatory authorities | WHO PQ Vaccine |
| | **Evaluation Remarks** | |
| | The applied product is WHO Prequalified. | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in view the WHO Prequalification; Registration Board approved the product subject to:<br><br>1. Compliance of current Import Policy for finished drugs.<br><br>2. Risk management plan (RMP) approved by the reference regulatory authority (RRA) for the applied formulation.<br><br>3. RMP developed by the applicant keeping in view the risks identified in RRA approved RMP on the format as specified in Module 4 of the DRAP's Guidelines on Good Pharmacovigilance Practices for Registration Holders, Document No. PHSR/GL/PV/07<br><br>4. Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division. | |
| 53 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **GENOME PHARMA** RCCI Industrial Estate, Plot No. C-19, Access Road, Rawat,Islamabad. **(DHO-ISB-2257)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DTJ-NB8-98XM, 2026-02-23) |
| | Detail of Fee Submitted | 313500,<br>2026-02-06, |
| | The proposed proprietary name / brand name | **Safacto AF 500 IU Lyophilized Powder for Infusion** |
| | Label Claim | Each vial contains: Moroctocog Alfa... 500 IU |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 3 Year(s)2-8 °C |
| | For generic drugs (me-too Status) | No recombinant factor VIII registered yet |

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| Pharmacotherapeutic Group of (API) | Antihemophilic factor (recombinant) ATC Code: B02BD02 |
| Name, address of Manufacturing site: | Saman Daroo 8-Khorasan Science and Technology Park, Mashhad-Iran |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | N/A |
| Name, address of Marketing Authorization Holder: | Saman Daroo 8, Khorasan Science and Technology Park, Mashhad, Iran |
| Details of Certificates (CoPP/FSC/cGMP): | Ministry of Foreign Affairs attested COPP No. 665/79752 dated 27-01-2026 is attached. |
| Details of Authorization Letter : | LOA No. 102/1656 dated 07-01-2026 attached with 3 years validity. |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | The bulk was stored at 4°C and tested at the 12, 24 and 48 hours after production. Accelerated testing was carried out at 25°C for 4 hours. |
| The status in reference regulatory authorities | XYNTHOPHILIA |

**Evaluation Remarks**

Certain queries were communicated to the applicant. The applicant has submitted responses to these queries, which are presented in the table below;

| S.No. | Queries | Response | Remarks |
|---|---|---|---|
| 1 | COPP not legalized. Submit valid legalized COPP. | Attached as Annex-VI | Ministry of Foreign Affairs attested COPP attached. |
| 2 | Module 3.2.S.7 (stability of drug substance) is not provided. | Attached as Annex-VII | The bulk was stored at 4°C and tested at the 12, 24 and 48 hours after production. Accelerated testing was carried out at 25°C for 4 hours. |
| 3 | Real time and accelerated stability of drug product on 3 commercial batches on Zone IVa conditions is required. | Attached as Annex-VIII | All parameters as per Ph.Eur are not tested. |
| 4 | Bio similarity data as per WHO Bio similarity guidelines in tabular form is required including; | | |
| | Ø Comparative structural and functional characterization with the Reference product. | Attached As Annex-l | Complete physicochemical and structural characterization is still required. |
| | Ø Comparative in vitro bioassays for receptor affinity and activation. | Technical documentation of the product is available in our company since it entered the clinical phase. In-Vitro research dates back a decade ago and was done in a university laboratory, and we do not have access to it. | Not provided. |
| | Ø Comparative in-vivo potency. | We do not have comparative in-vivo potency reports. Please pay attention our Product has been used in Iran for many years and no specific side effects have been observed | Not provided. |

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| | | | in clinical studies or during these years. Moreover, Safacto is also approved by the International Society of Hematology. | |
| | | Ø Impurity testing (product related and process related). | Attached as Annex-II | Comparative impurity testing with innovator is not provided. |
| | | Ø Comparative Pharmacokinetic studies | Attached as Annex-III At the time of the initial tests, Xyntha product was not available in the country due to the sanctions, and therefore these studies were not conducted in a comparative manner. However, the Pharmacokinetic studies on our product are available. | Comparative PK studies are not conducted. |
| | | Ø Comparative Toxicology studies (single dose and repeat dose). | Attached as Annex-IV Our product is biosimilar of Xyntha, it toxicological studies are also consistent and approved for our product. Our Product has been used in Iran for many years and no specific side effects have been observed in clinical studies or during these years. Moreover, Safacto is also approved by the International Society of Hematology. | Comparative toxicology studies are not conducted. |
| | | Ø Comparative Clinical trial study reports as per EMA guideline "Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products" including Efficacy in PTPs ≥12 years and Clinical investigation in children <12 years and Clinical investigation in PUPs as well as immunogenicity studies. | Attached as Annex-V Efficacy PTP >12 years ---> Report 2, page 45 and the result on page 62. Clinical investigation In PUPs ---> Is not available, since the product must be used after the patient has history of more than 50 days of exposure to FVIII, and in IRAN this process is mandatory. Immunogenicity studies ---> The inhibitory tests to investigate Immunogenicity have been done on the patients during the clinical trial study. This investigation has been done in the same clinical trial study on adults (age 4-43). Moreover, the product has been used by children in Iran for several years and also in Syria and Sri Lanka, | The firm has submitted single page summary of PK study conducted in 24 Hemophilia A patients (including 10 children and 14 adults). Firm has also submitted following study; “A Comparative Study of Efficacy, Safety and Immunogenicity of Recombinant Coagulation Factor VIII (Safacto) with Xyntha Recombinant Factor VIII in Patients with Severe Hemophilia A with a History of More Than 50 Days of Previous Exposure to Coagulation Factor in the Form of Multicenter in Iran” This study was performed on 33 patients (16 people used Xyntha and 17 people used Safacto). The average age of Xyntha and Safacto users was 16 and 19 years. However as |

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| | | without any written compliment. | per EMA guidelines; "Guideline on the clinical investigation of recombinant and human plasma-derived factor VIII products" Efficacy in PTPs ≥12 years (at least 50PTPs) and Clinical investigation in children <12 years (at least 50 children) is required as pre-authorization requirement. |

**Decision**

**Deferred**

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

1. Complete comparative physicochemical and structural characterization of the applied product against the reference product.
2. Comparative in vitro bioassays for receptor affinity and activation relative to the reference product.
3. Comparative impurity profile analysis with the innovator/reference product.
4. Comparative nonclinical toxicology studies conducted against the reference product.
5. Clinical study data generated in accordance with the applicable EMA Guideline on Factor VIII Products.

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| 54 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Z8N-YX1-QQQD, 2026-04-06) |
| | Detail of Fee Submitted | 75000,<br>2026-03-26, |
| | The proposed proprietary name / brand name | **Semma 1.5mg Tablet** |
| | Label Claim | Each Tablet Contains:<br>SEMAGLUTIDE.....1.5mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical CO., Ltd |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |

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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | EMA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The application fulfills the codal formalities. Submitted for consideration by the Board. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 55 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L5M-SUY-GNNZ, 2026-04-06) |
| | Detail of Fee Submitted | 75000,<br>2026-03-26, |
| | The proposed proprietary name / brand name | **Semma 9mg Tablet** |
| | Label Claim | Each Tablet Contains:<br>SEMAGLUTIDE.....9mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical CO., Ltd |
| | Detail of stability batches of drug product | |

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|---|---|---|
| | 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 | EMA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The application fulfills the codal formalities. Submitted for consideration by the Board. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 56 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L1M-89S-6AEB, 2026-04-06) |
| | Detail of Fee Submitted | 75000,<br>2026-03-26, |
| | The proposed proprietary name / brand name | **Semma 25mg Tablet** |
| | Label Claim | Each Tablet Contains:<br>SEMAGLUTIDE.....25mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 25°c |

| | | |
|---|---|---|
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical CO., Ltd |
| | Detail of stability batches of drug product | |
| | 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 | EMA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The application fulfills the codal formalities. Submitted for consideration by the Board. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 57 | Case Category | Routine (Anam Saeed) |
| | Name, address of Applicant. | **Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DX2-PPV-WPVW, 2026-04-06) |
| | Detail of Fee Submitted | 75000,<br>2026-03-26, |
| | The proposed proprietary name / brand name | **Semma 50mg Tablet** |

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|---|---|---|
| | Label Claim | Each Tablet Contains:<br>SEMAGLUTIDE.....50mg (Product complies Innovator's Specs) |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | As per SRO-As per SRO |
| | Shelf Life (Unit) | 2 YearStore below 25°c |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Fuxin Long Rui Pharmaceutical CO., Ltd |
| | Detail of stability batches of drug product | |
| | Documents for the procurement of API with approval from DRAP<br>(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 | EMA Approved |
| | GMP status of the firm | |
| | Evidence of approval of manufacturing facility | |
| | **Evaluation Remarks** | |
| | The application fulfills the codal formalities. Submitted for consideration by the Board. | |
| | **Decision** | |
| | **Approved**<br><br>Approved as per innovator's specifications with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 58 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **jovac global pak** Ground & Mezzanine Floor, Plaza No. 92, Block D, EME, DHA Phase 12, Lahore **(05-352-0066-072607D)** |

| | | |
|---|---|---|
| | Application Form Dy. No / Tracking ID & date of submission | (9LA-JHL-X42H, 2026-04-15) |
| | Detail of Fee Submitted | 313500,<br>2026-04-14, |
| | The proposed proprietary name / brand name | **Jova Zeit 6 Premium Vaccine emulsion for injection vaccine** |
| | Label Claim | Each dose of vaccine contains at minimum: Inactivated Adenovirus serotypes 2, 4, 8 (a,b) and 11 each.....$10^{6.5}TCID_{50}$ |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 300 ml bottle-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)2° to 8° C |
| | For generic drugs (me-too Status) | Yes (GPVAC Poly-Hep) Company (Grand Pharma) |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Jordan Bio Industries Center (Jovac)-Amman, Yajouz road, near Yajouz Agriculture Nursery Amman Jordan-Jordan |
| | Name, address of Marketing Authorization Holder: | Jovac Global Pak, Ground & Mezzanine Floor, Plaza No. 92, Block D, EME, DHA Phase 12, Lahore, Pakistan, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | CoPP No. 5/5/10/000932 dated 21-01-2026 |
| | Details of Authorization Letter : | Letter of Authorization no. 12/2026 dated 22-01-2026. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | In stability studies, in potency tests, the results are mentioned a Positive instead of actual titer values. The firm was asked for actual values and in response, the firm submitted potency results of three different batches at intervals 0, 5 & 10 hrs after first opening. | |
| | **Decision** | |
| | **Approved**<br><br>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. | |
| 59 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)** |
| | Application Form Dy. No / Tracking ID & date of submission | (YGX-M2G-E577, 2026-06-18) |
| | Detail of Fee Submitted | 97200,<br>2026-05-06, |
| | The proposed proprietary name / brand name | **Zepfit 15MG/0.5ML (Solution for Injection in Prefilled Syringe)** |
| | Label Claim | Each PFS (0.5ml) contains:<br>Tirzepatide.....15mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's -As per SRO,4's-As per SRO |
| | Shelf Life (Unit) | 2 Year2 - 8°C |
| | For generic drugs (me-too Status) | Brand Name: Zeptide Solution for injection in Prefilled Syringe 15mg/0.5ml Manufactured by: M/s BF Biosciences Limited |

| | | |
|---|---|---|
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s BF Biosciences Limited-5-KM Sunder Raiwind Road, Raiwind, Lahore- |
| | The status in reference regulatory authorities | Brand Name: MOUNJARO Solution for Injection in Prefilled Syringe 15mg/0.5ml Approval granted to : Eli Lilly and Company |
| | Detail of previous approval | Product Name: Zeptide 15mg/0.5ml (Solution for Injection in PFS) Meeting NO: 351th |
| | **Evaluation Remarks** | |
| | The applied product is already approved on CTD format in name of proposed manufacturer in 351st meeting of Registration Board. Registration letter has already been issued. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 60 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)** |
| | Application Form Dy. No / Tracking ID & date of submission | (R8E-75Y-XW1G, 2026-06-18) |
| | Detail of Fee Submitted | 97200,<br>2026-05-06, |

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|---|---|
| The proposed proprietary name / brand name | **Zepfit 12.5mg/0.5ml (Solution for Injection in Prefilled Syringe)** |
| Label Claim | Each PFS (0.5ml) contains:<br>Tirzepatide.....12.5mg |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 1's -As per SRO,4's-As per SRO |
| Shelf Life (Unit) | 2 Year2 - 8°C |
| For generic drugs (me-too Status) | Brand Name: Zeptide Solution for injection in Prefilled Syringe 12.5mg/0.5ml Manufactured by: M/s BF Biosciences Limited |
| Pharmacotherapeutic Group of (API) | |
| Name, address of Manufacturing site: | M/s BF Biosciences Limited-5-KM Sunder Raiwind Road, Raiwind, Lahore- |
| The status in reference regulatory authorities | Brand Name: MOUNJARO Solution for Injection in Prefilled Syringe 12.5mg/0.5ml Approval granted to : Eli Lilly and Company |
| Detail of previous approval | Product Name: Zeptide 12.5mg/0.5ml (Solution for Injection in PFS) Meeting NO: 351th |

**Evaluation Remarks**

The applied product is already approved on CTD format in name of proposed manufacturer in 351st meeting of Registration Board. Registration letter has already been issued.

**Decision**

**Approved**

The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore 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.

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| | 6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 61 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)** |
| | Application Form Dy. No / Tracking ID & date of submission | (HAR-55Q-M2Z6, 2026-06-18) |
| | Detail of Fee Submitted | 97200,<br>2026-05-06, |
| | The proposed proprietary name / brand name | **Zepfit 10mg/0.5ml (Solution for Injection in Prefilled Syringe)** |
| | Label Claim | Each PFS (0.5ml) contains:<br>Tirzepatide.....10mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's -As per SRO,4's-As per SRO |
| | Shelf Life (Unit) | 2 Year2 - 8°C |
| | For generic drugs (me-too Status) | Brand Name: Zeptide Solution for injection in Prefilled Syringe 10mg/0.5ml Manufactured by: M/s BF Biosciences Limited |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s BF Biosciences Limited-5-KM Sunder Raiwind Road, Raiwind, Lahore- |
| | The status in reference regulatory authorities | Brand Name: MOUNJARO Solution for Injection in Prefilled Syringe 10mg/0.5ml Approval granted to : Eli Lilly and Company |
| | Detail of previous approval | Product Name: Zeptide 10mg/0.5ml (Solution for Injection in PFS) Meeting NO: 351th |
| | **Evaluation Remarks** | |
| | The applied product is already approved on CTD format in name of proposed manufacturer in 351st meeting of Registration Board. Registration letter has already been issued. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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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| 62 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)** |
| | Application Form Dy. No / Tracking ID & date of submission | (EQH-4B8-NW9G, 2026-06-18) |
| | Detail of Fee Submitted | 97200,<br>2026-05-06, |
| | The proposed proprietary name / brand name | **Zepfit 7.5MG/0.5ML (Solution for Injection in Prefilled Syringe)** |
| | Label Claim | Each PFS (0.5ml) contains:<br>Tirzepatide.....7.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's -As per SRO,4's-As per SRO |
| | Shelf Life (Unit) | 2 Year2 - 8°C |
| | For generic drugs (me-too Status) | "Brand Name: Zeptide Solution for injection in Prefilled Syringe 7.5mg/0.5ml Manufactured by: M/s BF Biosciences Limited" |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s BF Biosciences Limited-5-KM Sunder Raiwind Road, Raiwind, Lahore- |
| | The status in reference regulatory authorities | "Brand Name: MOUNJARO Solution for Injection in Prefilled Syringe 7.5mg/0.5ml Approval granted to : Eli Lilly and Company" |
| | Detail of previous approval | "Product Name: Zeptide 7.5mg/0.5ml (Solution for Injection in PFS) Meeting NO: 351th " |
| | **Evaluation Remarks** | |
| | The applied product is already approved on CTD format in name of proposed manufacturer in 351st meeting of Registration Board. Registration letter has already been issued. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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 | |

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|---|---|---|
| | 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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 63 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)** |
| | Application Form Dy. No / Tracking ID & date of submission | (N8T-Y2W-8WHQ, 2026-06-18) |
| | Detail of Fee Submitted | 97200,<br>2026-05-06, |
| | The proposed proprietary name / brand name | **Zepfit 5mg/0.5ml (Solution for Injection in Prefilled Syringe)** |
| | Label Claim | Each PFS (0.5ml) contains:<br>Tirzepatide.....5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's -As per SRO,4's-As per SRO |
| | Shelf Life (Unit) | 2 Year2 - 8°C |
| | For generic drugs (me-too Status) | Brand Name: Zeptide Solution for injection in Prefilled Syringe 5mg/0.5ml Manufactured by: M/s BF Biosciences Limited |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s BF Biosciences Limited-5-KM Sunder Raiwind Road, Raiwind, Lahore- |
| | The status in reference regulatory authorities | "Brand Name: MOUNJARO Solution for Injection in Prefilled Syringe 5mg/0.5ml Approval granted to : Eli Lilly and Company" |
| | Detail of previous approval | Product Name: Zeptide 5mg/0.5ml (Solution for Injection in PFS) Meeting NO: 351th |
| | **Evaluation Remarks** | |
| | The applied product is already approved on CTD format in name of proposed manufacturer in 351st meeting of Registration Board. Registration letter has already been issued. | |
| | **Decision** | |
| | **Approved** | |

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| | The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 64 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Ferozsons Laboratories Limited** PO Ferozsons, Amangarh **(000038)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BHJ-SW6-XDQU, 2026-06-18) |
| | Detail of Fee Submitted | 97200,<br>2026-05-06, |
| | The proposed proprietary name / brand name | **Zepfit 2.5MG/0.5ML (Solution for Injection in Prefilled Syringe)** |
| | Label Claim | Each PFS (0.5ml) contains:<br>Tirzepatide.....2.5mg |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's -As per SRO,4's-As per SRO |
| | Shelf Life (Unit) | 2 Year2 - 8°C |
| | For generic drugs (me-too Status) | "Brand Name: Zeptide Solution for injection in Prefilled Syringe 2.5mg/0.5ml Manufactured by: M/s BF Biosciences Limited" |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s BF Biosciences Limited-5-KM Sunder Raiwind Road, Raiwind, Lahore- |
| | The status in reference regulatory authorities | "Brand Name: MOUNJARO Solution for Injection in Prefilled Syringe 2.5mg/0.5ml |

| | | |
|---|---|---|
| | | Approval granted to : Eli Lilly and Company" |
| | Detail of previous approval | "Product Name: Zeptide 2.5mg/0.5ml (Solution for Injection in PFS) Meeting NO: 351th " |
| | **Evaluation Remarks** | |
| | The applied product is already approved on CTD format in name of proposed manufacturer in 351st meeting of Registration Board. Registration letter has already been issued. | |
| | **Decision** | |
| | **Approved**<br><br>The Registration Board approved application for contract manufacturing from M/s BF Biosciences Limited, 5-KM Sunder Raiwind Road, Raiwind, Lahore with following conditions:<br><br>1. The firm shall conduct pharmacokinetic/ pharmacodynamics (PK/PD) equivalence studies using the reference/innovator product within six months of obtaining registration.<br><br>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.<br><br>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.<br><br>4. Post-authorization safety and efficacy studies as per Rule 11 of the Pharmacovigilance Rules, 2022 and submission of reports on a quarterly basis.<br><br>5. Actively collect, assess, and report ADRs as per the timelines defined in the Rule 11(5) of the Pharmacovigilance Rules 2022.<br><br>6. PBRERs (Periodic Benefit Risk Evaluation Reports) as per Rules 11(10) of the Pharmacovigilance Rules. | |
| 65 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **jovac global pak** Ground & Mezzanine Floor, Plaza No. 92, Block D, EME, DHA Phase 12, Lahore **(05-352-0066-072607D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VQM-2X8-L6QE, 2025-12-06) |
| | Detail of Fee Submitted | 313500,<br>2025-12-03, |
| | The proposed proprietary name / brand name | **Pestevac Vaccine**<br>**Lyophilisate suspension for injection with solvent** |
| | Label Claim | Lyophilized Part:<br>Each dose contains: |

| | | |
|---|---|---|
| | | Live attenuated Peste Des Petites Ruminants Virus strain Nig. 75/1.....at least $10^{2.5}TCID_{50}$<br>Solvent:<br>Each ml contains:<br>NaCl.....137M*<br>KCl.....2.7M<br>$KH_2PO_4$.....1.5M<br>$Na_2HPO_4$.....6.5M<br>Distilled Water.....q.s. 1ml<br>*M=mol/Liter |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 50 Doses Vial-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)2°-8° C |
| | For generic drugs (me-too Status) | Yes |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Jordan Bio Industries Center (Jovac)-Amman, Yajouz road, near Yajouz Agriculture Nursery Amman Jordan-Jordan |
| | Name, address of Marketing Authorization Holder: | Jovac Global PAK, Ground & Mezzanine Floor, Plaza No. 92, Block D, EME, DHA Phase 12, Lahore, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP CERTIFICATE No. 5/5/10/012081 dated 06-11-2025 CoPP No. 5/5/10/012711 dated 23-11-2025 |
| | Details of Authorization Letter : | LOA dated 19-11-2025 |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A. |
| | **Evaluation Remarks** | |
| | **Decision** | |
| | **Approved**<br><br>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. | |
| 66 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **jovac global pak** Ground & Mezzanine Floor, Plaza No. 92, Block D, EME, DHA Phase 12, Lahore **(05-352-0066-072607D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (U44-VT7-EEX4, 2026-06-02) |
| | Detail of Fee Submitted | 313500,<br>2026-04-20, |
| | The proposed proprietary name / brand name | **Combivac C vaccine**<br>**live attenuated freeze-dried pellet.** |
| | Label Claim | Each dose contains:<br>Live attenuated Newcastle Disease Virus strain Clone.....at least $10^{6.0}EID_{50}$<br>Infectious Bronchitis Virus strain H120.....at least $10^{3.0}EID_{50}$ |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 2500 Doses vial-De-Controlled |

| | | |
|---|---|---|
| | Shelf Life (Unit) | 2 Year(s)2°C - 8°C |
| | For generic drugs (me-too Status) | Medivac ND-IB (Hilton Pharma) Proof is attached as the last page of dossier |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Jordan Bio Industries Center (Jovac)-Amman, Yajouz road, near Yajouz Agriculture Nursery Amman Jordan-Jordan |
| | Name, address of Marketing Authorization Holder: | Jordan Bio Industries Center (Jovac), Amman, Yajouz road, near Yajouz Agriculture Nursery, Amman, Jordan, Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP CERTIFICATE No. 5/5/10/012081 dated 06-11-2025 CoPP No. 5/5/10/000925 dated 23-11-2025 |
| | Details of Authorization Letter : | LOA dated 22-01-2026. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | . | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for submission of details of Newcastle Disease, Clone strain and its immunological relevance and need for Pakistan. | |
| 67 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Inouko Animal Health (Private) Limited** 3rd Floor, Plaza No. 3, D-Block, DHA Phase 5, Cantt, District Lahore **(05-352-0058-043305D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (T9G-P9Y-U6ZR, 2025-07-15) |
| | Detail of Fee Submitted | 225000.0,<br>2025-07-10, |
| | The proposed proprietary name / brand name | **Nextmune** |
| | Label Claim | Each dose contains:<br>Avian infectious bursal disease virus, strain Winterfield 2512, G-61.....min. 0.7 log10 CID50 |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | Glass ampoule of 2000 & 4000Ds doses of the vaccin-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store and transport Vaccine in liquid Nitrogen Container |
| | For generic drugs (me-too Status) | N/A |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Ceva-Phylaxia Veterinary Biologicals Co.Ltd.-1107 Budapest, Szallas u. 5.,-Hungary |
| | Name, address of Marketing Authorization Holder: | Ceva-Phylaxia Veterinary Biologicals Co.Ltd., 1107 Budapest, Szallas u. 5.,, Hungary |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP Certificate No. 53 00/2904-6/2023 dated 18-10-2023 |
| | Details of Authorization Letter : | Sole Agency Agreement dated 01-09-2025. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |

| | | |
|---|---|---|
| | **Evaluation Remarks** | |
| | The firm has proposed 02 pack sizes and provided stability data of one batch of three different pack sizes each i.e. 2000, 4000 & 8000 doses. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for submission one pack size along with its stability study data of three commercial batches. | |
| 68 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Snam Pharma** 61-G, Phase 1, Commercial Area, DHA, Lahore **(05-352-0058-036985D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (XJV-7JY-1Y2U, 2025-12-15) |
| | Detail of Fee Submitted | 313500,<br>2025-12-11, |
| | The proposed proprietary name / brand name | **RINVAC ND+AI+FAD** |
| | Label Claim | Each 0.1ml contains:<br>Inactivated Newcastle disease virus, strain La Sota.....$10^{9.0}EID_{50}$ before inactivation<br>Inactivated Avian influenza virus (subtype H9) strain TJ-4.....$10^{9.0}EID_{50}$ before inactivation<br>Inactivated Fowl adenoviruses (Serotype 4 Group I) strain RP-8-C.....$10^{7.5}TCID_{50}$ before inactivation |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 500ml/Bottle-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store at 2°C - 8°C |
| | For generic drugs (me-too Status) | Same Strains already registered in Pakistan |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Tianjin Ringpu Bio-technology Co., Ltd., Airport E-No. 168, Huanhe South Road, Airport Economic Zone, Tianjin-China |
| | Name, address of Marketing Authorization Holder: | Tianjin Ringpu Bio-Technology Co., Ltd., No. 1 Dongjiu Road, Tianjin Free Trade Area (Airport Economic Area), Tianjin, China |
| | Details of Certificates (CoPP/FSC/cGMP): | Scanned Apostille GMP Certificate No. ( 2022) GMP 02002 dated 25-07-2025 valid till 13-01-2027.<br>Scanned Apostille FSC No. 2025041 dated 18-11-2025. |
| | Details of Authorization Letter : | Scanned Apostille Product Specific LOA valid till 03-11-2025. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | The N subtype of Avian Influenza virus was not mentioned in label claim. The firm was asked for clarification and they submitted that there is N2 in their composition. | |
| | **Decision** | |
| | **Deferred** | |

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| | Registration Board deferred the case for submission of immunological relevance and need of AIV TJ-4 strain and FAD RP-8-C strain for Pakistan. | |
| 69 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Bromed Animal Health** 246A, West Wood Colony **(05-352-0066-037660D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (VXT-3V8-PT8X, 2025-12-26) |
| | Detail of Fee Submitted | 313500,<br>2025-12-24, |
| | The proposed proprietary name / brand name | **Xin Bei Qing**<br>**Recombinant Newcastle Disease Virus Vaccine,Inactivated (Strain A-VII)** |
| | Label Claim | Each 0.1ml contains:<br>Inactivated Newcastle disease virus A-VII strain.....$\geq 10^{8.0}EID_{50}$ before inactivation. |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 500ml-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)2-8C |
| | For generic drugs (me-too Status) | QVAC ND G7 Reg. No.127287 Manufactured By QYH China Local Agent Vet line International. |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Jiangsu Nannong High-Tech Co., Ltd.-No. 890 Xicheng Road, Jiangyin City, Jiangsu Province, China.-China |
| | Name, address of Marketing Authorization Holder: | Jiangsu Nannong High-Tech Co., Ltd., No. 890 Xicheng Road, Jiangyin City, Jiangsu Province, China., China |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP certificate No. (2022) GMP 10069 dated 31-08-2022 valid till 30-08-2027. FSC No. SYZM2026-026 dated 12-05-2026. |
| | Details of Authorization Letter : | Apostille LOA dated 05-11-2025. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | The submitted FSC is indicating following statement: "registered in China and permitted to be freely sold and used within the territory of China, with no restrictions on export. This certificate is only for export use of the product and does not include any commitment to product quality. The manufacturer is responsible for the product quality." | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for submission of revised FSC which is not issued exclusively for export purpose and should indicate actual availability of product in country of origin. | |
| 70 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **VET PHARMA TRADING CO** NEW STEEL MARKET, G.T. ROAD GUJRANWALA **(09-341-0137-069656D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (43D-DJR-TM2L, 2026-02-26) |
| | Detail of Fee Submitted | 313500,<br>2026-02-24, |
| | The proposed proprietary name / brand name | **Himmvac Dalguban AN Plus Oil Vaccine** |

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| | Label Claim | Each dose before inactivation contains:<br>Low pathogenic Al virus (A/Chicken/Korea/01310/2001(H9N2) strain).....at least $10^{8.5}EID_{50}$<br>ND virus (KBNP-C4152R2L strain).....at least $10^{9.5}EID_{50}$ |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 1,000 Dose (500 ml)-De-Controlled |
| | Shelf Life (Unit) | 20 Year(s)(2-8°C) |
| | For generic drugs (me-too Status) | yes |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | M/s KBNP, INC.,-235-9, Chusaro, Sinam, Yesan, Chungnam, Republic of Korea.-South Korea |
| | Name, address of Marketing Authorization Holder: | Vet Pharma Trading Company,, New Steel Market, Near Regent Cinema, G.T. Road, Gujrawala., Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | CoPP NO. 20260838 dated 21-05-2026. |
| | Details of Authorization Letter : | Sole Agent Authorization dated 21-01-2026. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | The strains of both viruses are already registered in Pakistan in products Himmvac Dalguban AN Oil Vaccine (Reg. No. 099079) & Himmvac Dalguban N Plus Live Vaccine (Reg. No. 126147). The CoPP is not signed by authority, it is only stamped. | |
| | **Decision** | |
| | **Approved**<br><br>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 and submission of duly signed valid legalized CoPP issued by regulatory authority of country of origin. | |
| 71 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **SAADAT INTERNATIONAL** 117-HABITAT APARTMENTS, SHADMAN-II, JAIL ROAD **(05-352-0063-102851d)** |
| | Application Form Dy. No / Tracking ID & date of submission | (DVN-V4E-R1QW, 2026-03-05) |
| | Detail of Fee Submitted | 313500,<br>2026-03-04, |
| | The proposed proprietary name / brand name | **AVINEW + H120 Vaccine**<br>**Freeze Dried, Newcastle Disease and Infectious Bronchitis Vaccine, Live (VG/GA+H120 Strain)(10X1000DS)** |
| | Label Claim | AVINEW + H120 is used against Newcastle Disease and Infectious Bronchitis in chickens. |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 10X1000ds-De-Controlled |
| | Shelf Life (Unit) | 18 Year(s)+2'C to +8' C |
| | For generic drugs (me-too Status) | REG#033208 (Medivac ND-IB Vaccine) |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Nanchang Boehringer Ingelheim Animal Health Co., L-No.818, Chuangxin 2 Road, Nanchang |

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| | | High-tech Industrial Development zone, Jiangxi Province,-China |
| | Name, address of Marketing Authorization Holder: | Boehringer Ingelheim Vetmedica GmbH, Binger Strabe 173, 55216 Ingelheim am Rhein, , Germany |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP Certificate No. (2022) GMP 14011 dated 25-02-2022 valid till 24-02-2027 COPP No. 202601 dated 08-01-2026 valid till 31-12-2026. |
| | Details of Authorization Letter : | Copy of LOA dated 04-03-2026. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | LOA issued by Boehringer Ingelheim Vetmedica GmbH, Germany while manufacturer mentioned on CoPP is different. The firm need to establish the relationship between manufacturer as per CoPP and MAH as per LOA. | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in view CVPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and Apostille/ Legalized document issued by manufacturer establishing relationship between proposed Market Authorization Holder and manufacturer. | |
| 72 | Case Category | Routine (M. Zubair Masood) |
| | 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 | (NXL-XZX-XNWN, 2026-05-02) |
| | Detail of Fee Submitted | 313500,<br>2026-04-01, |
| | The proposed proprietary name / brand name | **PULIVAC H9** |
| | Label Claim | Each ml contains:<br>Inactivated Avian Influenza Virus (H9 subtype) strain SZ.....not less than $10^{8.67}EID_{50}$ |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 250 ml-De-Controlled |
| | Shelf Life (Unit) | 18 Year(s)Store at 2 8 |
| | For generic drugs (me-too Status) | CEVAC FLU H9 k, https://marush.com.pk/Ceva-Vaccines |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Pulike Biological Engineering , Inc.-Intersection of South Tianzhong Road and Binhe Road, High Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone-China |
| | Name, address of Marketing Authorization Holder: | Pulike Biological Engineering , Inc., Intersection of South Tianzhong Road and Binhe Road, High Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone, China |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP Certificate No. (2022) GMP 16014 dated 27-02-2024 valid till 29-03-2027.<br>FSC dated 10-02-2026. |
| | Details of Authorization Letter : | LOA dated 16-09-2025. |

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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | The N subtype of Influenza virus is not mentioned in FSC. The firm provided the clarification that the N2 subtype is present in their vaccine. | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in view GMP Certificate & FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. | |
| 73 | Case Category | Routine (M. Zubair Masood) |
| | 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 | (E6Y-J23-BXBQ, 2025-09-13) |
| | Detail of Fee Submitted | 313500,<br>2025-09-04, |
| | The proposed proprietary name / brand name | **VAvi NIE** |
| | Label Claim | Each 0.1ml (before inactivation) contains:<br>Newcastle Disease Virus, Strain LaSota.....$\geq 3\times10^{8.0}EID_{50}$<br>Infectious Bronchitis Virus, Strain M41.....$\geq 3\times10^{6.0}EID_{50}$<br>Egg Drop Syndrome Virus, Strain AV125.....HA $\geq$1:30720 |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 500mL/bottle-De-Controlled |
| | Shelf Life (Unit) | 18 Year(s)2-8 degree centigrade |
| | For generic drugs (me-too Status) | MEVAC ND+EDS |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Qingdao Vland Animal Health Group Co., Ltd.-No.85 Keyun Road, High-Tech Zone, Qingdao City, Shandong Province, China-China |
| | Name, address of Marketing Authorization Holder: | Qingdao Vland Animal Health Group Co., Ltd., No.85 Keyun Road, High-Tech Zone, Qingdao City, Shandong Province, China |
| | Details of Certificates (CoPP/FSC/cGMP): | Scanned Apostille GMP Certificate No. (2022) GMP 15174 dated 12-05-2025. Scanned Apsotille FSC No. (2026) 155 dated 12-06-2026. |
| | Details of Authorization Letter : | Scanned Apostille LOA. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | . | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in view GMP Certificate & FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. | |

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| 74 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **HIPHARMA (PRIVATE) LIMITED** 123-C (FIRST FLOOR), BLOCK E, MODEL TOWN LAHORE **(05-352-0065-127168D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (AYR-GJT-DAE8, 2026-04-11) |
| | Detail of Fee Submitted | 313500,<br>2026-04-10, |
| | The proposed proprietary name / brand name | **Hivac MG-MS**<br>**Mycoplasma gallisepticum and Mycoplasma synoviae Vaccine, Inactivated** |
| | Label Claim | Each ml contains:<br>Inactivated Mycoplasma gallisepticum, Strain R.....$\geq 10^{9.0}$CCU<br>Inactivated Mycoplasma synoviae, Strain MS01.....$\geq 10^{9.0}$CCU |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | The 500 ml/bottle presentation is requested for registration.-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store between 2-8°C. Protect from light. Do not freeze |
| | For generic drugs (me-too Status) | . |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Qixiang Biological Technology Co., Ltd-Heshuo Road 5-333 Wuzhi, Henan , China.-China |
| | Name, address of Marketing Authorization Holder: | Qixiang Biological Technology Co., Ltd, Heshuo Road 5-333 Wuzhi, Henan , China., China |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP certificate No. (2022) GMP 16016 dated 31-03-2022 valid till 30-03-2027. FSC dated 26-03-2026. |
| | Details of Authorization Letter : | Apostille Agreement dated 25-02-2026. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | . | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for submission of immunological relevance and need of Mycoplasma Synoviae MS01 strain for Pakistan. | |
| 75 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **HIPHARMA (PRIVATE) LIMITED** 123-C (FIRST FLOOR), BLOCK E, MODEL TOWN LAHORE **(05-352-0065-127168D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (L6R-A9S-MHVH, 2026-04-17) |
| | Detail of Fee Submitted | 313500,<br>2026-04-16, |
| | The proposed proprietary name / brand name | **Hivac ND-IB (Clone 30-H120)**<br>**ewcastle Disease and Infectious Bronchitis Vaccine, Live** |

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| | Label Claim | Each dose contains:<br>Newcastle disease virus, strain Clone 30.....not less than $10^{6.0}EID_{50}$<br>Infectious Bronchitis virus, strain H120.....not less than$10^{3.5}EID_{50}$ |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 2000 dose/vial presentation is requested for registration.-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)Store between 2-8°C. Protect from light. Do not freeze |
| | For generic drugs (me-too Status) | Ornimix Clone B1 + H120 (Reg. No. 087879) |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Qixiang Biological Technology Co., Ltd-Heshuo Road 5-333 Wuzhi, Henan , China.-China |
| | Name, address of Marketing Authorization Holder: | Qixiang Biological Technology Co., Ltd, Heshuo Road 5-333 Wuzhi, Henan , China., China |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP certificate No. (2022) GMP 16016 dated 31-03-2022 valid till 30-03-2027. FSC dated 26-03-2026. |
| | Details of Authorization Letter : | Apostille Agreement dated 25-02-2026. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | The specifications need revision as per European Pharmacopoeia. | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in view GMP Certificate & FSC indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs and fee for revision of specifications to European Pharmacopoeia. | |
| 76 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Pharmakon international enterprises** Suit no 2 , 1st floor Hum Heights service road east near sohan interchange Islamabad **(DHO-ISB-433)** |
| | Application Form Dy. No / Tracking ID & date of submission | (142-MDG-QBUD, 2024-06-13) |
| | Detail of Fee Submitted | 300000.0,<br>2024-02-15, |
| | The proposed proprietary name / brand name | **LIVE LSD, Lumpy Skin Disease Vaccine, Live (Neethling Strain)** |
| | Label Claim | Each dose (1ml) contains; Lumpy Skin Disease Virus, live, Neethling Strain...NLT 1x10^3.5 TCID50 |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 25 doses per vial-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)2-8°C |
| | For generic drugs (me-too Status) | LSD-NDOLL ( Distributor in Pakistan M/S Orion Group Sargodha Road Faislabad) |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | M/s Hester Biosciences Africa Limited-Plot No. 647 & 648, Tamco Industrial Estate, Kibaha |

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| | | Tanzania-Tanzania |
| | Name, address of Marketing Authorization Holder: | M/s Hester Biosciences Africa Limited, Plot No. 647 & 648, Tamco Industrial Estate, Kibaha Tanzania, Tanzania |
| | Details of Certificates (CoPP/FSC/cGMP): | Legalized FSC has been submitted mentioning that the product is registered for Export. Legalized GMP certificate has been submitted but is expired. |
| | Details of Authorization Letter : | Legalized LOA has been submitted. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability studies data of three batches has been submitted. |
| | **Evaluation Remarks** | |
| | Registration Board in its 347th meeting deferred the case for confirmation of reason behind the non-availability of the product in the country of origin and submission of valid legalized GMP certificate of the manufacturer abroad by the applicant. The firm submitted the revised FSC indicating free sale status in country of origin and submitted GMO certificate No. TAN 0025 D/GMP 0212 dated 18-09-2025. However, panel of inspectors of DRAP inspected the facility virtually for another product PPR Vaccine approved in 347th meeting of Registration Board and the panel did not recommend the registration due to critical observations. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case till decision on report of inspection of proposed manufacturer conducted by Panel of Inspectors of DRAP. | |
| 77 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Pharmakon international enterprises** Suit no 2 , 1st floor Hum Heights service road east near sohan interchange Islamabad **(DHO-ISB-433)** |
| | Application Form Dy. No / Tracking ID & date of submission | (3JU-QAX-EM1G, 2024-06-14) |
| | Detail of Fee Submitted | 300000.0,<br>2024-05-07, |
| | The proposed proprietary name / brand name | **Contagious Bovine Pleuropneumonia Vaccine, Live (LIVE CBPP) T1-sr/T1-44 Strain** |
| | Label Claim | Contagious Bovine Pleuropneumonia Vaccine, Live (LIVE CBPP) T1-sr/T1-44 Strain..NLT $1\times10^{7}$ $CCU_{50}$ |
| | Reference to Finished product specifications | Manufacturer Specification |
| | Proposed Pack Size | 25 doses per vial-De-Controlled |
| | Shelf Life (Unit) | 2 Year(s)2-8°C |
| | For generic drugs (me-too Status) | Not registered |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | M/s Hester Biosciences Africa Limited-Plot No. 647 & 648, Tamco Industrial Estate, Kibaha Tanzania-Tanzania |
| | Name, address of Marketing Authorization Holder: | M/s Hester Biosciences Africa Limited, Plot No. 647 & 648, Tamco Industrial Estate, Kibaha Tanzania, Tanzania |
| | Details of Certificates (CoPP/FSC/cGMP): | Legalized FSC has been submitted. Legalized GMP certificate has been submitted but is expired. |
| | Details of Authorization Letter : | Legalized LOA from MAH has been submitted. |

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| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Not Submitted (Dossier of Another product attached) |
| | **Evaluation Remarks** | |
| | The Registration Board deferred the case due to following deficiencies in the application; 1. The GMP certificate of manufacturer has expired on 04-04-2025. 2. The dossier/application of an other product has been attached instead of the applied product. Complete application of applied product is required to be submitted The Registration Board also endorsed the recommendations of sub-committee on veterinary drugs and directed the Division of BE&R to seek the opinion of M/o National Food Security & Research regarding immunological relevance and need of applied product in Pakistan. The firm submitted the GMP certificate No. TAN 0025 D/GMP 0212 dated 18-09-2025 and dossier of the product. The EWG in its 6th meeting decided to ask the firm to submit justification & need of applied strain for Pakistan. The firm has not submitted the data. Moreover, panel of inspectors of DRAP inspected the facility virtually for another product PPR Vaccine approved in 347th meeting of Registration Board and the panel did not recommend the registration due to critical observations. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case till decision on report of inspection of proposed manufacturer conducted by Panel of Inspectors of DRAP. | |
| 78 | Case Category | Routine (M. Zubair Masood) |
| | 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 | (S4P-SBN-8SVH, 2026-01-27) |
| | Detail of Fee Submitted | 313500,<br>2026-01-21, |
| | The proposed proprietary name / brand name | **PULIVAC ND Clone 30** |
| | Label Claim | This product contains Newcastle disease virus strain Clone 30. The virus titer per dose is not less than $10^{6.0}$ $EID_{50}$. |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 2000 doses/vial-De-Controlled |
| | Shelf Life (Unit) | 24 Month2-8 degree centigrade |
| | For generic drugs (me-too Status) | Nobilis® ND Clone 30 by MSD USA distributed by Vety Care |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | Pulike Biological Engineering, Inc.-No.3 Cuiwei Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone. - China |
| | Name, address of Marketing Authorization Holder: | Pulike Biological Engineering, Inc., No.3 Cuiwei Road, High-Tech Development Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone. , China |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | In clinical justification, following is mentioned: "It is not developed by Pulike Biological Engineering, INC., we didn't do field trial, it's impossible for us to submit clinical justification." In response, the firm submitted summary report of clinical trial conducted by Sindh Institute of Animal | |

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| | Health (SIAH) on 180 broilers in their Shed 02. Following are the observations: i. The trial is not a field trial. ii. There were no primary and secondary efficacy end points predetermined by the firm. iii. Proposed dosage and method of administration are mentioned while actual administered dosage and route of administration are not mentioned in report. iv. No evidence of vaccine import are provided. v. Details of sponsor are not mentioned in report. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for following:<br><br>1. Comments of M/o National Food Security & Research on clinical study report submitted by the firm.<br><br>2. Evidence of Import of vaccine used in clinical trial by the firm. | |
| 79 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **A&S Animal Health** 61-A Westwood Colony Thokar Niaz Baig, Lahore **(05-352-0066-98924D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (2ZS-VMJ-49GJ, 2026-02-13) |
| | Detail of Fee Submitted | 313500,<br>2026-02-11, |
| | The proposed proprietary name / brand name | **WIXPoul ND+IB+AI**<br>**Newcastle Disease, Infectious Bronchitis and Avian influenza (subtype H9) Vaccine, Inactivated Strain LaSota + Strain M41 + H9N2 substrain WD)** |
| | Label Claim | Each 0.1ml (before inactivation) contains:<br>Inactivated chicken Newcastle disease virus, strain La Sota.....$\geq 10^{8.5}EID_{50}$<br>Inactivated Infectious bronchitis virus, strain M41.....$\geq 10^{7.0}EID_{50}$<br>Inactivated Avian influenza virus (H9N2 subtype) strain WD.....$\geq 10^{7.5}EID_{50}$ |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 500ml-De-Controlled |
| | Shelf Life (Unit) | 24 Year(s)2-8◦C |
| | For generic drugs (me-too Status) | ND+IB+H9 (RN: 115116 Manufactured by: Beijing Sinder-Vet Technology Co., Ltd.) |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Shandong Lvdu Biology Science And Technology Co., -Lvdu Bioengineering High-Science and Technology Park, Binzhou Economic Development Zone, Shandong Province, China.-China |
| | Name, address of Marketing Authorization Holder: | Henan WIX Biological Technology Co., Ltd, . 2820, Block B, Building 3, Shenglong Plaza, No. 78, Shangding Road, Zhengzhou (East Of Zhengzhou), Henan Pilot Free Trade Zone, Henan Province, China |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP Certificate No. (2022) GMP 15051 dated 04-05-2023 valid till 25-05-2027. FSC No. (2025) 85 dated 03-07-2025. |

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| | Details of Authorization Letter : | LOA from M/s Shandong Lvdu Biology Science And Technology Co., China dated 19-06-2025. Authorization in name of M/s Shandong Lvdu Biology Science And Technology Co., China from manufacturer along with confirmation that manufacturer shall not appoint or authorize any other importer, distributor, or representative for the registration and marketing of the same products within the territory of Pakistan during the validity of this authorization. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |

**Evaluation Remarks**

| Sr. No. | Observation | Response |
|---|---|---|
| 1. | Revised FSC was required indicating actual availability of product in country of origin instead of only mentioning can be freely sold. The firm submitted the revised FSC but the number and date of issue was same as of previous FSC. | We discussed this matter with our principal manufacturer. They informed us that this is considered a minor change; therefore, the certificate number and issuance date will remain unchanged. We will submit new FSC before issuance of registration letter. |
| 2. | LOA was issued by other entity instead of manufacturer as per FSC. | The firm submitted authorization in name of M/s Shandong Lvdu Biology Science And Technology Co., China from manufacturer along with confirmation that manufacturer shall not appoint or authorize any other importer, distributor, or representative for the registration and marketing of the same products within the territory of Pakistan during the validity of this authorization. |

**Decision**

**Approved**

Keeping in view GMP Certificate & 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 revised FSC by the firm.

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| 80 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Bromed Animal Health** 246A, West Wood Colony **(05-352-0066-037660D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (1EB-PZU-9XL7, 2025-12-26) |
| | Detail of Fee Submitted | 313500,<br>2025-12-24, |
| | The proposed proprietary name / brand name | **Xin Quan Qing**<br>**Newcastle Disease Infectious Bronchitis, Egg Drop Syndrome and Avian Influenza (H9 Subtype) Vaccine, Inactivated (Strain La Sota+ strain M41+Strain AV127+ Strain NJ02)** |
| | Label Claim | Each 0.1ml before inactivation contains:<br>Inactivated Newcastle disease virus, LaSota |

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| | | strain.....not less than $4\times10^{8.0}EID_{50}$<br>Infectious bronchitis virus, M41 strain.....not less than $4\times 10^{6.7}EID_{50}$<br>Egg drop syndrome virus, AV127 strain hemagglutination titer.....not less than 1:10240<br>Avian influenza virus H9N2 subtype, NJ02 strain.....$\geq4 \times 10^{8.0}EID_{50}$ |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 500ml-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)2-8C |
| | For generic drugs (me-too Status) | RINVAC ND+IB+EDS+AI Reg. No.127219 Manufactured By Ringpu Biology China Local Agent Snam Pharma. |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Jiangsu Nannong High-Tech Co., Ltd.-No. 890 Xicheng Road, Jiangyin City, Jiangsu Province, China.-China |
| | Name, address of Marketing Authorization Holder: | Jiangsu Nannong High-Tech Co., Ltd., No. 890 Xicheng Road, Jiangyin City, Jiangsu Province, China., China |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP Certificate No. (2022) GMP 10069 dated 31-08-2022 valid till 30-08-2027. FSC No. SYZM2026-026 dated 12-05-2026. |
| | Details of Authorization Letter : | LOA dated 05-11-2025. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | Revised FSC was required indicating availability of product in country of origin instead of only mentioning registration status in China. The firm submitted the revised FSC but following statement is mentioned in it: "The aforementioned products have been registered in China and are permitted to be freely sold and used within the territory of China, with no restrictions on export. This certificate is only for export use of the product and does not include any commitment to product quality. The manufacturer is responsible for the product quality." | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for following:<br><br>1. Submission of revised FSC which is not issued exclusively for export purpose and should indicate actual availability of product in country of origin.<br><br>2. Differential fee of Rs. 1900/- for correction of formulation in Form-5A. | |
| 81 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Bromed Animal Health** 246A, West Wood Colony **(05-352-0066-037660D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (9EN-3L2-H2W1, 2025-12-26) |
| | Detail of Fee Submitted | 313500,<br>2025-12-24, |
| | The proposed proprietary name / brand name | **Xin Te Qing**<br>**Newcastle Disease, Infectious Bronchitis and** |

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| | | **Avian Influenza (H9 Subtype) Vaccine, Inactivated (Strain LaSota + Strain M41+ Strain WD)** |
| | Label Claim | Each dose (0.5ml) of the vaccine contains:<br>Inactivated Newcastle disease virus, strain La Sota.....$\geq 10^{8.3}EID_{50}$<br>Infectious bronchitis virus, strain M41.....$\geq 10^{6.3}EID_{50}$<br>AIV H9N2 subtype.....$\geq 10^{7.3}EID_{50}$ |
| | Reference to Finished product specifications | United States Pharmacopeia |
| | Proposed Pack Size | 500ml-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)2-8C |
| | For generic drugs (me-too Status) | SINVAC ND+IB+H9 Reg. No.115116 Manufactured By Beijing Sinder-Vet Tech. Ltd. China Local Agent Hivet Animal Health. |
| | Pharmacotherapeutic Group of (API) | Veterinary Vaccine |
| | Name, address of Manufacturing site: | Jiangsu Nannong High-Tech Co., Ltd.-No. 890 Xicheng Road, Jiangyin City, Jiangsu Province, China.-China |
| | Name, address of Marketing Authorization Holder: | Jiangsu Nannong High-Tech Co., Ltd., No. 890 Xicheng Road, Jiangyin City, Jiangsu Province, China., China |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP Certificate No. (2022) GMP 10069 dated 31-08-2022 valid till 30-08-2027. FSC No. SYZM2026-026 dated 12-05-2026. |
| | Details of Authorization Letter : | LOA dated 05-11-2025. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | 1. Revised FSC was required indicating availability of product in country of origin instead of only mentioning registration status in China. The firm submitted the revised FSC but following statement is mentioned in it: "The aforementioned products have been registered in China and are permitted to be freely sold and used within the territory of China, with no restrictions on export. This certificate is only for export use of the product and does not include any commitment to product quality. The manufacturer is responsible for the product quality." 2. Differential fee of Rs. 1900/- is required as firm submitted fee of Rs. 7500/- for correction of formulation in Form-5A instead of Rs. 9400/-. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for following:<br><br>1. Submission of revised FSC which is not issued exclusively for export purpose and should indicate actual availability of product in country of origin.<br><br>2. Differential fee of Rs. 1900/- for correction of formulation in Form-5A. | |
| 82 | 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) |

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| Detail of Fee Submitted | 300000.0,<br>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**

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. The firm submitted the response and following are the observations:

| Sr. No. | Observation | Response |
|---|---|---|
| 1. | Please explain that is there only one chromatogram for HPLC Peptide Mapping in Biosimilarity studies? | We only present a single chromatogram of the test drugsubstance for the following reasons: HPLC peptide mapping characterizes the fixed intrinsicprimary amino acid sequence of Semaglutide; our stable manufacturing process ensuresuniform primary structure across all API batches, so one representative batch suffices forcomparability assessment against the RLD. Moreover, finished dosage form production cannotalter Semaglutide's primary amino acid sequence. For this reason, the |

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| | | | peptide mappingcomparability test between test drug substance and RLD can fully substitute the test betweentest finished product and innovator product, which confirms the peptide mapping profile of ourfinished product matches the innovator product. |
| | 2. | Justification of not performing following tests in comparison with Innovator product: i. High-resolution mass spectrometry molecular weight ii.1H NMR spectrum. iii. Carbon-13 NMR spectrum iv. Elemental analysis | The firm has compared the results of their drug substance with theoretical data of Innovator product. |
| | 3. | Details of other pharmaceutical tablets & capsules manufactured in this Section as the GMP Certificate provided is for Tablet & Capsule. | 1. Deucravacitinib Tablets2. Ritlecitinib Tosylate Capsules3. Pretomanid Tablets4. Bedaquiline Fumarate Tablets5. Osilodrostat Tablets6. Vemurafenib Tablets7. Anamorelin Hydrochloride Tablets8. Mavacamten Capsules9. Aprocitentan Tablets ETC. |
| | 4. | Justification of not performing Molecular Weight Distribution of applied product in comparison with Innovator product. | Data Provided. |
| | 5. | Excipient compatibility study as one of the excipient is not as per Innovator? | All excipients in our test product are the same as those in the innovator product described inthe FDA Semaglutide tablet Product Quality Review (application number: 213051Orig1s000) |
| | 6. | Realtime stability data up to the proposed shelf life i.e. 24 months. | The full 24-month real-time stability testing is ongoing and will be finished in July 2026.Complete data will be supplemented subsequently after full testing completion. |

**Decision**

**Deferred**

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

- 1. Please provide any Reference Regulatory Authority guidelines confirming that the finished dosage form manufacturing process does not alter the structure of Semaglutide, and that characterization studies performed on the drug substance are sufficient to fulfill the characterization requirements for the finished pharmaceutical product.
- 2. Please provide the approved layout plan of the Tablet and Capsule manufacturing section, issued or approved by the regulatory authority of the country of origin, clearly identifying all manufacturing areas involved in the production of tablets and capsules.
- 3. Please provide real-time stability data covering the entire proposed shelf life of the product.

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| 83 | 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,<br>2025-05-08, |

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|---|---|
| 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**

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. The firm submitted the response and following are the observations:

| Sr. No. | Observation | Response |
|---|---|---|
| 1. | Please explain that is there only one chromatogram for HPLC Peptide Mapping in Biosimilarity studies? | We only present a single chromatogram of the test drugsubstance for the following reasons: HPLC peptide mapping characterizes the fixed intrinsicprimary amino acid sequence of Semaglutide; our stable manufacturing process ensuresuniform primary structure across all API batches, so one representative batch suffices forcomparability assessment against the RLD. Moreover, finished dosage form production cannotalter Semaglutide's primary amino acid sequence. For this reason, the peptide mappingcomparability test between |

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| | | | test drug substance and RLD can fully substitute the test betweentest finished product and innovator product, which confirms the peptide mapping profile of ourfinished product matches the innovator product. |
| | 2. | Justification of not performing following tests in comparison with Innovator product: i. High-resolution mass spectrometry molecular weight ii.1H NMR spectrum. iii. Carbon-13 NMR spectrum iv. Elemental analysis | The firm has compared the results of their drug substance with theoretical data of Innovator product. |
| | 3. | Details of other pharmaceutical tablets & capsules manufactured in this Section as the GMP Certificate provided is for Tablet & Capsule. | 1. Deucravacitinib Tablets2. Ritlecitinib Tosylate Capsules3. Pretomanid Tablets4. Bedaquiline Fumarate Tablets5. Osilodrostat Tablets6. Vemurafenib Tablets7. Anamorelin Hydrochloride Tablets8. Mavacamten Capsules9. Aprocitentan Tablets ETC. |
| | 4. | Justification of not performing Molecular Weight Distribution of applied product in comparison with Innovator product. | Data Provided. |
| | 5. | Excipient compatibility study as one of the excipient is not as per Innovator? | All excipients in our test product are the same as those in the innovator product described inthe FDA Semaglutide tablet Product Quality Review (application number: 213051Orig1s000) |
| | 6. | Realtime stability data up to the proposed shelf life i.e. 24 months. | The full 24-month real-time stability testing is ongoing and will be finished in July 2026.Complete data will be supplemented subsequently after full testing completion. |

**Decision**

**Deferred**

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

- 1. Please provide any Reference Regulatory Authority guidelines confirming that the finished dosage form manufacturing process does not alter the structure of Semaglutide, and that characterization studies performed on the drug substance are sufficient to fulfill the characterization requirements for the finished pharmaceutical product.
- 2. Please provide the approved layout plan of the Tablet and Capsule manufacturing section, issued or approved by the regulatory authority of the country of origin, clearly identifying all manufacturing areas involved in the production of tablets and capsules.
- 3. Please provide real-time stability data covering the entire proposed shelf life of the product.

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| 84 | 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,<br>2025-05-08, |
| | The proposed proprietary name / brand name | **L'OSEM-14 (14 mg) Tablet** |

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| 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**

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. The firm submitted the response and following are the observations:

| Sr. No. | Observation | Response |
|---|---|---|
| 1. | Please explain that is there only one chromatogram for HPLC Peptide Mapping in Biosimilarity studies? | We only present a single chromatogram of the test drugsubstance for the following reasons: HPLC peptide mapping characterizes the fixed intrinsicprimary amino acid sequence of Semaglutide; our stable manufacturing process ensuresuniform primary structure across all API batches, so one representative batch suffices forcomparability assessment against the RLD. Moreover, finished dosage form production cannotalter Semaglutide's primary amino acid sequence. For this reason, the peptide mappingcomparability test between test drug substance and RLD can fully |

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| | | | substitute the test betweentest finished product and innovator product, which confirms the peptide mapping profile of ourfinished product matches the innovator product. |
| | 2. | Justification of not performing following tests in comparison with Innovator product: i. High-resolution mass spectrometry molecular weight ii.1H NMR spectrum. iii. Carbon-13 NMR spectrum iv. Elemental analysis | The firm has compared the results of their drug substance with theoretical data of Innovator product. |
| | 3. | Details of other pharmaceutical tablets & capsules manufactured in this Section as the GMP Certificate provided is for Tablet & Capsule. | 1. Deucravacitinib Tablets2. Ritlecitinib Tosylate Capsules3. Pretomanid Tablets4. Bedaquiline Fumarate Tablets5. Osilodrostat Tablets6. Vemurafenib Tablets7. Anamorelin Hydrochloride Tablets8. Mavacamten Capsules9. Aprocitentan Tablets ETC. |
| | 4. | Justification of not performing Molecular Weight Distribution of applied product in comparison with Innovator product. | Data Provided. |
| | 5. | Excipient compatibility study as one of the excipient is not as per Innovator? | All excipients in our test product are the same as those in the innovator product described inthe FDA Semaglutide tablet Product Quality Review (application number: 213051Orig1s000) |
| | 6. | Realtime stability data up to the proposed shelf life i.e. 24 months. | The full 24-month real-time stability testing is ongoing and will be finished in July 2026.Complete data will be supplemented subsequently after full testing completion. |

**Decision**

**Deferred**

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

- 1. Please provide any Reference Regulatory Authority guidelines confirming that the finished dosage form manufacturing process does not alter the structure of Semaglutide, and that characterization studies performed on the drug substance are sufficient to fulfill the characterization requirements for the finished pharmaceutical product.
- 2. Please provide the approved layout plan of the Tablet and Capsule manufacturing section, issued or approved by the regulatory authority of the country of origin, clearly identifying all manufacturing areas involved in the production of tablets and capsules.
- 3. Please provide real-time stability data covering the entire proposed shelf life of the product.

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| 85 | Case Category | Routine (M. Zubair Masood) |
| | 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 | (EJW-LG9-M2BJ, 2025-06-25) |
| | Detail of Fee Submitted | 300000.0,<br>2025-06-23, |
| | The proposed proprietary name / brand name | **Premvac ND**<br>**Inactivated viral vaccine against Newcastle disease virus** |

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| | Label Claim | Each dose contains:<br>Newcastle disease viruses NDV Egypt/ NDV/ VIRO/ 1-LaSota/ RLQP/2021.....not less than 9 $\log_{10}EID_{50}$ |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 500ML (1000 Doses)-De-Controlled |
| | Shelf Life (Unit) | 24 Month(s)2°C - 8°C |
| | For generic drugs (me-too Status) | Product Name:: Gallivac Lasota Vaccine Registration No: 034556 Company Name: SAADAT INTERNATIONAL Company Address: 117-HABITAT APARTMENTS, SHADMAN-II, JAIL ROAD |
| | Pharmacotherapeutic Group of (API) | Veterinary vaccine |
| | Name, address of Manufacturing site: | Eva pharma for pharmaceutical industries -: Plot 27, Polaris International Park, North Expansion of 1st Industrial zone, 6th October of city, Giza-Egypt -Egypt |
| | Name, address of Marketing Authorization Holder: | Eva pharma for pharmaceutical industries , 176 El Sadat st. from Elmansouriya Canal - Kafr El Gabal -El Giza. Egypt, Egypt |
| | Details of Certificates (CoPP/FSC/cGMP): | GMP Certificate dated 31-01-2027. FSC No. 148/2024 dated 16-12-2024. |
| | Details of Authorization Letter : | Scanned LOA dated 26-03-2025 valid for one year. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | N/A |
| | **Evaluation Remarks** | |
| | 1. The firm has submitted stability data of 12 months while proposed shelf life is 24 months. The firm has provided following committment: "We commit to the continuous monitoring and evaluation for Premvac ND vaccine over the full 24 months period to ensure its stability, potency, and overall efficacy. Regular assessments will be conducted, including physical characterization, potency testing, and immune response evaluations, to confirm that the vaccine maintains its intended quality and performance. Any variations or deviations observed will be thoroughly investigated, and appropriate actions will be taken to uphold the vaccine's reliability. This ongoing commitment reflects our dedication to ensuring the highest standards of vaccine safety and effectiveness." 2. The LOA is expired. | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case for submission of following by the firm:<br><br>1. Immunological relevance and need of applied strain for Pakistan.<br><br>2. Stability study data of 03 commercial batches up to the proposed shelf life along with COAs of these batches. | |
| 86 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Genix Pharma (Pvt) Ltd,** Plot No. 44-45-B, Korangi Creek Road, Karachi **(0640)** |
| | Application Form Dy. No / Tracking ID & date of submission | (ZN8-6W1-HN3Q, 2026-04-15) |
| | Detail of Fee Submitted | 300000.0,<br>2025-07-15, |
| | The proposed proprietary name / brand name | **ADALIMOMAB** |

| | | |
|---|---|---|
| | Label Claim | Each 0.4 ml single dose of pre-filled syringe contains:<br>Adalimumab.....40 mg. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1x1's-As per SRO |
| | Shelf Life (Unit) | 2 YearsStore between + 2°C and + 8°C |
| | For generic drugs (me-too Status) | Schazoo Pharmaceutical Laboratories(Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | M/s Shilpa Biologicals Private Limited-Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India,580011.-India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Name, address of Marketing Authorization Holder: | Genix Pharma (Pvt) Ltd. Karachi, 44,45-B Korangi Creek Road, Karachi 75190 Pakistan , Pakistan |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | AbbVie Inc. North Chicago, IL 60064 U.S.A. |
| | **Evaluation Remarks** | |
| | Registration Board in its 357th meeting decided to ask M/s Martin Dow Marker Limited, Karachi for clarification regarding authorization of M/s Genix Pharma (Pvt.) Ltd., Karachi for Adalimumab 40mg Injection manufactured by M/s Shilpa Biologicals Private Limited, India already approved in name of M/s Martin Dow Marker Limited, Karachi in 351st meeting of Registration Board. Before 357th meeting, an email was sent to the manufacturer abroad on 06-04-2026: "two different importers/ indenters have applied for registration of subject mentioned Biological Drug in Pakistan proposed to be imported from M/s Shilpa Biologicals Private Limited, Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India: 1. M/s Martin Dow Marker Limited, Karachi. 2. M/s Genix Pharma, Karachi. It is pertinent to mention that both the agents have submitted Letter of Authorizations (LOAs) in their name from above said manufacturer. M/s Martin Dow Marker Limited, Karachi has provided scanned legalized LOA duly signed by Mr. Balaji Sunkara while M/s Genix Pharma, Karachi has provided scanned LOA digitally signed by Mr. Balaji Sunkara. As per prevailing policy for registration of drugs in Pakistan, only one importer/ indenter can import a drug from particular manufacturer. Hence, it is requested to confirm which of the above mentioned importers/ identers is sole authorization holder of M/s Shilpa Biologicals Private Limited, Plot 532-A, Belur Industrial Area, Dharwad, Karnataka, India for registration of subject mentioned Biological Drug in Pakistan." Following response of email has been received on 04-06-2026: "Greetings from Shilpa Biologicals Private Limited! Thank you for your email regarding the issue of having two different importers/indenters for the registration of our Adalimumab with DRAP, Pakistan. Being a product manufacturer, we would like to clarify that we intend to proceed with M/s Martin Dow Marker Limited, Karachi. Accordingly, we kindly request you to consider M/s Martin Dow Marker Limited as the sole authorized agent for the registration and import of our Adalimumab with DRAP, Pakistan." | |
| | **Decision** | |
| | **Rejected**<br><br>Keeping in view the email of M/s Shilpa Biologicals, India dated 04-06-2026; Registration Board rejected the application due to non-availability of Sole Agency Authorization in name of applicant from Market Authorization Holder abroad. | |
| 87 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Macter International Limited** F-216 S.I.T.E. Karachi-Pakistan. **(022)** |

| | | |
|---|---|---|
| | Application Form Dy. No / Tracking ID & date of submission | (1DJ-8A3-1E4V, 2025-08-15) |
| | Detail of Fee Submitted | 300000.0, 9400<br>2025-05-07, 2026-04-17 |
| | The proposed proprietary name / brand name | **V-tox** |
| | Label Claim | Each single dose vial contains 100 units of Clostridium Botulinum toxin Type A as a powder for injection. Upon reconstitution with 2.5 mL of sterile, preservative-free 0.9% sodium chloride injection, the solution yields a concentration of 4 units per 0.1 ml. |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | 1's-As per SRO |
| | Shelf Life (Unit) | 2 YearsStore the reconstituted V-tox in refrigerator at 2°C to 8°C & do not freeze. |
| | For generic drugs (me-too Status) | Botox powder for injection by Barrett Hodgson Pakistan |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | BNC KOREA Co., Ltd.-11, Cheomdan-ro 7-gil, Jeju-si, Jeju-South Korea |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | |
| | Name, address of Marketing Authorization Holder: | BMI KOREA CO. LTD., 11, Cheomdan-ro 7-gil, Jeju-si, Jeju-do, Republic of Korea |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | The status in reference regulatory authorities | FDA & EMA |
| | **Evaluation Remarks** | |
| | The firm was asked to clarify the subtype of Botulinum Toxin A as registered in USFDA. However, the firm has not clarified the subtypes instead submitted that these subtypes are US non-proprietary names that are not applicable to Korea. Moreover, the firm has requested for indications as approved for Botox Cosmetics in FDA. In Botox cosmetic, the subtype is Onabotulinum. Moreover, in 351st meeting, Registration Board while considering a similar type of application of M/s Ghazi Brother decided as follows: "Registration Board referred the case to DRAP Authority for guidance on processing of registration of products like Botox like having Clostridium Botulinum Toxin A as active ingredient." | |
| | **Decision** | |
| | **Deferred**<br><br>Registration Board deferred the case till finalization of Policy by DRAP Authority for such products as already referred by the Board in its 351st meeting. | |
| 88 | Case Category | Routine (M. Zubair Masood) |
| | Name, address of Applicant. | **Lab Diagnostic Systems (SMC) Pvt. Ltd.** 36-A, PSIC, SIE, Taxila, Rawalpindi, Pakistan **(01-374-0006-118530D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (86D-8UB-M2YP, 2026-06-08) |
| | Detail of Fee Submitted | 313500,<br>2026-03-20, |
| | The proposed proprietary name / brand name | **Tetanus Vaccine, Adsorbed** |

| | | |
|---|---|---|
| | Label Claim | Each 0.5 ml of Tetanus Vaccine, Adsorbed contains:<br>Tetanus Toxoid antigen.....4.5 Lf |
| | Reference to Finished product specifications | As per Innovators Specification |
| | Proposed Pack Size | Prefilled Syringe, 1 syringe/box-As per SRO |
| | Shelf Life (Unit) | 24 Year(s)Store and transport between 2°C and 8°C, and protect from light. |
| | For generic drugs (me-too Status) | Imatet Registration No. 017373 0.5 mL injection (ampoule/syringe) Pack Size: 10* 0.5ml. Amson Vaccines & Pharma (Pvt.) Ltd. |
| | Pharmacotherapeutic Group of (API) | Human Vaccine |
| | Name, address of Manufacturing site: | Sinovac Life Sciences Co., Ltd. -No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P. R. China No. 37, Simiao Road, Daxing Biomedicine Industrial Base of Zhongguancun-China |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | N/A |
| | Name, address of Marketing Authorization Holder: | Sinovac Life Sciences Co., Ltd. , No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P. R. China , China |
| | Details of Certificates (CoPP/FSC/cGMP): | CoPP No. Beijing20260144 dated 30-03-2026. |
| | Details of Authorization Letter : | LOA dated 27-03-2026. |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Three Batches: TT-202303003, TT-202303004, TT-202303005 Condition: 5℃±3℃ Frequency: 0, 1, 2, 3, 6, 9 months |
| | The status in reference regulatory authorities | TT VACCINE,Tetanus Toxoid Vaccine Adsorbed Manufacturer:PT Bio Farma (Persero) WHO Prequalified |
| | **Evaluation Remarks** | |
| | Registration Board in its 359th meeting deferred the case for submission of following by the firm: Pharmacovigillence system and Risk Management Plan developed by the Importer? Immunogenicity study data under clinical studies in comparison with any product approved by Reference Regulatory Authorities approved by Registration Board. The firm has submitted Pharmacovigillence system and Risk Management Plan developed by the Importer? Randomized, Double-Blind, Positive-Control Phase I/III Clinical Trials toEvaluate the Safety and Immunogenicity of Tetanus Vaccine, Adsorbed inAdults Aged 18–44 Years in comparison with an already licensed vaccine in China. | |
| | **Decision** | |
| | **Approved**<br><br>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. | |
| 89 | Case Category | Priority As Per 257-M of RB (Muneeb Ahmed Cheema) |
| | Name, address of Applicant. | **HOSPITAL SERVICES & SALES** 13-C Annexe, Block 6, PECHS, Shahrah e Faisal **(0398)** |
| | Application Form Dy. No / Tracking ID & date of submission | (Q5T-HHB-LLBY, 2026-06-27) |

| | | |
|---|---|---|
| | Detail of Fee Submitted | 313500,<br>2026-04-02, |
| | The proposed proprietary name / brand name | **Poliomyelitis vaccine (Inactivated), 10 Dose Vial** |
| | Label Claim | Each dose of 0.5 ml contains: Inactivated poliomyelitis virus type 1, Mahoney * 40 D antigen units Inactivated poliomyelitis virus type 2, MEF-I * 8 D antigen units Inactivated poliomyelitis virus type 3, Saukett * 32 D antigen units 2-Phenoxyethanol 2.5 mg Formaldehyde 12.5 mcg *Cultivated on vero-cells. |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | - 10 Dose x 5 ml Vial (Box of 25 Vials)-Controlled |
| | Shelf Life (Unit) | 36 Year(s)+2° C and +8° C |
| | For generic drugs (me-too Status) | Imovax Polio Vaccine MD, Inactivated by Sanofi Aventis – France (Now Hoechst Pakistan), Reg. # 077526 |
| | Pharmacotherapeutic Group of (API) | Inactivated Vaccine against Polio |
| | Name, address of Manufacturing site: | Serum Institute of India Pvt. Ltd.-212/2, Hadapsar, Pune - 411 028, INDIA.-India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | NA |
| | Name, address of Marketing Authorization Holder: | Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune - 411 028, INDIA., India |
| | Details of Certificates (CoPP/FSC/cGMP): | WHO PQ Product |
| | Details of Authorization Letter : | NA |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability Data of Drug Substance is sufficient |
| | The status in reference regulatory authorities | WHO PQ Product |
| | **Evaluation Remarks** | |
| | Poliomyelitis Vaccine (Inactivated), produced by Serum Institute of India Pvt. Ltd., is a sterile suspension of three types of inactivated poliovirus: Type 1 (Mahoney), Type 2 (MEF-1), and Type 3 (Saukett). Poliomyelitis Vaccine (Inactivated) is a highly purified, inactivated poliovirus vaccine. Each of the three strains of poliovirus is individually grown in vero cells, a continuous line of monkey kidney cells cultivated on microcarriers. Polio vaccine is manufactured from the bulk imported from Bilthoven Biologicals B.V., Bilthoven, The Netherlands. The vaccine meets the requirements of W.H.O. when tested by the methods outlined in the current W.H.O. requirements. Poliomyelitis vaccine mutidose \| WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control) | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in WHO PQ status; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. | |
| 90 | Case Category | Priority As Per 257-M of RB (Muneeb Ahmed Cheema) |
| | Name, address of Applicant. | **HOSPITAL SERVICES & SALES** 13-C Annexe, Block 6, PECHS, Shahrah e Faisal **(0398)** |
| | Application Form Dy. No / Tracking ID & date of submission | (GZL-999-MMGT, 2026-06-27) |

| | | |
|---|---|---|
| | Detail of Fee Submitted | 313500,<br>2026-04-02, |
| | The proposed proprietary name / brand name | **Poliomyelitis Vaccine (Inactivated) - 5 Dose Vial** |
| | Label Claim | Each dose of 0.5 ml contains: Inactivated poliomyelitis virus type 1, Mahoney * 40 D antigen units Inactivated poliomyelitis virus type 2, MEF-I * 8 D antigen units Inactivated poliomyelitis virus type 3, Saukett * 32 D antigen units 2-Phenoxyethanol 2.5 mg Formaldehyde 12.5 mcg *Cultivated on vero-cells. |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 5 Dose x 2.5ml Vial (Box of 50 Vials)-Controlled |
| | Shelf Life (Unit) | 36 Year(s)+2°C and +8°C |
| | For generic drugs (me-too Status) | Imovax Polio Vaccine MD, Inactivated by Sanofi Aventis (Now Hoechst Pakistan), Reg. No. 077526. |
| | Pharmacotherapeutic Group of (API) | Poliomyelitis Vaccine (Inactivated) |
| | Name, address of Manufacturing site: | Serum Institute of India Pvt. Ltd. -212/2, Hadapsar, Pune - 411 028, INDIA.-India |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | NA |
| | Name, address of Marketing Authorization Holder: | Serum Institute of India Pvt. Ltd. , 212/2, Hadapsar, Pune - 411 028, INDIA., India |
| | Details of Certificates (CoPP/FSC/cGMP): | WHO PQ Product |
| | Details of Authorization Letter : | NA |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Stability data provided is sufficient |
| | The status in reference regulatory authorities | WHO PQ Vaccine |
| | **Evaluation Remarks** | |
| | Poliomyelitis Vaccine (Inactivated), produced by Serum Institute of India Pvt. Ltd., is a sterile suspension of three types of inactivated poliovirus: Type 1 (Mahoney), Type 2 (MEF-1), and Type 3 (Saukett). Poliomyelitis Vaccine (Inactivated) is a highly purified, inactivated poliovirus vaccine. Each of the three strains of poliovirus is individually grown in vero cells, a continuous line of monkey kidney cells cultivated on microcarriers. Polio vaccine is manufactured from the bulk imported from Bilthoven Biologicals B.V., Bilthoven, The Netherlands. The vaccine meets the requirements of W.H.O. when tested by the methods outlined in the current W.H.O. requirements. Poliomyelitis Vaccine (Inactivated) \| WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control) | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in WHO PQ status; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. | |
| 91 | Case Category | Routine (Muneeb Ahmed Cheema) |
| | Name, address of Applicant. | **QAS INTERNATIONAL** PLOT # 153/155, MUSTAFA ABAD TEHSIL KAMOKE **(09-341-0134-103105D)** |
| | Application Form Dy. No / Tracking ID & date of submission | (A8L-JPS-97NT, 2025-07-04) |
| | Detail of Fee Submitted | 300000.0, 9400.0<br>2025-07-02, 2025-08-27 |
| | The proposed proprietary name / brand name | **ANIVAC FAdV 5** |

| | | |
|---|---|---|
| | Label Claim | Fowl Adenovirus (FAdV) Serotype 2, 4, 8a, 8b and 11 Fowl Adenovirus Serotype 2 > 1x106.5 TCID50 Fowl Adenovirus Serotype 4 > 1x106.5 TCID50 Fowl Adenovirus Serotype 8a > 1x106.5 TCID50 Fowl Adenovirus Serotype 8b > 1x106.5 TCID50 Fowl Adenovirus Serotype 11 > 1x106.5 TCID50 |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 500ml/1000 doses-De-Controlled |
| | Shelf Life (Unit) | 12 MonthStore at 2 ~ 8°C |
| | For generic drugs (me-too Status) | ANIVAC FAdV 5 |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | SAN Group Biotech Germany GmbH-Muehlenstraße 13 49685 Hoeltinghausen Germany-Germany |
| | Name, address of Marketing Authorization Holder: | SAN Group Biotech Germany GmbH, Muehlenster 13, 49685 Hoeltinghuasen,, Germany |
| | Details of Certificates (CoPP/FSC/cGMP): | |
| | Details of Authorization Letter : | |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | |
| | **Evaluation Remarks** | |
| | In compliance to decision of 358th meeting of Registration Board the response is as under:The stability study report for ANIVAC FAdV5 demonstrates that three consecutive commercial-scale batches (500 L each) were evaluated under both real-time (2–8°C, up to 12 months) and accelerated (25 ± 2°C, up to 6 months) stability conditions. Throughout the study, all batches consistently met the predefined specifications for potency (>10^6.5 TCID50/dose), sterility, inactivation, emulsion integrity, and appearance, with no deviations, out-of-specification results, or quality deterioration observed. The data confirm that the vaccine remains stable under the recommended storage conditions (2–8°C) and adequately supports the proposed shelf life and product quality throughout its intended expiry period. The submitted regulatory clarification explains that ANIVAC Mg, Ms, and ANIVAC FAdV5 are autogenous inactivated veterinary vaccines, which constitute a distinct regulatory category under the EU framework and are not subject to the conventional marketing authorisation or commercial registration requirements applicable to standard veterinary vaccines. The letter cites official regulatory provisions and guidance from the European Union, Germany (Paul-Ehrlich-Institut), France, Austria, and Spain to demonstrate that such products are regulated through manufacturer authorisation, GMP compliance, competent authority oversight, veterinary prescription, and epidemiological justification, rather than country-of-origin product registration.Howeever the firm submits evidence of their registration in Jordan. Registration Board in its 357th meeting referred the case to Expert Working Group on Veterinary Drugs for their opinion regarding safety, efficacy data submitted by the firm and antigenic similarity of applied product with Pakistani field isolate as recommended by M/s NFS&R. EWG in its 10th meeting recommended the product for grant of Registration | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in view the recommendations of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. | |
| 92 | Case Category | Routine (Muneeb Ahmed Cheema) |
| | Name, address of Applicant. | **QAS INTERNATIONAL** PLOT # 153/155, MUSTAFA ABAD TEHSIL KAMOKE **(09-341-0134-103105D)** |

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|---|---|---|
| | Application Form Dy. No / Tracking ID & date of submission | (1NN-RD7-YZJP, 2025-07-25) |
| | Detail of Fee Submitted | 300000.0, 9400<br>2025-07-22, 2026-02-17 |
| | The proposed proprietary name / brand name | **ANIVAC Mg, Ms** |
| | Label Claim | Active substances Quantity per dose (0.5 ml)<br>Mycoplasma gallisepticum > 1x107 CFU<br>Mycoplasma synoviae > 1x107 CFU |
| | Reference to Finished product specifications | European Pharmacopeia |
| | Proposed Pack Size | 500ml/1000 doses-De-Controlled |
| | Shelf Life (Unit) | 12 MonthStore at 2 ~ 8°C |
| | For generic drugs (me-too Status) | ANIVAC Mg, Ms |
| | Pharmacotherapeutic Group of (API) | |
| | Name, address of Manufacturing site: | SAN Group Biotech Germany GmbH-Muehlenstr. 13 49685 Hoeltinghausen GERMANY-Germany |
| | Name, address of Marketing Authorization Holder: | Ahmed Saleem Goriya, Plot # 153/155, Mustafa Abad, Tehsil Kamoki, District 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** | |
| | In compliance to decision of 358th meeting of Registration Board the response is as under:The stability study demonstrates that ANIVAC Mycoplasma gallisepticum and Mycoplasma synoviae Inactivated Vaccine remains stable under both real-time (2–8°C for up to 12 months) and accelerated (25 ± 2°C for up to 6 months) storage conditions across three consecutive commercial-scale batches. Throughout the study, the vaccine consistently met all predefined specifications for potency, identity, sterility, inactivation, emulsion stability, and appearance, with no deviations, out-of-specification results, or evidence of quality deterioration. These findings support the proposed shelf life and recommended storage condition of 2–8°C. The submitted regulatory clarification explains that ANIVAC Mg, Ms, and ANIVAC FAdV5 are autogenous inactivated veterinary vaccines, which constitute a distinct regulatory category under the EU framework and are not subject to the conventional marketing authorisation or commercial registration requirements applicable to standard veterinary vaccines. The letter cites official regulatory provisions and guidance from the European Union, Germany (Paul-Ehrlich-Institut), France, Austria, and Spain to demonstrate that such products are regulated through manufacturer authorisation, GMP compliance, competent authority oversight, veterinary prescription, and epidemiological justification, rather than country-of-origin product registration. However, the firm has submitted evidence of their registration in Jordan. Registration Board in its 357th meeting referred the case to Expert Working Group on Veterinary Drugs for their opinion regarding safety, efficacy data submitted by the firm and antigenic similarity of applied product with Pakistani field isolate as recommended by M/s NFS&R. EWG in its 10th meeting recommended the product for grant of Registration | |
| | **Decision** | |
| | **Approved**<br><br>Keeping in view the recommendations of EWG; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. | |
| 93 | Case Category | Priority As Per 257-M of RB (Muneeb Ahmed Cheema) |
| | Name, address of Applicant. | **Biological Production Divison, National Institute of Health** National Institute of Health |

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|---|---|---|
| | | **(000092)** |
| | Application Form Dy. No / Tracking ID & date of submission | (BSB-VYA-YX2S, 2026-07-03) |
| | Detail of Fee Submitted | 38700,<br>2026-03-12, |
| | The proposed proprietary name / brand name | **Tetanus Toxoid (Adsorbed)** |
| | Label Claim | Each dose (0.5ml)contains: Tetanus Toxoid .....NLT 40IU |
| | Reference to Finished product specifications | Any Other |
| | Proposed Pack Size | 10-As per SRO |
| | Shelf Life (Unit) | 2 Year(s)Store in a refrigerator (2°C – 8°C). |
| | For generic drugs (me-too Status) | Tetanus Toxoid (Adsorbed) Registration No 003842 |
| | Pharmacotherapeutic Group of (API) | Bacterial vaccines; tetanus vaccine (tetanus toxoid), used for active immunization against tetanus. ATC code: J07AM01. |
| | Name, address of Manufacturing site: | Self Manufacturing |
| | Name & address of API manufacturer | Beijing Minhai Biotechnology Co., Ltd., Zhongguancun Science Park, Daxing District, Beijing, China |
| | Detail of stability batches of drug product | Provided |
| | Documents for the procurement of API with approval from DRAP<br>(in case of Import) | - |
| | Pharmaceutical Equivalence and Comparative Dissolution Profile | NA |
| | Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| | The status in reference regulatory authorities | WHO |
| | GMP status of the firm | - |
| | Evidence of approval of manufacturing facility | Vaccine Section is available with the firm |
| | **Evaluation Remarks** | |
| | The Bulk Concentrate shall be imported from Beijing Minhai Biotechnology Co., Ltd China and shall be formulated and filled by the applicant locally. Three batches (TT-Trial-01, TT-Trial-02, and TT-Trial-03) were placed on both real-time (5 ± 3°C) and accelerated (25 ± 2°C/60% RH ± 5% RH) stability on 14 November 2025, which is the stability study start date for all three batches. The stability data demonstrated that the vaccine consistently met all predefined specifications, including identity, appearance, antigen content/potency, pH, filling volume, aluminium content, thiomersal content, free formaldehyde, sterility, bacterial endotoxins, and container closure integrity, with no significant changes affecting product quality, safety, or potency. Nonclinical and Clinical data of finished product of bulk concentrate of country of origin has also been provided. Firm submitted NMPA approval of registration of finished product of Beijing Minhai Biotechnology Co., Ltd China which is bulk concentrate supplier. | |
| | **Decision** | |
| | **Approved**<br><br>Approved. | |
| 94 | Case Category | New Molecule/Formulation (Muneeb Ahmed Cheema) |
| | Name, address of Applicant. | **Novo Nordisk Pharma (Pvt.) Ltd.** 113, Shahrah-e-Iran, Clifton **(636)** |
| | Application Form Dy. No / Tracking ID & date of submission | (PPA-B67-AZM1, 2026-06-23) |

| | |
|---|---|
| Detail of Fee Submitted | ,<br>, |
| The proposed proprietary name / brand name | **Wegovy® HD** |
| Label Claim | Each single-dose pre-filled pen contains:<br>7.2 mg semaglutide* in 0.75 mL solution. One mL of solution contains 9.6 mg of semaglutide*.<br>*human glucagon-like peptide-1 (GLP-1) analogue produced in Saccharomyces cerevisiae cells by recombinant DNA technology. |
| Reference to Finished product specifications | As per Innovators Specification |
| Proposed Pack Size | 4 pre-filled pens - single dose-As per SRO |
| Shelf Life (Unit) | 2 Year(s)Store in a refrigerator (2°C to 8°C). Keep away from the cooling element. Do not freeze. Wegovy may be stored unrefrigerated for up to 28 days at a temperature not above 30°C. Discard the pen if it has been out of the refrigerator for more than 28 days. |
| For generic drugs (me-too Status) | N/A |
| Pharmacotherapeutic Group of (API) | Antidiabetic agent; glucagon-like peptide-1 (GLP-1) receptor agonist. ATC code: A10BJ06 |
| Name, address of Manufacturing site: | Primary Packaging - Patheon Manufacturing Services LLC-5900 Martin Luther King Jr Highway Greenville, North Carolina 27834 United States -United States of America ,Secondary Packaging and Batch Release - Novo Nordisk Pharmaceutical Industries, LP-3612 Powhatan Road Clayton, North Carolina 27527 United States-United States of America |
| Pharmaceutical Equivalence and Comparative Dissolution Profile | NA |
| Name, address of Marketing Authorization Holder: | Novo Nordisk Inc.,, P.O. Box 846, 800 Scudders Mill Road, Plainsboro, NJ 08536 United States of America, United States of America |
| Details of Certificates (CoPP/FSC/cGMP): | Provided CPP indicates GMP Compliance |
| Details of Authorization Letter : | NA |
| Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies) | Provided |
| The status in reference regulatory authorities | Approved in USFDA - EMA opinion is expected in May 2026 |
| **Evaluation Remarks** | |
| **Decision** | |
| **Approved**<br><br>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 No. 01: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Agriprom Pakistan (Pvt.) Ltd., Lahore approved in 347th meeting of Registration Board.**

Following products of M/s Agriprom Pakistan (Pvt.) Ltd., Lahore were approved in 347th meeting of Registration Board as per following details:

| Name of Manufacturer | Brand Name & Composition | Pack Size & Shelf Life | Decision of RB in 347th Meeting |
|---|---|---|---|
| M/s. Beijing Centrebio Biology Co., Ltd.-No. 44, Yongda Road, Daxing bio-medicine Industrial, Base, Zhongguancun Science Park, Daxing District, Beijing-China. | CENTRE-NDFLU H9 Each dose (0.5 ml) contains: Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... 10^8.175 EID50 Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... 10^7.175 EID50 | 250ml/500 doses 18 months ($2^0$C -$8^0$C) | Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs. |
| | CENTRE-NIEA H9 Each dose (0.5 ml) of vaccine contains: Newcastle Disease Virus, Strain La Sota ..... ≥ 10^8.5 EID50 Infectious Bronchitis Virus, Strain M41 ..... ≥ 10^6.5 EID50 Egg Drop Syndrome Virus, Strain HSH23 ..... ≥ 1000 HA units Avian Influenza (subtype H9) Virus, Strain WD ..... ≥ 10^7.5 EID50 | 250ml/500 doses 18 months ($2^0$C -$8^0$C) | Keeping in view the legalized GMP & FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs. |

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 5th to 6th November, 2025:

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

Following are the observations & conclusion of Panel:

**1. <u>Observations</u>**

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

| Observation | Impact on quality and GMP compliance |
|---|---|
| The firm had provided a common production area for the manufacture of inactivated virus and bacterial vaccines. Antigen production activities | The use of a shared area for emulsification and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of |

| | |
|---|---|
| were carried out in separate, dedicated production lines; however, the emulsification and filling operations for finished product manufacturing were performed within the same area. | operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in compliance with GMP requirements for the physical and operational segregation of processes involving different biological products. |

**2. Conclusion**

Based on the virtual inspection of **M/s Beijing Centrebio Biology Co., Ltd.-No. 44, Yongda Road, Daxing bio-medicine Industrial, Base, Zhongguancun Science Park, Daxing District, Beijing-China** conducted, the documents reviewed, and the interviews held with management and technical personnel, the panel of inspectors is of the view that grant of registration for the below-mentioned embryo cultured inactivated virus vaccines is **not recommended** because of the manufacturing (emulsification and filling operations) of inactivated virus and bacterial vaccine within the same area.

**i) CENTRE-NDFLU H9**

Each dose (0.5 ml) contains:
Minimum concentration of Avian Newcastle Disease Virus, LaSota strain ... 10^8.175 EID50
Minimum concentration of Avian Influenza (subtype H9) Virus, WD strain ... 10^7.175 EID50

**ii) CENTRE-NIEA H9**

Each dose (0.5 ml) of vaccine contains:
Newcastle Disease Virus, Strain La Sota ..... ≥ 10^8.5 EID50
Infectious Bronchitis Virus, Strain M41 ..... ≥ 10^6.5 EID50
Egg Drop Syndrome Virus, Strain HSH23 ..... ≥ 1000 HA units
Avian Influenza (subtype H9) Virus, Strain WD ..... ≥ 10^7.5 EID50

**Decision of 353rd meeting:**

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

In the light of above decision, a personnel hearing letter was issued to M/s Agriprom Pakistan (Pvt.) Ltd., Lahore.

**Proceedings of 354th Meeting:**

The following representatives of the firm appeared before the Registration Board for deliberation on the matter:

i. Dr. Ali Aun
ii. Dr. Ahsan

The representatives of the firm provided justifications/clarifications regarding the observations noted by the panel during the virtual audit.

**Decision of 354th Meeting:**

After deliberation, the Registration Board decided to **defer the case for further consideration in the next meeting.**

**Decision of 357th meeting:**

Registration Board deferred to seek opinion of Licensing Division of DRAP regarding the current regulatory practice and requirement (local manufacturing) for granting same/dedicated manufacturing

sections for Killed or live bacterial or viral vaccines under the Drugs (Licensing, Registering & Advertising) Rules, 1976 so that there shall be no discrimination in the manufacturing requirement of imported and locally manufactured products.

Opinion of Licensing Division of DRAP shall be placed in Expert Working Group on Veterinary Drugs for discussion.

**Remarks of BE&R:**

The case was referred to the Licensing Division, DRAP, for soliciting its comments and opinion. The comments of the Licensing Division are reproduced below:

"As per Drug (L, R&A) Rules section 5.2 of schedule adopted under compliance framework circular document-II for PIC/s adaptation vide circular No.6-1/2026-Lic(M-314) dated 24-02-2026.

**Dedicated facilities for production**

**Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g., penicillin) or biological preparations (e.g., live microorganisms)** or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones as may be identified by the Central Licensing Board at any stage in order to minimize the risk of a serious medical hazard due to cross-contamination. Veterinary products containing ingredients similar to those used for human health and of the same quality can be manufactured in the same premises used for manufacture of pharmaceutical. Products, however, simultaneously human drugs shall not be manufactured. Non-pharmaceutical products, technical positions, such as pesticides shall not be manufactured in the same premises already used for the manufacture of pharmaceutical products. In exceptional cases of emergency, the principle of campaign working in the same facilities may be allowed by the Central Licensing Board provided that specific precautions are taken and the necessary validations are made.

**Moreover, the WHO TRS 999 regarding manufacturing of Vaccine is as under.**

**9.3 Killed vaccines, antisera and other biological products – including those made by rDNA techniques, toxoids and bacterial extracts – may, following inactivation, be manufactured on the same premises provided that adequate decontamination and cleaning measures are implemented on the basis of QRM.**

**10.3 Dedicated production areas should be used for the handling of live cells capable of persistence in the manufacturing environment, for pathogenic organisms of Biosafety Risk Group 3 or 4 and/or for spore-forming organisms until the inactivation process is accomplished and verified.** For Bacillus anthracis, Clostridium tetani and Clostridium botulinum strictly dedicated facilities should be utilized for each individual product. Up-to-date information on these and other high-risk or "special" agents should be sought from major information resources (27). Where campaign manufacture of spore-forming organisms occurs in a facility or suite of facilities only one product should be processed at any one time. Use of any pathogenic organism above Biosafety Risk Group 3 may be permitted by the NRA according to the biohazard classification of the organism, the risk assessment of the biological product and its emergency demand.

Above documents may be taken in consideration. Submitted please."

**Decision of 360th meeting:**

**Registration Board deferred the case for further deliberation.**

**Case No. 02: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccines applied by M/s Hi Tech Pharmaceuticals I-C Shadman Chowk Jail Road Lahore approved in 347th meeting of Registration Board.**

Following products of M/s Hi Tech Pharmaceuticals I-C Shadman Chowk Jail Road Lahore was approved in 347th meeting of Registration Board as per following details:

i. **Polimun SALMO (**vaccine against avian salmonellosis, polyvalent, inactivated)

One dose (0.5 ml) contains;
Inactivated antigens in the titer before inactivation:
Salmonella enteritidis strain SE-15 at least 10^8 CFU
Salmonella typhimurium strain ST-15 at least 10^8 CFU
Salmonella gallinarum strain SG-15 at least 10^8 CFU

ii. **POLIMUN ND Hitchner B1 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

Each dose contains:
Newcastle disease, strain Hitchner B1 ≥ 10^6 EID50
Avian Infectious Bronchitis, strain H-120 ≥ 10^3.5 EID50

iii. **Polimun POX (**vaccine against fowl pox, live)

Each dose (1ml) contains:
Fowl pox virus, strain Cutter ≥ 10^2.8 TCID50
Solvent contains:
Glycerol HOCH2CH(OH)-CH2OH (kh.h) – 250 ml
Brilliant blue dye E 133 - 0.5 g
Phosphate-buffered saline (PBS) - up to 1000 ml

iv. **Polimun ND CLON 124 (**vaccine against Newcastle disease of poultry, live)

Each one dose contains:
Virus of Newcastle disease, strain "La-Sota" DK-124 ≥ 10^6.0 EID50 per dose, obtained on SPF chicken embryos.

v. **Polimun ND Clone 124 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

One dose of the vaccine contains;
Newcastle disease virus, strain "La-Sota" DK-124 ≥ 10^6.0 EID50
Avian infectious bronchitis virus, strain H-120 ≥ 10^3.5 EID50.

vi. **Polimun ND inac (**vaccine against Newcastle disease, inactivated)

Each dose (0.1 ml) contains:
Newcastle disease virus strain "La Sota" DK-124 ≥ 10^9 EID50 before inactivation.

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 31-10-2025:

1- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.
2- Mr. Nafees ur Rehman, Deputy Director (H&OTC), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

**Observation**

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

| Observations | Impact on quality and GMP compliance |
|---|---|
| The firm has provided a common production area for the manufacture of inactivated viral and bacterial vaccines. Antigen production activities are carried out in separate, dedicated production lines; however, the emulsification and filling | The use of a shared area for emulsification and filling of different vaccine types (viral and bacterial) does not ensure adequate segregation of operations, increasing the potential risk of cross-contamination and mix-ups. This practice is not in |

| | |
|---|---|
| operations for finished product manufacturing are performed within the same area. | compliance with GMP requirements for the physical and operational segregation of processes involving different biological products. |
| The firm has one live bacterial vaccine among its registered products. Upon inquiry, the firm stated that this product is manufactured once per year and that no segregated area is available for live bacterial vaccine production. Instead, mixing of the live bacterial vaccine is carried out in the Antigen Preparation Room (1-2107). For filling operations, a semi-automatic filling machine installed in the live virus vaccine mixing room (1-2133) is used, and the lyophilizer is shared for the manufacture of both live virus and live bacterial vaccines. | Live viral and live bacterial products present a high risk of **biological cross-contamination**, particularly when mixing, filling, and lyophilization activities are performed in **non-segregated areas.** |
| During a virtual inspection, it was observed that inoculation and harvesting were carried out in a **laminar flow cabinet without side curtains**. Eggs were manually disinfected, inoculated, and subsequently harvested. The firm stated that the area under the laminar flow cabinet was classified as Grade A, with the surrounding environment classified as Grade B. However, without side curtains, maintaining Grade A conditions during manufacturing is challenging. | Without side curtains, **Grade A air cannot be reliably maintained** over the critical zone.<br><br>Risk of **particulate and microbial contamination** increases during inoculation and harvesting.<br><br>Proper segregation and enclosure of critical activities are recommended to maintain aseptic conditions. |

**Conclusion**

Based on the virtual inspection of **M/s "BIOTESTLAB" LLC-1/3, Listrovoho Oleksandra St., Vasylkiv, Obukhiv District, Kyiv Region, 08600-Ukraine** conducted, the documents reviewed, and the interviews held with management and technical personnel, the panel of inspectors is of the view that grant of registration for the below-mentioned products is **not recommended** taking into consideration the potential risk of cross-contamination and mix-ups as detailed in paragraph 7.

i. **Polimun SALMO (**vaccine against avian salmonellosis, polyvalent, inactivated)

One dose (0.5 ml) contains;
Inactivated antigens in the titer before inactivation:
Salmonella enteritidis strain SE-15 at least 10^8 CFU
Salmonella typhimurium strain ST-15 at least 10^8 CFU
Salmonella gallinarum strain SG-15 at least 10^8 CFU

ii. **POLIMUN ND Hitchner B1 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

Each dose contains:
Newcastle disease, strain Hitchner B1 ≥ 10^6 EID50
Avian Infectious Bronchitis, strain H-120 ≥ 10^3.5 EID50

iii. **Polimun POX (**vaccine against fowl pox, live)

Each dose (1ml) contains:
Fowl pox virus, strain Cutter ≥ 10^2.8 TCID50
Solvent contains:
Glycerol HOCH2CH(OH)-CH2OH (kh.h) – 250 ml
Brilliant blue dye E 133 - 0.5 g

Phosphate-buffered saline (PBS) - up to 1000 ml

iv. **Polimun ND CLON 124 (**vaccine against Newcastle disease of poultry, live)

Each one dose contains:

Virus of Newcastle disease, strain "La-Sota" DK-124 ≥ 10^6.0 EID50 per dose, obtained on SPF chicken embryos.

v. **Polimun ND Clone 124 + IB H120 (**vaccine against Newcastle disease and avian infectious bronchitis, live)

One dose of the vaccine contains;

Newcastle disease virus, strain "La-Sota" DK-124 ≥ 10^6.0 EID50

Avian infectious bronchitis virus, strain H-120 ≥ 10^3.5 EID50.

vi. **Polimun ND inac (**vaccine against Newcastle disease, inactivated)

Each dose (0.1 ml) contains:

Newcastle disease virus strain "La Sota" DK-124 ≥ 10^9 EID50 before inactivation.

**Decision of 353rd meeting:**

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

In the light of above decision, a personnel hearing letter was issued to M/s Hi Tech Pharmaceuticals, Lahore. Moreover, following applications have been applied by other firms on E-App from same manufacturer:

i. POLIMUN ND+IB inac– vaccine against Newcastle disease and avian infectious bronchitis,
ii. BOVIMUN 4
iii. POLIMUN REO 1133 inac – vaccine against poultry viral arthritis (tenosynovitis)
iv. POLIMUN REO 1133 – vaccine against poultry viral arthritis
v. POLIMUN La-Sota + H120 – vaccine against Newcastle disease and avian infectious bronchitis, live
vi. BOVIMUN LSD – vaccine against lumpy skin disease, live
vii. BOVIMUN NEO - vaccine against rotavirus, coronavirus infection, escherichiosis and clostridiosis in cattle, inactivated
viii. POLIMUN IBD light – vaccine against avian infectious bursal disease, Live
ix. POLIMUN ND IB EDS – vaccine against Newcastle disease virus, avian infectious bronchitis, and egg drop syndrome, inactivated
x. POLIMUN ND Hitchner B1– vaccine against Newcastle disease of poultry, live
xi. POLIMUN La-Sota – vaccine against Newcastle disease of poultry, live
xii. BOVIMUN MAST – vaccine against bovine mastitis, polyvalent, inactivated
xiii. POLIMUN IB H120

**Proceedings of 354th meeting:**

Following representative of firm appeared before Registration Board for deliberation on the matter:

**1. Brig. Khalid Mahmud Akhter(Retd) (Group head planning, int'l business development & Regulatory Affairs, Hi-Tech)**

**2. Dr. Ali Afzal (Pharmacist, Hi-Tech)**

**3. Maksim Vorohobin (Head of the Regulatory Affairs Department, Biotestlab Ukraine)**

**4. Maria Sinchuk, (Head of the Quality Department — Biotestlab Ukraine)**

The representatives of the firm provided justifications/clarifications regarding the observations noted by the panel during the virtual audit.

**Decision of 354th Meeting:**

After deliberation, the Registration Board decided to **defer the case for further consideration in the next meeting.**

**Decision of 357th meeting:**

Registration Board deferred to seek opinion of Licensing Division of DRAP regarding the current regulatory practice and requirement (local manufacturing) for granting same/dedicated manufacturing sections for Killed or live bacterial or viral vaccines under the Drugs (Licensing, Registering & Advertising) Rules, 1976 so that there shall be no discrimination in the manufacturing requirement of imported and locally manufactured products.

Opinion of Licensing Division of DRAP shall be placed in Expert Working Group on Veterinary Drugs for discussion.

**Remarks of BE&R:**

The case was referred to the Licensing Division, DRAP, for soliciting its comments and opinion. The comments of the Licensing Division are reproduced below:

"As per Drug (L, R&A) Rules section 5.2 of schedule adopted under compliance framework circular document-II for PIC/s adaptation vide circular No.6-1/2026-Lic(M-314) dated 24-02-2026.

**Dedicated facilities for production**

**Dedicated and self-contained facilities for the production of particular drugs shall be provided in addition to the general facilities such as highly sensitizing materials (e.g., penicillin) or biological preparations (e.g., live microorganisms)** or cytotoxic substances or radiopharmaceutical or veterinary immunological preparations or sterile products or for that matter such other highly active pharmaceutical products, antibiotics, hormones as may be identified by the Central Licensing Board at any stage in order to minimize the risk of a serious medical hazard due to cross-contamination. Veterinary products containing ingredients similar to those used for human health and of the same quality can be manufactured in the same premises used for manufacture of pharmaceutical. Products, however, simultaneously human drugs shall not be manufactured. Non-pharmaceutical products, technical positions, such as pesticides shall not be manufactured in the same premises already used for the manufacture of pharmaceutical products. In exceptional cases of emergency, the principle of campaign working in the same facilities may be allowed by the Central Licensing Board provided that specific precautions are taken and the necessary validations are made.

**Moreover, the WHO TRS 999 regarding manufacturing of Vaccine is as under.**

**9.3 Killed vaccines, antisera and other biological products – including those made by rDNA techniques, toxoids and bacterial extracts – may, following inactivation, be manufactured on the same premises provided that adequate decontamination and cleaning measures are implemented on the basis of QRM.**

**10.3 Dedicated production areas should be used for the handling of live cells capable of persistence in the manufacturing environment, for pathogenic organisms of Biosafety Risk Group 3 or 4 and/or for spore-forming organisms until the inactivation process is accomplished and verified.** For Bacillus anthracis, Clostridium tetani and Clostridium botulinum strictly dedicated facilities should be utilized for each individual product. Up-to-date information on these and other high-risk or "special" agents should be sought from major information resources (27). Where campaign manufacture of spore-forming organisms occurs in a facility or suite of facilities only one product should be processed at any one time.

Use of any pathogenic organism above Biosafety Risk Group 3 may be permitted by the NRA according to the biohazard classification of the organism, the risk assessment of the biological product and its emergency demand.

Above documents may be taken in consideration. Submitted please."

**Decision of 360th meeting:**

**Registration Board deferred the case for further deliberation.**

**Case No. 03: Virtual Inspection of Manufacturer Abroad for Biological product applied by M/s Aspire Life Sciences (Private) Limited, Jhelum approved in 352nd meeting of Registration Board.**

Following product of M/s Aspire Life Sciences (Private) Limited Street No. 2, Rehman Colony, Opposite Old Sadar Thana Tehsil Road, Jhelum was approved in 352nd meeting of Registration Board as per following details:

| Name of Manufacturer | Brand Name & Composition | Decision of 352nd meeting |
|---|---|---|
| M/s SHREE VENKATESH INTERNATIONAL LIMITED, Block No. 311, Kosamba Pardi Road, Village: Nandav, Taluka: Mangrol, Dist. Surat – 394125, Gujarat-INDIA. | **Ovigil GP 5000IU**<br><br>2ml Vial of Chorionic Gonadotrophin for Injection BP (5000 IU & 2ml Ampoule of Sodium Chloride Injection BP (0.9% w/v) | Registration Board approved the product subject to compliance of current Import Policy for finished drugs and submission of valid legalized COPP. |

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 23-04-2026:

1- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.
2- Mrs. Saima Hussain, Deputy Director (PE&R), DRAP, Islamabad.

Following is the recommendation of panel:

**Recommendation**

Based on the virtual inspection of M/s SHREE VENKATESH INTERNATIONAL LIMITED, Block No. 311, Kosamba Pardi Road, Village: Nandav, Taluka: Mangrol, Dist. Surat – 394125, Gujarat- INDIA, documents reviewed, interview of the management and technical personnel conducted, panel of inspectors is of the view, **not to recommend registration of below mentioned product based on the non-availability of the approval of biological section of the manufacturer by Regulatory Body of Country of origin.**

**Ovigil GP 5000IU**

2ml Vial of Chorionic Gonadotrophin for Injection BP (5000 IU & 2ml Ampoule of Sodium Chloride Injection BP (0.9% w/v)

**Decision of 360th meeting:**

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

**Case No. 04: Virtual Inspection of Manufacturer Abroad for Biological product applied by M/s PharmEvo Private Limited Karachi approved in 353rd meeting of Registration Board.**

Following product of M/s PharmEvo Private Limited Plot No. A-29, North Western Industrial Zone, Port Qasim, Karachi was approved in 353rd meeting of Registration Board as per following details:

| Name of Manufacturer | Brand Name & Composition |
|---|---|
| M/s Limited Liability Company "PK-137"-LLC PK-137, Russia 124460, Moscow, Intracity, Territory of the Silino Municiple District ,Zelenograd, Proyezed 5557-y, d.2-Russia. | **Pembro Injection 100mg/4ml**<br>One vial of 4 mL contains:<br>Pembrolizumab.....100mg |

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 23-04-2026:

1. Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.
2. Mrs. Iqra Aftab, Deputy Director (PE&R), DRAP, Islamabad.

Following is the recommendation of panel:

**Conclusion**

Based on the virtual inspection of M/s Limited Liability Company "PK-137"-LLC PK-137, Russia 124460, Moscow, Intracity, Territory of the Silino Municiple District, Zelenograd, Proyezed 5557-y, d.2-Russia, documents reviewed, interview of the management and technical personnel conducted, the panel of inspectors concludes that the grant of registration for the below-mentioned biological product is **not recommended** due to the following observations:

**Pembro Injection 100mg/4ml**
One vial of 4 mL contains:
Pembrolizumab.....100mg

I. **Dedicated and self-contained facilities for the manufacture of biological products were not available. Pharmaceutical and biological products, including COVID-19 vaccines (at the time of outbreak), manufactured in common areas on a campaign basis.**
II. **The submitted product development data and drug product dossier indicated that manufacturing activities were performed by JSC "BIOCAD" rather than M/s Limited Liability Company "PK-137".**

**Decision of 360th meeting:**

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

**Case No. 05: Virtual Inspection of Manufacturer Abroad for Veterinary Vaccine applied by M/s Pharmakon International Enterprises, Islamabad approved in 347th meeting of Registration Board.**

Following product of M/s Pharmakon International Enterprises, Islamabad was approved in 347th meeting of Registration Board as per following details:

| Name of Manufacturer | Brand Name & Composition | Decision of RB in 347th Meeting |
|---|---|---|
| M/s. Hester Biosciences Africa Limited-Plot No. 647 & 648, Tamco Industrial Estate, Kibaha Tanzania. | **PESTE DES PETITS RUMINANTS VACCINE,** Live Nigerian 75/1 Strain<br>PESTE DES PETITS RUMINANTS VIRUS, Live Nigerian 75/1 Strain…….Not Less Than (NLT) $1\times10^{2.5}$ $CCU_{50}$. | Keeping in view the legalized FSC indicating product availability in the country of origin, the Registration Board approved the product subject to compliance to the current Import Policy for finished drugs and submission of valid legalized GMP certificate of the manufacturer abroad by the applicant. |

Accordingly, the virtual inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 5th to 6th November, 2025:

1- Mrs. Anam Saeed, Deputy Director (BE&R), DRAP, Islamabad.
2- Mr. Zubair Masood, Deputy Director (BE&R), DRAP, Islamabad.

Following are the observations & conclusion of Panel:

**1. <u>Observations</u>**

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

| Observations | Potential GMP Impact |
|---|---|
| Common blending area used for mixing all types of vaccines, including | Increases the risk of cross-contamination and mix-ups between different vaccine types and microorganisms. |

| Observations | Potential GMP Impact |
|---|---|
| bacterial, viral, live, and killed/inactivated vaccines. | |
| Vaccine mixing room also used for preparation/mixing of diluent, which is non-biological. | Use of the same area for vaccine and diluent may lead to contamination, cleaning validation challenges, and increased risk of carryover residues. |
| Common filling line used for live virus vaccines and live bacterial vaccines. | Sharing of the same filling line for different live organisms creates a high risk of cross-contamination and potential contamination of one product with another live microorganism. This can adversely affect product quality, patient safety, and compliance with GMP requirements. |
| Vials transferred from DHS unloading area to filling area using open trolleys. | Open transfer of sterilized vials exposes them to the surrounding environment, increasing the risk of particulate and microbial contamination prior to filling. This practice may compromise sterility and indicates inadequate protection during material transfer. |
| Complete HVAC validation covering all required parameters is not provided. | Incomplete HVAC validation demonstrates inadequate qualification and monitoring of critical environmental control systems. Lack of documented evidence for parameters such as temperature, humidity, differential pressure, recovery, air flow pattern, and viable/non-viable particle control may result in non-compliance with GMP requirements and reduced confidence in cleanroom performance and contamination prevention. |
| Performance Qualification (PQ) reports Phase 1 and Phase 2 is provided only that had been conducted in the year 2021 with no Phase III/ongoing verification evidence. | Absence of ongoing monitoring evidence indicates insufficient lifecycle validation of the water system. This reduces assurance that the system consistently performs within qualified parameters over time. |

## 2. Conclusion

Based on the virtual inspection of **M/s Hester Biosciences Africa Limited-Plot No. 647 & 648, Tamco Industrial Estate, Kibaha Tanzania** conducted, the documents reviewed, and the interviews held with management and technical personnel, the panel of inspectors is of the view that grant of registration for the below-mentioned Live attenuated virus vaccines is **not recommended** because of the critical observations contained in paragraph 7.

**PESTE DES PETITS RUMINANTS VACCINE,** Live Nigerian 75/1 Strain

PESTE DES PETITS RUMINANTS VIRUS, Live Nigerian 75/1 Strain…….Not Less Than (NLT) $1\times10^{2.5}$ $CCU_{50}$.

**Decision of 360th meeting:**

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

**Case No. 6: Virtual Inspection of Manufacturer Abroad for Liraglid (Liraglutide) Solution for injection in prefilled Pen 18mg/3ml applied by M/s Getz Pharma (Pvt.) Ltd., Karachi approved in 351st meeting of Registration Board.**

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

| Name of Manufacturer | Brand Name & Composition | Pack Size & Shelf Life | Decision of RB in 339th Meeting |
|---|---|---|---|
| M/s. Hangzhou Jiuyuan Genetic Biopharmaceutical Co., Ltd., East of No.8th Street, Hangzhou Economic and Technological Development Zone, Hangzhou, Zhejiang, China. | Liraglid 18mg/3mL Pre-Filled Pen Solution for Injection<br>Each 3mL Pre-Filled Pen contains:<br>Liraglutide.....18mg | 1's Prefilled Pen<br>2 Years ($2^0$C -$8^0$C) | Keeping in view COPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs subject to submission of fee for pre-registration change in name of bulk labelled Pens manufacturer. M/s Getz Pharma (Pvt.) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area, Karachi shall be responsible for final batch release. |

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

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

Following are the observations & conclusion of Panel:

Observations:

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

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

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

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

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

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

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

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

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

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

**Decision of 358th meeting:**

*"The Registration Board deferred the case due to paucity of time."*

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

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

Registration Board in its 359th meeting adjourned the hearing on request of firm till next meeting. The personal hearing notice for this meeting was issued on 01-07-2026.

**Personal Hearing:**

Mr. Adnan Zahid (Director Laboratory Operations and Regulatory Management), Ms. Rehana Bano (Director Biotech Injectable Operations), Mr. Ayub Khan (Director Corporate Affairs), Mr. Saqib Siddiqui (Deputy Director Regulatory Management & Artwork Development) appeared before the Board on behalf of firm and they submitted that they are following WHO & PIC/s recommendations regarding dedication and cleaning validation for manufacturing of two rDNA products in the same section.

**Decision:**

**Registration Board decided to reinspect the manufacturer abroad by following panel of inspectors:**

i. **Mr. Ijaz Alvi, Director Drug Testing Laboratory, Rawalpindi.**
ii. **Mr. M. Zubair Masood, Deputy Director DRAP, Islamabad.**
iii. **Mr. Adil Saeed, Deputy Director DRAP, Islamabad.**

**Case No. 7: WHO Prequalified Vaccines applied by M/s Amson Vaccines & Pharma Pvt. Ltd., Islamabad.**

Following WHO prequalified vaccines were applied in 2018 by the firm as per following details:

| Sr. No. | Product License Holder & Manufacturer | Brand Name & Composition | Document Details, Pack Size & Shelf Life | Application & Fee Details |
|---|---|---|---|---|
| 1. | M/s. Biological E. Limited,<br>Plot No. 1, Biotech Park, Phase-II, Kolthur Village - 500 078, Shameerpet Mandal, Medchal - | BEVAC Vaccine Single Dose 0.5ml<br>Hepatitis B Vaccine (rDNA) BP (For Paediatric use)<br>Each dose of 0.5 mL contains: | CoPP No. 4365090/TS/2025 dated 12-03-2025 valid till 16-01-2026.<br>Sole Agency dated 26-02-2025.<br>1's Vial (0.5ml) | R&I dated 09-07-2018.<br>Fee dated 06-07-2018 |

| | | | | |
|---|---|---|---|---|
| | Malkajgiri District, Telangana State, India. | Purified HBsAg - 10µg (Microgram) | 36 Months (2-8$^0$C) | |
| 2. | M/s. Biological E. Limited, Plot No. 1, Biotech Park, Phase-II, Kolthur Village - 500 078, Shameerpet Mandal, Medchal - Malkajgiri District, Telangana State, India. | BEVAC Vaccine Single Dose 1ml Hepatitis B Vaccine (rDNA) BP (For Adult use) Each dose of 1 mL contains: Purified HBsAg - 20µg (Microgram) | CoPP No. 4365092/TS/2025 dated 12-03-2025 valid till 16-01-2026. Sole Agency dated 26-02-2025. 1's Vial (1ml) 36 Months (2-8$^0$C) | R&I dated 09-07-2018. Fee dated 06-07-2018 |

The firm has submitted letter of WHO Prequalification, but the address of manufacturer is neither mentioned on letter nor on WHO website. Moreover, CoPP submitted by the firm is also expired.

**Decision:**

**Registration Board advised DBE&R Division to write an email to WHO for confirmation of address of manufacturing site of above mentioned WHO PQ vaccines. Registration Board further advised the firm to submit valid legalized CoPPs for both products.**

**Case No. 8: Imported Veterinary Biological applied by M/s Pharmakon International Enterprises, Islamabad deferred in 344th meeting of Registration Board.**

Following product of M/s Pharmakon International Enterprises, Islamabad was deferred in 344th meeting of Registration Board as per following details:

| | |
|---|---|
| Name and address of Importer | **M/s Pharmakon International Enterprises,** 1st Floor HUM Heights, Service Road East, Sohan, Islamabad |
| Detail of DSL | **M/s Pharmakon International Enterprises,** 1st Floor HUM Heights, Service Road East, Sohan, Islamabad **DSL No.** Distribution License/DHO-ISB-433 **Expiry: 08-11-2024** |
| Type of Form Dy. No. Date of Application Fee submitted | Form 5A Dy. No. 256686 dated 08th Dec, 2022 Rs. 150,000/- |
| Name of Manufacturer & MAH | **Jinyu Baoling Bio-pharmaceutical Co., Ltd.** No. 1 Jinyu Street, Shaerqin Industrial Park of Economic and Technological Development Zone, Hohhot, Inner Mongolia, China |
| Name of exporting country | People's Republic of China |
| Brand Name + Dosage Form + Strength | **Brucellosis Vaccine, Live (Strain A19)** Brucella abortus (Strain A19) (CVCC 70202)…. $\geq 6.0\times10^{10}$ CFU per dose |
| Composition | Brucella abortus (Strain A19) (CVCC 70202)…. $\geq 6.0\times10^{10}$ CFU per dose |
| inished product specifications | Manufacturer's Specifications |
| Pharmacological Group | Live Bacterial Veterinary Vaccine |
| Shelf life | 12 Months (2-8 ºC or below -15ºC) |
| International availability | China |
| Products already registered in Pakistan | Not Registered. |

| | |
|---|---|
| Demanded Price / Pack size | Decontrolled. 20ml/bottle |
| Certificates Submitted | **CoPP/FSC:** Original, Valid, Legalized FSC, has been provided.<br>**GMP:** Legalized copy of Valid GMP certificate of foreign manufacturer has been provided.<br>**LOA:** Legalized copy of Valid LOA from MAH has been provided but is not signed.<br>. |
| Evaluator Remarks | During evaluation, following deficiencies have been observed in application;<br>• **As per available record, formulation with applied strain, is not already registered in Pakistan.**<br>• The DSL of the firm has expired on 08-11-2024.<br>• Letter of Authorization from MAH submitted, is unsigned.<br>• Stability Studies of three batches is required.<br>• Safety & efficacy studies data is required.<br>• Information regarding international availability of the product is required to be submitted. |
| **Decision of 344th meeting:**<br>*The Registration Board referred the case to sub-committee on veterinary drugs for the expert opinion of expert working group (EWG) on veterinary drugs for comments regarding immunological relevance and need of applied strain in Pakistan. Moreover, the Board directed to ask the applicant for rectification of following deficiencies in their application;*<br>• *The DSL of the firm has expired on 08-11-2024.*<br>• *Letter of Authorization from MAH submitted, is unsigned.*<br>• *Stability Studies of three batches is required.*<br>• *Safety & efficacy studies data is required.*<br>• *Information regarding international availability of the product is required to be submitted.* | |
| EWG in its 11th meeting recommended the product with special instructions on Label. Moreover, The firm's response is submitted and following are observations:<br>i. DSL is expired.<br>ii. LOA dated 07-11-2024 submitted.<br>iii. Stability study data is not submitted.<br>iv. Safety & efficacy studies data is submitted.<br>v. The Brucellosis vaccine is registered in Pakistan in name of other firms. | |
| **Decision:**<br>**Registration Board deferred the case for submission of following by the firm:**<br>**i. Labelling Information.**<br>**ii. Valid Drug Sale License of applicant.**<br>**iii. Stability study data of three commercial batches of vaccine along with their COAs.** | |

**Case No. 9: Adoption of WHO Recommendations for Influenza Vaccine Composition for the 2026-2027 Northern Hemisphere Season**

Seasonal influenza is an acute viral respiratory infection caused by influenza viruses and remains a major global public health concern. It is estimated to cause approximately one billion infections annually, including 3–5 million cases of severe illness and 290,000–650,000 respiratory deaths worldwide.

Global influenza surveillance has been conducted through the World Health Organization (WHO) Global Influenza Surveillance and Response System (GISRS) since 1952, making it the world's longest-standing platform for systematic influenza surveillance. Based on the virological and epidemiological data generated

through GISRS, WHO convenes consultations twice annually to recommend the optimal viral composition of influenza vaccines for the forthcoming influenza seasons in the Northern and Southern Hemispheres.

On 27 February 2026, following a four-day consultation involving experts from WHO Collaborating Centers and Essential Regulatory Laboratories, WHO announced its recommendations for the viral composition of influenza vaccines for the 2026–2027 Northern Hemisphere influenza season.

The recommendations take into account the continuous evolution of influenza viruses and the emergence of new circulating strains. During August 2025, a genetically distinct A(H3N2) variant (J.2.4.1, also referred to as "Subclade K") emerged and rapidly became the predominant circulating strain globally, contributing to an earlier and more intense influenza season in several countries. Influenza A viruses predominated during the surveillance period, while only low levels of influenza B/Victoria lineage viruses were detected, and no B/Yamagata lineage viruses have been detected since March 2020.

WHO recommends the following:

**Egg-based vaccines**

- an A/Missouri/11/2025 (H1N1)pdm09-like virus;
- an A/Darwin/1454/2025 (H3N2)-like virus; and
- a B/Tokyo/EIS13-175/2025 (B/Victoria lineage)-like virus.

**Cell culture-, recombinant protein- or nucleic acid-based vaccines**

- an A/Missouri/11/2025 (H1N1)pdm09-like virus;
- an A/Darwin/1415/2025 (H3N2)-like virus; and
- a B/Pennsylvania/14/2025 (B/Victoria lineage)-like virus.

WHO recommendations on influenza vaccine composition are globally recognized scientific standards and are routinely adopted by National Regulatory Authorities to facilitate the development, manufacture, licensing, and supply of influenza vaccines that are antigenically matched to the viruses expected to circulate during the upcoming influenza season. Adoption of these recommendations ensures that influenza vaccines registered in Pakistan remain aligned with current international standards and provide optimal protection against circulating influenza viruses.

In view of above it is requested to approve the adoption of the WHO recommendations issued on 27 February 2026 regarding the viral composition of seasonal influenza vaccines for the 2026–2027 Northern Hemisphere influenza season. All manufacturers and marketing authorization holders of seasonal influenza vaccines intended for the 2026–2027 Northern Hemisphere season shall ensure that their vaccine composition conforms to these WHO recommendations and submit the requisite regulatory documentation in accordance with applicable requirements.

**Decision:** **Registration Board directed the BE&R Division to ensure compliance with the WHO Recommendations for "Influenza Vaccine Composition for the 2026–2027 Northern Hemisphere influenza season for all influenza vaccines" at the time of registration and to ensure that the composition of already registered trivalent influenza vaccines is updated in accordance with the applicable WHO recommendations.**
**Registration Board further directed the BE&R Division to issue show cause notices to the registration holders of tetravalent influenza vaccines under Section 7(11)(b) and (d), read with Section 42 of the Drugs Act, 1976, requiring them to explain why registration may not be suspended/cancelled under said provisions.**

**Case No. 10:** **Request of M/s BF Biosciences Limited Lahore to import bulk concentrate instead of the already approved Ready-to-Fill (RTF) bulk for their registered Etanercept containing products**

M/s BF Biosciences Lahore has submitted a post-registration variation application under the category of change in manufacturing process, seeking approval to import bulk concentrate in place of the currently approved Ready-to-Fill (RTF) bulk for their registered Etanercept products. The details of the product and the data submitted in support of the proposed variation are provided below:

| e-App TID | Reg. No. | Product details | Approved RTF Site as per reg letter | Proposed concentrate mfg. site |
|---|---|---|---|---|
| 7NR-1ZS-RVMX | 107921 | **Eterna 25mg** (Solution for Injection in PFS) Each PFS of 0.5ml contains: Etanercept...25mg | **Bulk concentrate site:** ZELLTEK S.A. Ruta Nacional No. 168 S/N, Pasaje "El Pozo", Parque Tecnológico Litoral, Province of Santa Fe Argentina **RTF Bulk site:** (Imported in Pakistan) GEMABIOTECH S.A.U. Fray Justo Sarmiento Estate, 2350–5 Piso Edificio E2, Olivos, Partido de Vicente Lopez, Provincia de Buenos Aires Argentina | ZELLTEK S.A. Ruta Nacional No. 168 S/N, Pasaje "El Pozo", Parque Tecnológico Litoral, Province of Santa Fe Argentina |
| A5T-GD8-XED1 | 107922 | **Eterna 50mg** (Solution for Injection in PFS) Each PFS of 1ml contains: Etanercept...50mg | | |

Following data has been submitted:

1. Description of the manufacturing process, including equipment type and working capacity, process parameters
2. Justification for shifting from RTF bulk to bulk concentrate.
3. Comparability report of Etanercept injection with the Eterna Injection along with certificate of analysis and/or batch analysis data (in a comparative tabulated format) of drug product for a minimum of one production batch manufactured according to approved and proposed processes.
4. Finished product specifications
5. DRAP Clearance certificate for import API and stability data of 6 months
6. Approval of regulatory authority of country of origin (ANMAT) for production of Etanaecept API and for its use in country.
7. CoPP of Etanercept Solution for Injection issued by regulatory authority of country of origin (ANMAT) indicates product is registered and available for sale in Argentina.

**Decision**: **Registration Board acceded to the firm's request for the import of bulk concentrate from ZELLTEK S.A., Ruta Nacional No. 168 S/N, Pasaje "El Pozo", Parque Tecnológico Litoral, Province of Santa Fe, Argentina, for local formulation, filling, and packaging of Eterna 25 mg (Reg. No. 107921) and Eterna 50 mg (Reg. No. 107922).**

**Case No. 11: Termination of Sole Agency Authorization in Name of M/s Immunowell Pvt Limited Lahore for Sinovac Varicella Vaccine (Reg. No: 115173)**

Below mentioned human vaccine has been registered in name M/s Immunowell Pvt Limited Lahore as per particulars below:

| Reg. No. | Product details | MA Holder and Manufacturer | Pack size & shelf life |
|---|---|---|---|
| 115173 | **Sinovac Varicella Vaccine** (Lyophilized Vaccine) | **Vaccine Manufacturer:** | 1's vial + 1's Ampoule |

| | | | |
|---|---|---|---|
| | Each vial of 0.5mL (after reconstitution) contains:<br>Live varicella herpes zoster virus ≥ 3.3lg PFU<br>**Diluent:**<br>Each ampoule contains:<br>Water for Injection…0.5ml | Sinovac (Dalian) Vaccine Technology Co., Ltd., 36 2nd Life Road, DD Port, Economic and Technical Development Zone, Dalian China<br><br>**Diluent Manufacturer:**<br>Jiangsu Desano Pharmaceutical Co., Ltd., China | 24 Months<br>(2ºC 8ºC) |

2. M/s Sinovac (Dalian) Vaccine Technology Co., Ltd., China, the Product License Holder (PLH) of the above-mentioned registered vaccine, has terminated the distribution agreement pertaining to the above vaccine, as communicated through termination letter dated 01st January 2026.

3. The termination of sole agency/ distribution agreement by the manufacture abroad, invokes the provisions of Section 7 (11) (b) (c) and 42 of the Drug Act, 1976 & Rule 24 (17) of Drugs (Licensing, Registering & Advertising) Rules, 1976.

4. Accordingly, a show cause notice was issued to the applicant on 18th June 2026. In response of the notice firm has submitted a reply through e-App which is reproduced as under:

"*The core need of any authorization / agency agreement is:*

1. *Registration of Product,*
2. *Regular import/business,*
3. *Availability of products in the country,*
4. *Coverage of clients,*
5. *Future plans & goodwill.*

*In our case:*
*1. Registration of the Product*
*Registration of Sinovac Varicella is intact up to February 2029.*
*2. Regular Import / Business*
*Since the registration of the product, regular import has been made without any gap.*
*3. Availability of the product in the country*
*Availability of the product remained 100% right from the Peshawar to Karachi.*
*4. Coverage of Clients*
*There is no pediatrician in the country who has not used / known to Sinovac Varicella Vaccine.*
*5. Future plan & goodwill*
*Before registration of Sinovac Varicella in Pakistan, the Punjab Province continued to purchase Varicella Vaccine only 2,000 doses per annum.*
*After registration of Sinovac Varicella it became the only (single) qualifier for this tender of Varicella Vaccine.*

*Keeping in view that we (Sinovac) are single qualifiers for this tender we started efforts to increase quantity. It took us one and half years to create demand of 75,000 doses.*
*Now, at the moment, the required quantity of varicella vaccine by Govt. of Punjab is 75,000 doses. This tender is ready and will be floated any time. This is the evidence of our efforts to make the Sinovac Varicella Vaccine No.1 brand in Pakistan. The Sinovac will enjoy this tender of 75,000 doses anytime.*
*If the cancellation is made, we will lose a business of Rs. 285 million for which Sinovac is the only qualifier.*
*Soft copy of NOC*
*The soft copy of NOC was exchanged during negotiations process with the view that*
*"As the original hard copy of authorization letter is mandatory similarly the original hard copy of NOC will also be mandatory for cancellation of registration".*

*Surely the Registration Board will ask for an original hard copy of NOC from the manufacturer. We have not issued that one up till now.*
*Our performance and cooperation are unchallengeable the above are ground realities and can be verified by any third party. Therefore, there is no solid reason / logic for the cancellation of authorization of ImmunoWell (Pvt) Ltd., for Varicella Vaccine. This is nothing but the blackmailing to increase the price.*
*We request the Honorable Registration Board to direct the manufacturer to maintain regular supply and cooperation so that this vaccine remains available for the public of Pakistan. If respected Board is not satisfied with our above arguments we request for personal hearing".*

An email was also sent to the manufacturer i.e., Sinovac (Dalian) Vaccine Technology Co., Ltd., Dalian China on 17.06.2026 wherein they reconfirm the termination of agreement with M/s Immunowell Pvt Limited Lahore for Sinovac Varicella Vaccine and transferred product rights to M/s Lab Diagnostic Systems (SMC) Pvt. Ltd. Taxila Rawalpindi.

Moreover, personal hearing notice was issued to the firm on 23rd June 2026 and 29th June 2026 through DRAP e-APP system vide Tracking ID: E2Q-ZPN-8L8B and through UMS.

**Proceedings of Board:**

No representative of M/s Immunowell (Pvt.) Limited, Lahore, appeared before the Registration Board despite due notice. Registration Board considered and deliberated upon the written response submitted by the registration holder in reply to the Show Cause Notice dated 18 June 2026. Upon examination of the record, the Board noted that the overseas manufacturer has terminated its agreement with M/s Immunowell (Pvt.) Limited, Lahore, in respect of the Sinovac Varicella Vaccine and same has been reconfirmed by the Division in response to an email. Therefore, in these circumstances, Registration Board is satisfied that the registration holder has ceased to possess the requisite authorization and legal entitlement from the manufacturer to import, distribute and market the registered product in Pakistan. Consequently, the very basis upon which the registration was granted no longer subsists.

**Decision:** **In view of the foregoing facts and circumstances, Registration Board cancelled registration of Sinovac Varicella Vaccine registered vide No. 115173 in name of M/s Immunowell Pvt Limited Lahore under Section 7(11)(b) and (d), read with Section 42 of the Drugs Act, 1976 in light of termination of sole agency agreement by the manufacturer abroad i.e., Sinovac (Dalian) Vaccine Technology Co., Ltd China.**

**Case No. 12: Additional data requirements for Biological Drug Products (rDNA) Manufactured Locally Through Fill-and-Finish Operations**

1. A legalized Certificate of Pharmaceutical Product (CoPP) for the finished biological drug product issued by the competent regulatory authority of the country of origin of the Ready-to-Fill (RTF) bulk manufacturer/supplier, demonstrating that the product is duly authorized for marketing and is freely sold in the country of origin. However, the requirement for submission of a CoPP may be waived by the Registration Board on a case-by-case basis, taking into consideration the public health need for the product and circumstances related to patent protection, market exclusivity, or other justified regulatory considerations.
2. A complete Common Technical Document (CTD) dossier for the finished biological drug product manufactured from the Ready-to-Fill (RTF) bulk, as provided by the bulk manufacturer/supplier in accordance with WHO guidelines on biosimilarity

3. A comprehensive Quality Risk Management (QRM) assessment conducted in accordance with the principles outlined in ICH Q9. The assessment shall identify, evaluate, and control potential risks associated with transportation, storage, aseptic processing, filling operations, packaging activities, environmental monitoring and control, sterility assurance, and container-closure integrity.

4. Shipping validation and/or transportation qualification studies demonstrating that predefined storage and transportation conditions, including temperature requirements, are consistently maintained throughout the distribution process from the bulk manufacturing site to the fill-and-finish facility.

5. Bulk holding-time studies demonstrating that storage of the bulk biological product prior to filling does not adversely affect its quality, safety, efficacy, or stability.

6. A comparability study demonstrating that the fill-and-finish and packaging operations do not adversely impact the quality attributes of the biological drug product. The comparability exercise shall include testing of the locally filled product against both the reference product and the finished product manufactured by the RTF bulk supplier. Analytical evaluation shall include, but not be limited to, identity, protein concentration, potency, product-related impurities, aggregate content, charge variant profile, particulate matter, sterility, bacterial endotoxins, pH, and any other product-specific critical quality attributes, as applicable.

7. Inspection of bulk manufacturer and finished product manufacturer.

**Decision:** **Registration Board directed the BE&R Division to require all applicants whose applications are currently under review to submit the above-mentioned requirements. The Board further directed that all prospective applicants shall be required to submit the same requirements as part of their applications at the time of filing.**

**Case No. 13: Change in brand name and manufacturing site of Foot and Mouth Disease Vaccine applied by M/s Vetline International, Lahore.**

M/s Vetline International, Lahore applied for change in brand name, manufacturing site & composition of their already registered product as per following details:

| Reg. No. | Existing Brand Name, Composition & Manufacturing Site | Proposed Existing Brand Name, Composition & Manufacturing Site |
|---|---|---|
| 101725 | Foot and Mouth Disease Trivalent Vaccine, Inactivated (Type O, Type A and Asia 1)<br>Each ml contains:<br>FMD virus O/HB/HK/99 strain..$10^{7}TCID_{50}$ before inactivation<br>AF/72 strain.....$\geq 10^{7.0}TCID_{50}$ before inactivation<br>Asia-1/XJ/KLMY/04 strain.....$10^{7.0}TCID_{50}$ before inactivation<br>Manufacturer: M/s Lanzhou Bio-Pharmaceutical Factory of China Animal Husbandry Industry Co., Ltd., No. 2, Yanchang Road, Lanzhou City, Gansu Province, China | CAVac FMD O+A+Asia-1<br>Each ml contains:<br>Strain shall be at least 6PD50 FMD Virus O/HB/HK/99 Strain……$10^{7}TCID_{50}$ before inactivation-<br>AF/72 Strain…….$10^{7}TCID_{50}$ before inactivation<br>Asia-1/XJ/KLMY/04 Strain……$10^{7}$ $TCID_{50}$ before inactivation.<br>Manufacturer: M/s Lanzhou Bio-Pharmaceutical Factory of China Animal Husbandry Industry Co., Ltd., No. 6, Jinzhou Road, Science and Technology City, East Lanzhou City Gansu Province, P.R.China. |

During processing the case it was observed that the FSC submitted by the firm is indicating could be freely sold instead of actual availability. Moreover, following statement is available at official website of Ministry of Agriculture and Rural Affairs of the People's Republic of China: “Starting from July 1, 2018, immunization against Asian type I foot-and-mouth disease will be suspended nationwide, and the

production and sale of vaccines containing Asian type I foot-and-mouth disease virus components will be stopped."

Accordingly, the cases of FMD vaccines from China were placed before the Board in its 353rd meeting wherein a Committee was constituted for consultative discussion on Foot and Mouth Disease Vaccines imported from different Pools than Pakistan.

The nominations from different provinces are under process. Now, firm has submitted the following:

"We respectfully submit that our Foot and Mouth Disease (FMD) Vaccine, registered in Pakistan since 2019 having Registration No. 101725 under Vet Line International, is an approved veterinary biological product and is being supplied for the prevention and control of Foot and Mouth Disease and we have applied for PRV Case on Dated: 26-11-2024 vide Tracking ID: 57A-BLS-UYYY

We are submitting the original, legalized, updated, and duly authenticated documents issued by the manufacturer for your kind consideration.

The study results were independently validated by the international reference laboratory: The Pirbright Institute, test results provide robust evidence of vaccine efficacy, confirming that the trivalent vaccine strains show broad cross-neutralization serotypes O, A, and Asia 1 circulating in Pakistan.

We would also like to bring to your kind notice that our FMD vaccine has demonstrated highly satisfactory results, confirming the vaccine's effectiveness against the circulating field strains. The study supports the vaccine's quality, safety, and efficacy and further reinforces its suitability for continued use in Pakistan.

Considering the significance of Foot and Mouth Disease and the importance of maintaining the availability of an effective and quality-assured vaccine for the livestock sector, we kindly request your esteemed office to process our application based on the enclosed updated documentation.

Furthermore, we humbly request your kind consideration for the clearance of our PRV FMD case, as the decisions regarding the recommendations are still pending and have not yet been finalized. In view of the ongoing business commitments and collaboration with our Chinese manufacturing partner, we respectfully request your office to kindly facilitate the processing and clearance of the PRV FMD case to avoid any potential delays. With Delay in this case, we are facing a lot of crises in terms of non-Availability of Qualitative Product in Pakistan.

We confirm that all submitted documents are complete, authentic, legalized where applicable, and comply with the relevant DRAP regulatory requirements."

**Decision:**

**Registration Board deferred the case till final recommendations of Committee constituted for consultative discussion on FMD Vaccines imported from different antigenic pools.**

Meeting ended with vote of thanks to and for the Chair.

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