MINUTES OF 361ST MEETING OF REGISTRATION BOARD HELD ON 21ST AUGUST, 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.	Mr. Iftikhar Ahmed Choudhury, Ex-Chief Pharmacist, Hospital Pharmacist, Government of Punjab, Lahore.	Member (Virtual)
3.	Dr. Syed Asad Ali Shah, Principal Animal Husbandry In-Service Training Institute, Peshawar.	Member (Virtual)
4.	Dr. Tehseen Fatima, Dow College of Biotechnology, Dow University of Health Sciences, Karachi.	Member
5.	Syed Adnan Rizvi, Director Drugs Testing Laboratory, Govt. of Sindh, Karachi.	Member
6.	Mr. Imranullah Khan, Director Drugs Testing Laboratory, Govt. of Khyber Pakhtunkhuwa, Peshawar.	Member
7.	Mr. Asad Abrar, Director, Drugs Testing Laboratory, Govt. of Punjab, Bahawalpur.	Member
8.	Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.	Member
9.	Mr. Muhammad Aslam, Additional Draftsman, Law & Justice Division, Islamabad.	Member
10.	Mr. Ghulam Mujtaba, Deputy Director, Representative of IPO, Islamabad.	Member (Virtual)
11.	Ch. Zeeshan Nazir Bajar, Director, Quality Assurance & Lab Testing Division, DRAP.	Member
12.	Dr. Ghazanfar Ali Khan, Director, of Biological Evaluation & Research Division, DRAP.	Member
13.	Hafiz M. Ali Tayyab, Additional Pharmaceutical Evaluation & Registration Division / Secretary Registration Board.	Member
14.	Dr. Junaid Akhtar, Director, Drugs Testing Laboratory, Govt. of Gilgit Baltistan.	Co-Opted Member (Virtual)
15.	Dr. Shah Jahan, Representative of M/o National Food Security & Research, Islamabad.	Co-Opted Member

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

Item No. I Confirmation of minutes of 360th meeting of Registration Board.

360th meetings of Registration Board were held on 07th July, 2026. Accordingly, draft minutes of the 360th meeting of Registration Board were prepared and circulated among the members through email for their perusal / approval / comments (if any). All members agreed to the draft minutes. Accordingly, fair minutes were processed to Chairman, Registration Board for perusal/approval. After approval from Chairman Registration Board, fair minutes of 360th meeting of Registration Board were circulated among concerned divisions/sections for implementation.

Decision: Registration Board confirmed the minutes of 360th meeting.

Item No. II Division of Pharmaceutical Evaluation & Registration

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 Each 100ml contains:- 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 of 360th Meeting:

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.

With ref. to above decision of the Board firm vide tracking ID: 569-VNB-S912 has submitted all requisite documents.

Decision: **Registration Board decided to approve above product in the name of M/s. N.B.S. Pharma, 8-KM, Thoker Raiwand Road, Lahore.**

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 Each ml contains: Hydroxyprogesterone caproate....……250mg	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore	Renewal is not yet due
2.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is not yet due
3.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate....……250mg	M/s. Zafa Pharmaceutical, Karachi.	Renewal is valid

4.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate…. 250mg	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
5.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd	Renewal Not Submitted
6.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate....……250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore	Renewal Not Submitted
7.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: Hydroxyprogesterone caproate....……250mg	Haji Medicines, Rawalpindi	Renewal Not Submitted
8.	003833	HYDROXYPROGESTRONE Each ml contains: 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 Each ml contains: Hydroxyprogesterone caproate_ 250 mg 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 Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is valid
3.	077108	Z-Bron Injection Each ml contains: Hydroxyprogesterone caproate_ 250 mg Estradiol valerate _ 5 mg	Pharma Health Pakistan (Pvt) Ltd.	Renewal is valid
4.	011155	VIO-DEPOT INJ HYDROXYPROGESTERONE CARPOATE 250MG QUESTRADIOL VALERATE 5MG SESAME OIL 693MG	Wilson's Pharmaceuticals	Renewal Not Submitted
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.**
>
> **If 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 Hydroxyprogesterone caproate....250mg	M/s. Bayer
2.	096479	Nandrosol 250mg Injection Each ml contains: Hydroxyprogesterone caproate....250mg	Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore
3.	094205	Hygest Injection Each ml contains: Hydroxyprogesterone caproate....250mg	Shaigan Pharmaceuticals (Pvt) Ltd
4.	003531	Hydroxyprogesterone Injection Each ml contains: Hydroxyprogesterone caproate....250mg	M/s. Zafa Pharmaceutical, Karachi.
5.	030526	Globinan 2Ml Injection Hydroxy Progesterone Caproate…. 250mg	Global Pharmaceuticals Pvt Ltd
6.	030525	Globinan 1Ml Injection Hydroxy Progesterone	Global Pharmaceuticals Pvt Ltd
7.	013624	VIO-DEPOT INJ Each ml contains: Hydroxyprogesterone caproate....……250mg	Venus Pharma, 23 Km Multan Road Lahore. , Lahore
8.	003746	HYDROXYPROGESTRONE INJECTION Each ml contains: 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* *Each ml contains:* *Hydroxyprogesterone caproate....250mg*	*Pharmasol (Pvt) Ltd, Plot 549, Sunder Industrial estate, Lahore., Lahore*
2.	*094205*	*Hygest Injection* *Each ml contains:* *Hydroxyprogesterone caproate....250mg*	*Shaigan Pharmaceuticals (Pvt) Ltd*
3.	*003531*	*Hydroxyprogesterone Injection* *Each ml contains:* *Hydroxyprogesterone caproate....250mg*	*M/s. Zafa Pharmaceutical, Karachi.*
4.	*030526*	*Globinan 2Ml Injection* *Hydroxy Progesterone Caproate…. 250mg*	*Global Pharmaceuticals Pvt Ltd*
5.	*030525*	*Globinan 1Ml Injection* *Hydroxy Progesterone*	*Global Pharmaceuticals Pvt Ltd*
6.	*013624*	*VIO-DEPOT INJ* *Each ml contains:* *Hydroxyprogesterone caproate.……250mg*	*Venus Pharma, 23 Km Multan Road Lahore. , Lahore*
7.	*003746*	*HYDROXYPROGESTRONE INJECTION* *Each ml contains:* *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 Each ml contains: Hydroxyprogesterone Caproate…….250mg 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 Each ml contains: Hydroxyprogesterone Caproate…….250mg Estradiol Valerate……5mg	Shaigan Pharmaceuticals (Pvt) Ltd	Renewal is valid
3.	077108	Z-Bron Injection Each ml contains: Hydroxyprogesterone Caproate……..250mg Estradiol Valerate……..5mg	Pharma Health Pakistan (Pvt) Ltd.	Renewal is valid
4.	011155	Vio-Depot Injection Hydroxyprogesterone Carpoate…… 250mg Estradiol Valerate……..5mg Sesame Oil…….693mg	Wilson's Pharmaceuticals	Renewal Not Submitted
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

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.

Decision of the 360th meeting of the Registration Board:

The Board decided to call the firm for personal hearing along with Principle Investigator.

The firm is called for personnel hearing.

Proceeding of the Board:

Mr. Kamran Mirza. Director operations and Dr . Tahir Lead Researcher of M/s Agha Khan University appeared before the board on behalf of the firm. Lead Researcher gave a brief presentation to the Board. According to their conclusion study provides the first real world institution evidence on Gravibinan use and Offspring Outcome in Pakistan. Short and Medium Term outcomes are favorable, however, the central long term safety question-which is adult onset cancer must be pursued through active long term surveillance. The representatives of the firm emphasized that reference of RRA reference product was suspended but not recalled and is still available in Germany and PMDA (Japan) and they will provide the documented evidence accordingly.

Decision:

The Board decided to constitute the following Committee:-

i. Mr. Adnan Rizvi, Director, DTL, Government of Sindh, Karachi.
ii. Dr. Tehseen Fatima, Member, Registration Board.
iii. Dr. Ali Jan, Director, Drugs Testing Laboratory, Govt. of Baluchistan Quetta.
iv. Mr. Asad Abrar, Director Drug Testing Laboratory, Bahawalpur.
v. Dr. Mahvash Ansari, Additional Director, PE&R, Coordinator.

Following shall be the TOR's of the Committee:

i. To review the details and data provided by the Company,
ii. To gather the facts of the case including Market Authorization Cases in EMA and other RRA.
iii. To evaluate the study conducted by Agha Khan University.
iv. To give its recommendations to the Board with in one month.

Case. No, 2. **REQUEST BY M/S SAMI PHARMACEUTICALS (PVT) LTD, KARACHI FOR MARKETING OF EXPORT ONLY PRODUCTION BATCHES OF NOVIDAT SUSPENSION IN LOCAL MARKET**

M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi has submitted that the firm has manufactured multiple batches of our following product for export to **Afghanistan:**

Product Name	Generic	Batch No.	Available Quantity
NOVIDAT 125mg/5ml Dry Powder Suspension	Ciprofloxacin HCl	FJM393	29,408.00
		FJM394	29,251.00
		FJM395	29,275.00
		FJM396	29,285.00
		FJM397	29,261.00
		FJM398	29,256.00
		FJM399	29,263.00

		FJM400	29,269.00
		FJM401	29,277.00
		FJM402	29,284.00
		FJM403	29,242.00
		FJM404	29,374.00
Total			**351,445.00**

However, due to the current border closures, ongoing conflict situation, and related geopolitical circumstances in Afghanistan, we are unable to proceed with our planned export operations. These unforeseen developments have resulted in significant financial constraints for our company, as we have incurred substantial manufacturing costs, raw material expenses, and operational overheads for these batches.

It is pertinent to mention that NOVIDAT Suspension (125mg/5ml and 250mg/5ml) were originally registered with Ciprofloxacin HCl. Subsequently, upon the advisory and directive of DRAP, we transitioned to the base form of Ciprofloxacin for local market compliance. However, the aforementioned export batches designated for Afghanistan were manufactured in the salt form in accordance with the importing country's requirements. It is also noteworthy that prior to the advisory, companies across Pakistan were manufacturing Ciprofloxacin in its salt form and those brands were widely available and sold throughout the country

In view of the above, we respectfully seek your kind approval for marketing these manufactured batches in the local market

Furthermore, as per the advisory F.No. 1-2/2026-(CEO) DRAP issued by DRAP dated *9th March, 2026:*

"It is mandatory to maintain appropriate buffer stocks of raw material and finished products. These reserves must be sufficient to mitigate the impact of potential delays in shipping or any other unforeseen circumstances."

Allowing utilization of the available export inventory in the local market would, inter alia, support continuity of supply and prevent unnecessary wastage of compliant pharmaceutical stock and valuable foreign exchange incurred on import. However, now the firm has withdrawn its request and decided to destroy its stock.

We look forward to your favorable response.

Submitted for Consideration of the Board

Decision:

The Board decided to defer the case for further deliberation in the next meeting.

CASE NO 3: COMPARISON OF COUNTERFEITS OF "PYODINE SOLUTION" IN COMPLIANCE WITH DIRECTIONS OF REGISTRATION BOARD

Registration Board in its 339th meeting held on 06th to 08th of August, 2024, on the directions of the Honorable Islamabad High Court, Islamabad (Order dated 03-07-2024 passed W.P No. 2073/2024) decided as under:

*"**M/s Brooks Pharma (Pvt.) Ltd. Karachi (Complainant) through representative Dr. Arif Hussain Siddique along with Council Mr. Umar Hameed Advocate appeared before Board for personal hearing/representation and presented physical samples /Bottles of allegedly counterfeit Pyodine manufacturers along with list of 26 alleged counterfeit Pyodine Products and urged their claim that these products have close resemblance and imitation with their product Pyodine.***

The Board after hearing the arguments of the firm in detail and after thorough discussion and deliberation and nominated Director QA&LT to review each individual claimed counterfeit product in comparison with Pyodine for resemblance of packs for lookalike imitation of label which may deceive the patients. The shortlisted reviewed imitation product cases on individual basis would be presented by QA/LT division before next Board meeting for consideration and further decision of the Board."

Accordingly, after extensive review by QA&LT division, following imitated / counterfeit products of "Pyodine Solution" of M/s Brookes Pharma, Karachi have been shortlisted below:

Resemblance status of Counterfeit Products of "Pyodine Solution" (Reg No. 009528)

Sr. No.	Name of the Manufacturer	Brand name	Reg. No / Product enlistment number	Resemblance parameters				Final Remarks
				Brand name	Color Scheme	Text	Graphic	
1.	M/s Cortex Pharmaceuticals, Rawalpindi. (DML No. 000826)	Pyidine Solution	080824	Yes	Yes	Yes	Yes	Both label and Brand name
2.	M/s Zanctok Pharmaceutical Laboratories, Sindh (DML No. 000251)	Zyodine Solution	045451	Yes	Yes	Yes	Yes	Both label and Brand name
3.	M/s Oval Pharmaceuticals, Lahore. (DML No. 000156)	Septodine Solution	049925	No	No	Yes	No	Only label
4.	M/s Lahore Pharma, Sheikhupura. (DML No. 000084)	Plasodine liquid	014228	Yes	Yes	Yes	Yes	Both label and Brand name
5.	M/s Paradise Pharma, Lahore. (DML No. 000742)	Povidone Iodine solution	071551	No	No	No	No	No resemblance
6.	M/s Kohinoor Industries, Sahiwal. (DML No. 000197)	Prodine Solution	037440	Yes	No	Yes	No	Both label and Brand name
7.	M/s Hoover Pharmaceuticals, Lahore. (DML No. 000676)	Poviderm Solution	094559	No	No	Yes	No	Only label revision
8.	M/s Pharmawise Labs, Lahore. (DML No. 000182)	Povine Solution	037527	Yes	No	No	No	Only Brand name
9.	M/s N.B.S. Pharma, Lahore. (DML No. 000467)	Povidone-I Solution	025552	No	No	Yes	No	Only label
10.	M/s Jawa Pharmaceuticals (Pvt.) Ltd, Lahore. (DML No. 000150)	Japodon Solution	096512	No	Yes	Yes	Yes	Only Label
11.	M/s Trigon Pharmaceuticals, Lahore. (DML No. 000342)	Halodine Solution	057302	No	Yes	No	Yes	Only Label

12.	M/s Perfect Pharma (Pvt.) Ltd. Lahore. (DML No. 000469)	Povidone Iodine Solution	026935	No	Yes	Yes	Yes	Only Label
13.	M/s Irza Pharma, Sheikhupura. (DML No. 000108)	Wondseptic Solution	030073	No	No	No	No	No resemblance
14.	M/s ISIS Pharmaceuticals & Chemical works, Karachi (DML No. 000126)	ISIS Povidone Iodine Solution	110071	No	No	Yes	Yes	Only label
15.	M/s A. Mannan Lab. Karachi.	Payodine Solution	004377	Yes	Yes	Yes	Yes	Both label and Brand name
16.	M/s Glorious Laboratories, Islamabad. (Mfg. Enl. No. 002)	Pyogon Solution	002. 0062	Yes	Yes	Yes	Yes	Both label and Brand name
17.	M/s Zaiam Pharma Nutraceuticals, Lahore. (Mfg. Enl. No. 00233)	Pyoline Solution	00233. 0001	Yes	Yes	Yes	Yes	Both label and Brand name

The findings of the Division of QA&LT are submitted for consideration by the Board.

Proceedings and Decision of 343rd Meeting of Registration Board

QA&LT Division presented the case in the light of decision of 339th meeting of Registration Board. After thorough deliberation, the Registration Board decided to proceed in the light of the findings / recommendations of Division of Quality Assurance and Laboratory Testing. Keeping in view findings / remarks of QA&LT Division, the Board decided to refer the cases as follows: -

a. Registered Drugs under Section 7 of the Drugs Act, 1976 to the Pharmaceutical Evaluation & Registration (PE&R) Division for issuance of letters to the firms for respective variations.

b. Enlisted products under SRO 412 (I)/2014 to Health & OTC Division for necessary action at their end.

3. In the light of the decision of the Registration Board, letter no. F-12/2025 (PR-I) E-App dated 15th January, 2025 was forwarded to the respective firms regarding change of brand name. label claim or both within 07 days for further necessary action.

4. The brand name resemble letter communicate to the firm vide letter no. F-12/2025 (PR-I) E-App vide 15th January, 2025 (Annex-I). However seven firms have submitted reply and the same are reproduced as below:

M/s Kohinoor industries Sahiwal submitted a reply against our letter of even number in which they stated that:-

- Why brookes Pharma used the door of honorable high court, this act is showing de-interest on respectable government institute DRAP for lable claim & similar brand name. Even this brand name allotted us from respectable institute DRAP in 1996, because we have owned the name **prodine Solution** despite of this Brookes Pharma has owned the Name of Pyodine Solution. These brand names cannot match from each other & this brand name was registered after the approval of DRAP.
- Our registered brand also does not fall under the category of counterfeit drugs. Accordingly section 3 clause (F) of The Drug Act 1976, Counterfeit Drug" means a drugs the label or outer packing of

which is an imitation of or resembles or so nearly resembles as to be calculated to deceived the label or outer packing of a drug of another manufacturer. We deny any intention to deceive the public with our product label or banding.

- With reference to letter no. 14280/2020DRAP (L-IV) we have already changed the label of this brand name through legal process. That time same competitor filed letter to your respective institute & we fully complied your letter & immediately change the label of this registered brand name **Prodine Solution.**
- The department has proceeded without giving us a fair opportunity to plead or differentiate the differences, which is in contradiction with Article-10 of constitution of Pakistan 1973. We hereby agitate the same as our fundamental right of fair trial has been breached.
- Moreover, the subject letter is based on the facts. Based on the missing facts which area necessary to be incorporated as following
- **Label differences:**
- We have already changed the label of this brand through legal process. "Prodine's" label is brown & Peach in long rectangular shape. While the label color of Brookes products "Pyodine Solution" is red and orange in color and it is in oval shape.
- **Font Style:**
- The font style of both solution is totally different from each other. Prodine Solution is written in Arial Style on bottle, while pyodine solution is pasted in Times New Roman Style on bottle
- **Pronunciation:**
- Here is vital difference in pronunciation of both words between prodine solution & pyodine solution. The Oval sound getting no break in word of prodine solution but this sound gets a break when we speak the word Pyodine Solution.
- Here are some actual facts that we area oppressed under the hand of Brookes Pharma, this firm has attached us several time by different ways.
    1. This firm filed a f=grievance in every government institute for the purpose to sale their expensive brand and trying to damage the popularity of our product.
    2. In KPK the DG health KPK rejected this firm due to quoted high rates in this institute.
    3. This firm approaching the government health officers to stop the sale in government semi-government institutes and also in market and finally this firm is declared with low handed thugs in every field. After this the firm has approached at your door.
    4. We are supplying this item in Reputable institute throughout Pakistan and not a single batch is declared substandard.
    5. The firm M/s Brookes Pharma refused to give the supplies in different government institute but the institues approached to us and we given immediate supply o no profit no loss.
    6. Our import raw material is FDA approved, our stability reports on long terms showing the excellent result. Under all the aspects this pharma use those weapon which are just open for to attain illegal means and to establish its monarchy but remain failed every time.

    We humbly request your good office to withdraw the letter keeping in view all the facts narrated above. We also hereby our right to file an appeal against this arbitrary order, if our consideration are not taken into account by your esteemed authority.

Reply of M/s. Pharmawise Lab.

- The matters of Drug & Medicine area highly technical nature which other than a Pharmacist all cannot understand. For the subject matter it is consoling that whole of the DRAP at executive level comprises of pharmacist.
- A minute study of brand names of drug and medicine reveals that the same are extracted from the Generic name of the same drug or from leading proprietary / brand name. Whole of the world market of drugs / medicine is flooded with such names. The Drug and Medicine market of we the Pakistan is no exception. For your ease and ready reference following are Symbolic examples. Not to antagonize the learned Drug Registration Board but to appreciate that now realistically the learned board has adopted it as short of such practices the system will get stuck up.

a) Tablets / suspension Ponsac of M/s. Brookes Pharma, Karachi. This name was extract from the leading proprietary / brand name Postan of M/s Pfizer. Other name are Phontan of M/s. Pharmwise Lab Protan of Proressive, Nobstan of M/s. Nawabson Lahore. Kindly appreciate that where all the above names, with many other partly qualify to be counterfeit drug as defined in drug act 1976, yet the same are helpful for the prescribed as well the patient as their phonetic sounds ensure all that the same are what the leading propiatory / brand name ponstant is
b) The same is the case with every other leading Trade Name of every Generic Name of Medicine.

- Now coming to our name Povine Solution Registration no. 037527 alleged to be counterfeit the name Pyodine Solution Registration No. 009528 of our friend M/s. Brookes Pharma Karachi it is to respectfully explain that.
    - The Generic name of both the above drug i.e. Povidine solution and pyodine is povidone iodine.
    - Only a pharmacist can appreciate who each worthy member of registration board is, that phonetic sound the above name guides that both have been extracted from the generic name Povidone Iodine.
    - It is requested to appreciate what while pronouncing loudly both the names each distinguished it from the other being different
    - Every manufacturer has equal right to extract his brand / proprietary name of Drug from it generic name the way our friend M/s. Brookes Pharma Karachi Invented their name Pyodine.
    - It seems the present management of M/s. Brookes Pharma Karachi particularly my friend learned D. Arif Hussain Siddiqui Advisor on Regulatory & Marketing Affair is not well conversant with legalities recorded as above he being not a Pharmacist.
    - In view of the submission tendered as above it is respectfully stated that we need not to tender to worthy Registration Board alternate 3 names.

Reply of M/s. Hoover Pharmaceuticals Pvt Ltd.

It is submitted that DRB in its 339th meeting has announced their decision without taking our point of view or issuing show cause notice to us.
It is incorrect to say that hoover Pharmaceuticals Pvt Ltd is involved to manufacturer any counterfeit product in particular to the alleged drug poviderm solution. The product poviderm having reg. no. 094559 has been properly registered with DRAP and the concerned department of DRAP has given us the name products after thorough and careful consideration.

Complainant Products Pyodine
Our Product Poviderm

You can find that there is a differences in 7 figure regarding sesquences / spelling of alphabet in the name of both brands. Furthermore our product Poviderm is logically based on two terms

Povi from Povidone
Derm from Skin

So there is no question that we have copied / followed that name of the product of complainant. As far as label of primary packaging is concerned it's designed and graphics are totally different from the product of complainant.
In the circumstances stated above as our product is not a counterfeit product, it is requested that initiation of any proceeding may kindly be dropped against us and the said letter may be withdrawn in the interest of justice.

Reply of M/s. ISIS Pharmaceuticals & Chemical Works.

The firm has submitted reply which say that, A close perusal of the minuets of the meeting 339th Pages 397-398 indicate that our particular case, the requirement was to change only in the text, and graphics and

as only complainant was present in the meeting with the allegation of labeling, so we request you as follow before forward with change to be made in our labeling.

a) Provide us with a clear copy of the complaint with it legal grounds.
b) Text of label is a regulatory requirement and is already approved by the registration Bo0ard. So please clarify what change has to be made.
c) Same in graphic please clarify what extract has to be change.

As per regulations in place after making changes without violating, we shall follow the procedure as laid down by DRAP, in its guideline on PR variations.

Reply of M/s. Lahore Pharma

M/s. Lahore Pharma products registered as brand name Plasodine Liquid 7.5% with under the Drug Act 1976 Plasodine Liquid 7.5% Registration no. 014228. And colour scheme of lables is not resemble to any other product.
But M/s. Brookes Pharma Karachi registered product with brand name Pyodine Solution 10% brand name & Products of color of label scheme is not resemble to M/s. Lahore Pharma labels.
Kindly accept the letter if any query about for registration of registered product plasodine liquid 7.5% we have fulfilled all requirement of registration of Plasodine liquid 7.5% according to Drug Act 1976.

Reply of M/s. Oval Pharmaceuticals

The firm mentioned that it is not manufacturing counterfeit drug. Our product septodine Antiseptic Solution 049925 packing do not resemble with Pyodine Solution 009528 of M/s. Brookes Pharma Pvt Ltd, Karachi
It is stated m/s. oval pharmaceuticals is a well know and well reputed company. We do not believe in unethical marketing practices. Label design of Septodine Antiseptic Solution is of orange color and have different segment in design which do not resemble with pyodine. Furthermore if you are not satisfied with packing we will change our label designed and color.

Reply of M/s. Zanctok Pharmaceuticals Laboratories

With reference to letter of even number dated 15-01-2025 the firm submit following point which is as under:-

- It is to put forth on record that we granted registration of the products "Zyodine " by the Registration Board after thorough review and analysis , approving the stated brand name vide Registration letter dated 09-07-2007 and later in 2009 also received approval for additional pack size 50ml &400ml with the same brand name
- That we had been succefully manufacturing and marketing the said product for the past 17s without having received any complaint regarding drug quality packaging brading etc or any instance of medicine error on account of similarity of the product brand or appearance.
- The due to established high quality efficacy and safety of our products we had obtained considerable market share and good repute among health care professional and patient both. That our brand commercial is well perceived in the market such that the name itself has wide acceptability and patient association.
- That subsequently the federal inspector of drug, Karachi referred the complaint to central drug laboratories Karachi with a sample of Zyodine 7.5% w/v Solution. For their necessary analysis. The CDL vide their test report No. KQ-4-24-000092 dated 09th May 2024 cleared our product of any such j violation an excerpt of the report finding is reproduced hereunder:

  "The sample Zyodine 7.5% w/v solution has been compared with brand leader i.e. Pyodine Solution registration number 009528, manufactured by M/s. Brookes Pharmam, Karachi. The colour scheme of the label and outer packing font size font style and graphic of the sample are different as compared with the brand leader. Therefore the sample cannot be declared as imitation product"

- That the Federal Laboratory CDL Test Report has clearly stated that our product cannot be declared as an imitation product which is to be considered as a conclusive report. The under such circumstances, where a verdict has been given on the matter filling of this suit is just another weak attempt of M/s. Brookes to create nuisance of us.
- That our brand has attained good market repute and acceptability among users over past 17 years such that requiring us to change the brand name will negatively impact our business as well as patient compliance.

In the above mentioned argument and supporting evidence it is request to withdraw the case of change of brand name and label claim. If not an opportunity for personal hearing may be given to appear before the registration board in its forth coming meeting to defend our case.

No reply is received from following firms:

1. M/s Cortex Pharmaceuticals, Rawalpindi.
2. M/s N.B.S. Pharma, Lahore.
3. M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore.
4. M/s Trigon Pharmaceuticals, Lahore.
5. M/s Perfect Pharma, Label.

Decision of the 345th meeting of the Registration Board:-
The Registration Board decided to give an opportunity of Personal Hearing to the respective firms.

M/s Perfect Pharma, Lahore has submitted that the firm will revised the label claim once it is finalized but no request regarding revised label claim is received

In the light of the decision of the Registration Board, all the firms have been called for personal hearing .

In light of above decision of the Board, firms have been called for personal hearing.

Proceedings of 346th meeting of the Registration Board:

Proceedings of Meeting:

Nine firms appeared for person hearing before the Registration Board, the detail is as under:-

S.No.	Name of the Firm	Name of Representative.	Designation.
1.	M/s. Lawrance Pharma.	Naveed Iqbal	Production Manager.
2.	M/s. Kohinoor Industries	Haroon Rashid	Director
3.	M/s. Havoor Pharma	Anjum Ishaq	Chief Executive.
4.	M/s. Pharwise	Ch. Nadir Nuaman Nadir	CEO
5.	M/s. Perfect Pharma	Nasir Hussain	Manager.
6.	M/s. Oval Pharmaceuticals	Wasim Haider	Quality Control Manager.
7.	M/s. Jawa Pharma	Ahmed Ali	Quality Control Incharge.
8.	M/s. Cortex Pharmaceutical	Muhammad Nazir	CEO
9.	M/s. Zanctok Pharmaceutical	Advocate Rashid Mureed Mr. Feroz Lasi Mr. Faisal	Council. Managing Partner. -do-

Majority of the firms contended that their products has no resemblance with the brand name and label of M/s. Brookes Pharma. The firm added that M/s. Brookes Pharma is using these tactics to get the commercial benefits in tender business for which the procurement is made after pre-qualification of the manufacturer. Representatives from M/s. Kohinoor Industries and M/s. Cortex Pharmaceuticals also presented the notice of the Registrar, Intellectual Property Tribunal, Lahore, for Case No. 98/IPT/28, filed by M/s Brookes Pharma. Date of hearing of the case is 10-05-2025.

Decision:

The Registration Board thoroughly discussed the matter and decided as under:

i. The order dated 03.07.2024 passed by the Islamabad High Court in Writ Petition No. 2073 of 2024 filed by M/s Brookes Pharma against DRAP reveals that the contention raised by the petitioner (Brookes Pharma) was of sale of counterfeit versions of PYODINE Solution (see, paragraph 2). Section 3(f) of the Drugs Act, 1976 defines "counterfeit drug" as a drug the label or outer packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer-packing of a drug of another manufacture. Section 3(o) provides a definition of "label" as a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package. Neither the Writ Petition No. 2073 of 2024 nor the representations filed by Brookes Pharma alleged the trademark infringement rather they alleged availability of counterfeit versions of PYODINE Solution in the market.

ii. It is not the prerogative of Registration Board to decide the matter of infringement of trademarks which is an exclusive domain of Intellectual Property Tribunals under section 18 of the Intellectual Property Organization of Pakistan Act, 2012. The aforesaid Act read with the Trade Marks Ordinance, 2001 have adequate provisions and remedies to which an owner or right holder of a registered trademark may resort in case of being aggrieved.

iii. Recently, in Writ Petition No. 3227/2022 titled M/s Vifor International AG Vs Drugs Appellate Board, etc, the Islamabad High Court has held that the Intellectual Property Tribunal has competent jurisdiction over the matter.

iv. Infringement of a trademark (if any) has to be established in a court of law (IP Tribunal) under the provisions of the Trade Marks Ordinance, 2001.

v. Notwithstanding anything stated hereinabove, pharmaceutical trademarks are usually coined from the drug's treatment, indication, salt composition, or any other associated medical word. Therefore, there is more degree of acceptance of resemblance between pharmaceutical trademarks around the world. Like PYODINE, other alleged marks are arbitrary word marks coined from the generic name of the product i.e. POVIDONE IODINE. No one can be allowed exclusive rights to use of generic name of the product POVIDONE IODINE.

vi. The Registration Board considers it appropriate to confine itself to the regulatory jurisdiction of the DRAP Act, 2012 and the Drugs Act, 1976 and not to encroach upon the matter to be dealt under the provisions of the Trade Marks Ordinance, 2001 by specialized IP courts.

vii. Foregoing in view, M/s Brookes Pharma may approach the IP Tribunal for any alleged infringement of its trademark 'PYODINE' (like it has already filed a Suit No, 95/IPT/28 against M/s Kohinoor Industries in the IP Tribunal, Lahore) and this Board will act accordingly in light of the determination(s) made by the Tribunal. The representation of M/s Brookes Pharma is disposed of in above terms.

M/s. Brookes has submitted an appeal against above decision of the Registration Board before the Appellate Board. Decision of 172nd meeting of the Appellate Board is as under:

1. Brookes Pharma Pvt. Ltd. (the '**Appellant**') has challenged the Decision passed by the Registration Board in its 346th Meeting held on 22.04.2025 ('**Impugned Decision**'), whereby its complaint against the manufacture and sale of counterfeits of 'PYODINE' has been disposed of.

2. Mr. Umer Hameed Khan, Advocate appearing on behalf of the Appellant argued in brief that the impugned order is passed without granting an opportunity hearing to the appellant. The drug regulatory framework provides a comprehensive and self-contained mechanism for the identification and determination of a *"counterfeit drug,"* which being 'criminal' in nature, is distinct and independent from the procedures and standards set out under intellectual property laws, which protect the civil property rights.

3. At the very outset, the Board took note of the fact that the Appellant had submitted an Affidavit affirming that no appeal or other proceedings pertaining to the matter in hand are pending before any court of law or forum. However, it was brought to the Board's attention that the Appellant has instituted four separate civil suits before the learned Intellectual Property Tribunal, Lahore, against four different companies for alleged infringement of its intellectual property rights. Upon query, learned Counsel for the Appellant clarified that the subject matter of the said suits is not the Impugned Order passed by the Registration Board in its 346th meeting. Rather, they pertain strictly to the claims of trademark infringement under the Trade Marks Ordinance, 2001. The learned Counsel further contended that the Appellant has approached the DRAP for action under the Drugs Act, 1976 and DRAP Act, 2012 for alleged commission of offence of 'counterfeiting', which is independent of the trademark infringement claims.

4. Be that as it may, the matter is remanded back to the Registration Board to decide afresh after affording an opportunity of hearing to the appellant and all other companies having registration of povidone-iodine solution whose label (i.e. display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of drug package) or outer packing is imitating or resembling or so nearly resembling as to be calculated to deceive the label or outer packing of the appellant's drug.

5. The appeal is disposed of in above terms.

Decision of the 351st meeting of the Registration Board:
The Registration board deliberated the matter and decided that the firms due to resemblance with previously registered product i.e. **Pyodine Solution" (Reg No. 009528)**,will change the brand name, color and packaging design of registered products (as per following details to avoid regulatory action under Section 3(f) read with Section 23 (1) (ii) & 27 (2) (a) of the Drugs Act, 1976:

Sr. No.	**Name of the Manufacturer**	**Brand name**	**Reg. No**	Resemblance
1.	M/s Cortex Pharmaceuticals, Rawalpindi. (DML No. 000826)	Pyidine Solution	080824	Brand name
2.	M/s Zanctok Pharmaceutical Laboratories, Sindh (DML No. 000251)	Zyodine Solution	045451	Both label and Brand name
3.	M/s Lahore Pharma, Sheikhupura. (DML No. 000084)	Plasodine liquid	014228	Only label
4.	M/s Kohinoor Industries, Sahiwal. (DML No. 000197)	Prodine Solution	037440	Only Brand name
5.	M/s Hoover Pharmaceuticals, Lahore. (DML No. 000676)	Poviderm Solution	094559	Only label revision
6.	M/s N.B.S. Pharma, Lahore. (DML No. 000467)	Povidone-I Solution	025552	Only label
7.	M/s Jawa Pharmaceuticals (Pvt.) Ltd, Lahore. (DML No. 000150)	Japodon Solution	096512	Only Label
8.	M/s Trigon Pharmaceuticals, Lahore. (DML No. 000342)	Halodine Solution	057302	Only Label
9.	M/s Perfect Pharma (Pvt.) Ltd. Lahore. (DML No.	Povidone Iodine Solution	026935	Only Label

	000469)			
10.	M/s ISIS Pharmaceuticals & Chemical works, Karachi (DML No. 000126)	ISIS Povidone Iodine Solution	110071	Only Label

The Decision of the 351st meeting of the Registration Board was communicated to the respective firms vide letters dated 22nd October, 2025. Till date, only M/s Hoover Pharmaceuticals, Lahore has submitted application on E-App for change of the label claim of its registered product.

The firms are called for Personal hearing vide letter dated 24th February, 2026.

Decision of the 354th meeting of the Board:

Mr. Haroon Shahid, MD of M/s Kohinoor Industries , Sahiwal, Mr. Atif Ejaz, Production Manager of M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore, Mr. Noor Mehar Advocate on behalf of M/s Cortex Pharmaceuticals, Rawalpindi and Mr. Sohail Qasim representative of M/s ISIS Pharmaceuticals (Pvt) Ltd, Karachi appeared before the board. The said representatives contended that they will comply the decision of 351st meeting of Registration Board and will apply for change of respective brand names/ label claim.

M/s Hoover Pharmaceuticals, Lahore and M/s Perfect Pharma, Lahore have submitted application for change of label of the respective products.

The Registration Board heard the appeared representatives of the firms and considered their positive intend decided to give time of two weeks to comply the decision of the 351st meeting of the registration board.

The Board also noticed the absence of other firms namely M/s Zanctok Pharmaceutical Laboratories, Sindh, M/s Lahore Pharma, Sheikhupura, M/s N.B.S. Pharma, Lahore and M/s Trigon Pharmaceuticals, Lahore. which neither appeared before the board nor complied the decision of the 351st meeting of the Registration Board , and decided that the registration of the products of the firms shall remain suspended till the implementation of the orders of the Registration Board.

In the light of the decision of the Registration Board, suspension orders were issued to the respective firms.

In response to the previous decision of the Registration Board following are the responses of the firms:

1. M/s ISIS Pharmaceuticals (Pvt) Ltd, Karachi has revised the packaging design and color scheme of its registered product and the same is approved.
2. M/s NBS Pharmaceuticals (in response to the suspension orders issued) has revised the packaging of its registered product and the same is approved. **Suspension orders may be revoked accordingly.**
3. M/s Kohinoor Industries, Sahiwal has submitted request for change of brand name to POVI-PLUS and the same is approved.
4. M/s Cortex Pharmaceuticals , Rawalpindi and M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore have not submitted application for change / revision of brand name and label respectively therefore, **the registration of the respective products may be suspended.**

Decision:

The Board decided as under:

1. **Revoke the suspension of M/s NBS Pharmaceuticals.**
2. **Suspended the registration of the products of the firms namely M/s Cortex Pharmaceuticals, Rawalpindi and M/s Jawa Pharmaceuticals (Pvt) Ltd, Lahore till the implementation of the orders of the Registration Board.**

CASE NO 4: GRANT OF ONE TIME APPROVAL FOR RELEASE OF SINGLE PRODUCTON

BATCH WITH TWO GTIN(s):

M/s Scilife Pharmaceuticals (Pvt) Ltd, Karachi has submitted following request:

During the transition of our product **Dydrotab** from **contract marketing** (Manufacturer: M/s Aries Pharmaceuticals; Contract Marketer: Scilife Pharma (Pvt.) Ltd.) to **contract manufacturing by M/s Aries Pharmaceuticals**, an inadvertent error related to the **pre-printed Global Trade Item Number (GTIN)** on the final packaging material was identified during the final packaging stage.

The pre-printed GTIN on the packaging material inadvertently reflected the GTIN previously assigned to Aries Pharmaceuticals during the contract marketing time, as the same manufacturer was retained following the transition. This discrepancy remained unnoticed until the final packaging stage.

Upon identification of the issue, immediate corrective action was taken as a **one-time measure** to avoid disruption in product availability. The correct GTIN was printed on the pack along with the Batch Manufacturing/Expiry (BME) details, and the QR code was generated using the correct GTIN and encoded with the accurate product information. Accordingly, the GTIN printed together with the BME details and represented in the QR code is the valid and traceable GTIN for the batch.

Consequently, the finished packs of this **single batch** (approximately **30,000 packs**) contain two GTINs:

- the **pre-printed GTIN**, which incorrectly corresponds to the previous contract marketing arrangement; and
- the **later-printed GTIN** appearing with the BME details and encoded in the QR code, which is the correct GTIN and should be considered the valid identifier for this batch.

In view of the above, we respectfully request your kind consideration to grant **one-time approval** for the release of this batch and condone this inadvertent and unintentional error.

The batch details are as follows:

B.NO: 8369

MFG: 07-26

EXP: 07-28

MRP: RS: 1198.00

We further request your guidance regarding the appropriate regulatory course of action in this matter.

Decision: The Board did not accede to the request of the firm.

Import & Vet-I Section

Case.No.01: Application for registration of veterinary drug product.

M/s Main Trader, Railway Road Morre Eminabad Gujrawala , Punjad-Pakistan has submitted request via tracking ID (**AMH-EJN-ETPT)** for registration of following imported products as per details mentioned alongside.

Sr.	Product(s) Name	Manufacturer	Me-too details
1.	**SPECTRA DOX FORTE** Each gm contains: Doxycycline Hyclate…500mg	M/s.Al-Mutawwaj Veterinary Pharmaceutical Industries Address	DOX PLUS 50% NO. 082498

	Shelf life 36 months Pack size: 100gm;500gm;1000gm	Building 401, Street 16, Industries King Abdullah, 2nd industrial city, Sahab, Amman, Jordan	
2.	**SPECTRA COL FORTE** **Each gm contains:** Colistin (as sulphate) 6,000,000IU Shelf life 36 months Pack size: 100gm;500gm;1000gm		COLISTIN-600 Reg. 035112
3.	**SPECTRA BROM D.S** Each ml contains: Bromhexine HCl…10mg Shelf life 24 months Pack size: 100ml;500ml;1000ml		BRO-SAL 1% LIQUID REG.NO 130090
4.	**SPECTRA FLOR** **Each ml contains:** Florfenicol…100mg Shelf life 36 months Pack size: 100ml;500ml;1000ml		Aviflor 10 Liquid, Reg. No. 088150
5.	**SPECTRA TILCOSIN** Each ml contains: Tilmicosin (as Tilmicosin phosphate)…250mg Shelf life 36 months Pack size: 60ml;240ml;300ml;960ml		Xealth Til 25% Liquid, REG NO. 134628

Firm has submitted following supporting documents:

1. Form-5A
2. Scan Copy of GMP certificate
3. Scan copy of FSC certificate
4. Scan copy of LOA certificate
5. Fee challan
6. Undertaking

Decision:-Approved as per current import policy for inspection of manufacturer abroad. The firm shall submit original legalized CoPP/FSC+GMP certificate before issuance of registration letter.

2.	Name and address of manufacturer / Applicant	M/s. Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	PARA-Cool Powder
	Composition	Each 100gm contains:- Paracetamol…….….20gm Vitamin C……...5gm Potassium Carbonate…….12.5gm Sodium Bicarbonate……..12.5gm Vitamin E……...1.25gm
	Diary No. Date of R& I & fee	Dy. No. 11636; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	Firm has claimed In-house specification
	Pack size & Demanded Price	100gm, 500gm, 1Kg, 2.5Kg, 5 Kg, 25 Kg : Decontrolled
	Me-too status	PARACE by Biogen Pharmaceuticals (Reg. No. 063812)
	GMP status	New License (Inspection Date: 04-10-2018 & 05-11-2018).

	DML issued on 05.03.19
Remarks of the Evaluator	Firm was asked to correct API Strength in Master formulation as per Me-too or justify the formulation. Firm in reply submitted same formulation which is not as per Me-too.

Decision of 289th meeting:

Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.

Submission by the firm:

- The firm has submitted revised formulation according to available me too along with the revised Form 5.
- The revised label claim is given in the following;

  Each 100gm contains:-
  Paracetamol……..…..20gm
  Vitamin C……..……...5gm
  Potassium Carbonate…...….12.5gm
  Sodium Bicarbonate…….…..12.5gm
  Vitamin E……12.5gm*
  *Strength of Vitamin E is changed from 1.25gm to 12.5gm.
- Me too: PARA CE ORAL POWDER by M/s Biogen Pharma, Reg. no. 063812
- The firm has not submitted any fee for revision of formulation.

Deferred: (M-316) for further deliberation by Expert Working Group on Veterinary Drugs.
Sub-committee on veterinary drug recommended such formulations.

Submitted for consideration of the Board

Decision:

Approved

Case No. 3 Registration of Veterinary drug product

The following below mentioned products deferred in 360th meeting of registration board applied by m/s. Avicenna laboratories, 14-km sheikhupura faisalabad road bhikki, sheikhupura. Details are as under.

S. No.	ID Tracking No.	Name of Drug(s)/Composition, Specifications and Pack Size(s) applied by M/s. Avicenna	Decision of RB in 360th meeting	Revised Composition by M/s. Avicenna	Generic status of applied product	Fee
1	MSJ-BHN-WXQJ	Necosin Powder Each Kg contains:- Neomycin Sulphate..200gm Oxytetracycline HCL……200gm Colistin Sulphate12.631gm (Manufacturer's specifications) 10gm;100gm;	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number,	Necosin Powder Each Kg contains:- Neomycin Sulphate…..200gm Oxytetracycline HCl……..…200gm Colistin Sulphate..240 MIU	M/s. Vetec Laboratories Oxzacin KT-200 Powder 097967	Firm has deposited fee of Rs.9430/- for change of composition vide fee challan No.997766686

		250gm;500gm;1Kg	brand name and name of firm.			
2	G33-2JD-MWLA	Clomet Suspension Each ml contains:- Closantel…...50mg Ivermectin…...2mg (Manufacturer's specifications) 100ml;250ml; 500ml;1Litre		Clomet Suspension Each 100ml contains:- Closantel…12.5gm Ivermectin…...1gm	Grand Pharma Pvt Ltd Iver-Par Oral Liquid 062036	Firm has deposited fee of Rs.9430/- for change of composition vide fee challan No.210582489
3	EXJ-PTT-QUQU	Piperacena Suspension Each ml contains:- Piperazine……..10mg (Manufacturer's specifications) 100ml;250ml;500ml;1 Litre		Piperacena Suspension Each 100ml contains:- Piperazine Citrate…….37%	Biogen Pharma Piprasol Oral Solution; 058981	Firm has deposited fee of Rs.9430/- for change of composition vide fee challan No.947881350
4	6P9-73Q-4GYZ	Triclacina Suspension Each ml contains:- Triclabendazole……120mg Albendazole……….100mg Ivermectin……2mg (Manufacturer's specifications) 100ml;250ml; 500ml;1Litre		Triclacina Suspension Each 100ml contains:- Triclabendazole……..12gm Albendazole.10gm Ivermectin…0.2gm	Star Laboratories Thunder Drench 058941	Generic submitted

5	**7DH-TL1-7T1W**	Faciozan 1.5% Oral Liquid Each 1000ml contains:- Rafoxanide…15gm Levamisole HCl……...15gm (Manufacturer's specifications) 100ml;250ml; 500ml;1 Litre		Faciozan Forte Oral Liquid Each 100ml contains:- Levamisole Hydrochloride……3 gm (3%w/v) (As per innovator's specification)*	M/s. Aptly Pharmaceuticals Faisalabad. Evasole-3 Liquid 093860	Firm has deposited fee of Rs.9430/- for change of composition vide fee challan No.25078 23072
6	TGA-645-D4ND	Avifen Plus Suspension Each ml contains:- Fenbendazole…… ……..25mg Selenium ...0.40mg Cobalt Sulphate….0.94mg (Manufacturer's specifications) 50ml, 100ml, 200ml, 500ml, 1000ml		Avifen Plus Suspension Each 100ml contains:- Fenbendazole..2.5gm Selenium…...0.05gm Cobalt Sulphate...0.167gm	International Pharma Labs. I-Fenzol Drench 062073	Firm has deposited fee of Rs.9430/- for change of composition vide fee challan No.22487 45638
7	5N3-RDA-EN1Y	Alba-Raf Oral Liquid Each 1000ml contains:- Rafoxanide……..…22.70gm Albendazole…… ……..25gm (Manufacturer's specifications) 30ml, 50ml, 100ml, 500ml, 1000ml M-336		Alba-Raf Oral Liquid Each vial contains: - Alpha tocopheryl Acetate (vitamin e) BP……100mg Sodium Selenite BP…… 2mg	Vim-Sel Oral Solution Nawan Laboratories (Pvt) Ltd., Karachi. 053999	Firm has deposited fee of Rs.9430/- for change of composition vide fee challan No.17166 40846

8	ZDQ-RTR-5AG4	Feverceena Oral Solution Each ml contains:- Meloxicam.7.50mg Paracetamol..10mg 50ml, 100ml, 500ml, 1Litre M-347		Metacam Oral Suspension Each ml contains:- Meloxicam…15mg	MHRA Vet approved	Firm has deposited fee of Rs.9430/- for change of composition vide fee challan No.73677365
Decision: **Approved**						

Import & Vet-II Section

Case.No.01: **REQUEST FOR CHANGE OF MANUFACTURING SITE & CHANGE OF CATEGORY FROM BLISTER FORM IMPORT TO FINISHED PRODUCT IMPORT METEOSPASMYL CAPSULE REG. NO.033849.**

M/s Tabros Pharma (Pvt) Ltd, L-20/B, Block-22, F.B. Industrial Area, Karachi has submitted request for change of manufacturing site & change of category from blister form import to finished product import meteospasmyl capsule Reg. No.033849 as per details mentioned alongside.

S. No	Product(s) Name	Reg. No.	Previous details of product.	Proposed details of product.
1.	Meteospasmyl Capsule Each capsule contains: Alverine Citrate…..60mg Simethicone…..300mg	033849	Import in blister from M/s Laboratories Mayolyspindler, France and repacked locally.	Product License Holder: M/s Laboratoires Mayoly Spindler 3, Place Renault 92500 Rueil-Malmaison, France. Manufacturer: Laboratoires Galeniques Vernin, 20 Rue Louis – Charles Vemin, 77199 Dammarie-les-Lys

Firm has submitted following supporting documents:

a. Copy of Registration letter, post registration variation & renewal trail.
b. Copy of CoPP & Letter of Authorization
c. Fee of Rs.67,900/- (01022772362) dated 22-05-2026 & Fee of Rs.67,900/- (12256942373) dated 02-07-2026 for above product.

Decision:
Registration Board acceded the firm's request for change of manufacturing site & change of category from blister import to finished product import for the meteospasmyl capsule reg. No.033849 as per CoPP.

Case.No.02: **REQUEST OF M/S BAYER PAKISTAN (PVT) LTD, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.**

M/s Bayer Pakistan (Pvt) Ltd, Plot No.23, Sector No.22, Korangi Industrial Area, 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.	Avelox Infusion Each 250 ml contains: Moxifloxacin HCL eq. to Moxifloxacin base.....400mg	109733	Product has been divested by Bayer AG globally.	Moxiget Infusion of M/s Getz Pharma. Biofloxacin Infusion of M/s Medisure Laboratories. Infu-mox M/s Elko Pharma.
2.	Avelox Tablets Each film coated tablet contains: Moxifloxacin HCL Eq. to Moxifloxacin…..400mg	024653	Product has been divested by Bayer AG globally.	Moxiget 400mg of M/s Getz Pharma. Mofilox 400mg of M/s Macter Interational. M-Floxin 400mg M/s Searle Pakistan Ltd.

Firm has submitted following supporting documents:

Avelox Infusion

a. Copy of Registration letter issued on 06-12-2003.
b. Approval of change of final release site on 22-08-2022.
c. Approval for change of local storage facility address on 09-10-2023.
d. Last renewal submits on 18-05-2020
e. Fee of Rs.12500/- for above product.
f. Justification as mentioned above.
g. List of alternate medicines.

Avelox 400mg Tablet

a. Copy of Registration letter issued on 15-04-2002.
b. Approval of change of registration status from bulk to finished import along with change in manufacturing site on 10-08-2021.
c. Approval for change of local storage facility address on 09-10-2023.
d. Approval for increase in shelf life on 15-01-2024.
e. Last renewal submits on 11-04-2022
f. Fee of Rs.12500/- for above product.
g. Justification as mentioned above.
h. List of alternate medicines.

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

S. No	Product(s) Name	Reg. No.
1.	Avelox Infusion Each 250 ml contains: Moxifloxacin HCL eq. to Moxifloxacin base.....400mg	109733
2.	Avelox Tablets Each film coated tablet contains: Moxifloxacin HCL Eq. to Moxifloxacin…..400mg	024653

Case.No.03: **REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LTD, KARACHI FOR DE-REGISTRATION OF REGISTERED PRODUCTS.**

M/s GlaxoSmithKline Pakistan Ltd, F-268, SITE, 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.	Flixotide Evohaler 125mcg Each Actuation Contains:- Fluticasone Propoinate (Micronised) 125mcg.	028446	Suitable therapeutic alternatives and advance therapies are available in the market. Better / new molecules to cater the same portfolio are also available in the market. Virtually there is no demand of this product in local market.	Bekson of M/s Getz Pharma. Clenil 250 of M/s Chiesi Ipneb M/s Atco Pharma.
2.	Flixotide Evohaler 50mcg Each Actuation Contains:- Fluticasone Propoinate (Micronised) 50mcg.	028445		
3.	Augmentin Drops Each ml contains:- Amoxicillin trihydrate equivalent to amoxicillin 50mg. Potassium clavulanate equivalent to clavulanic acid 13.125mg.	052208		Amclav Drops of M/s Getz Pharma. Amoxi Clav of M/s Novartis Calamox M/s Bosch.

Firm has submitted following supporting documents:

Flixotide Evohaler 125mcg & 50mcg

a. Copy of Registration letter issued on 10-04-2003.
b. Last renewal submits on 22-03-2023
c. Fee of Rs.12500/- for above product.
d. Justification as mentioned above.
e. List of alternate medicines.

Augmentin Drops

a. Copy of Registration letter issued on 13-09-2008.
b. Last renewal submits on 04-09-2023
c. Fee of Rs.12500/- for above product.
d. Justification as mentioned above.
e. List of alternate medicines.

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

S. No	Product(s) Name	Reg. No.

1.	Flixotide Evohaler 125mcg Each Actuation Contains:- Fluticasone Propoinate (Micronised) 125mcg.	028446
2.	Flixotide Evohaler 50mcg Each Actuation Contains:- Fluticasone Propoinate (Micronised) 50mcg.	028445
3.	Augmentin Drops Each ml contains:- Amoxicillin trihydrate equivalent to amoxicillin 50mg. Potassium clavulanate equivalent to clavulanic acid 13.125mg.	052208

Case No: 04: <u>REQUEST OF M/S SEARLE PAKISTAN LIMITED, KARACHI FOR DE-REGISTRATION OF JANUVIA 100MG TABLET.</u>

M/s Searle Pakistan Limited, Section E, 2nd Floor, One IBL Centre, Plot No. 1, Block 7&8, D.M.C.H.S., Tipu Sultan Road, Off Shahrah-e-Faisal, Karachi has requested for de-registration of already registered drug with a fee of Rs.12,500/- as per following details;

S. No	Product(s) Name	Reg. No.	Reason for De-Reg. (stated by firm)	Alternate Brands
1.	Januvia Tablets. Each tablet contains:- Sitagliptin phosphate monohydrate, equivalent to 100mg sitagliptin	059077	Due to some business decision, it has been decided to discontinue the registered product. Request letter from principal, Merck sharp & Dohme attached.	Sita Tablet 100mg of M/s CCL. Trevia Tablet 100mg of M/s Getz Pharma Sitaglu Tablet 100mg M/s Hilton Pharma. Inosita Tablet 100mg of M/s Pharmevo Pvt Ltd. Tagip Tablet 100mg of M/s Highnoon

a. Copy of Registration letter issued on 07-10-2009.
b. Last renewal submits on 22-04-2024
c. Fee of Rs.12500/- for above product.
d. Justification as mentioned above.
e. List of alternate medicines.
f. An undertaking that no case is pending at any forum / court of law regarding this product.

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

S. No	Product(s) Name	Reg. No.
1.	Januvia Tablets. Each tablet contains:- Sitagliptin phosphate monohydrate, equivalent to 100mg sitagliptin	059077

Deferred Cases of 360th meeting

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 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: 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.
	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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
2.	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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
3.	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 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
4.	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.
	Remarks of the Evaluator	
	Decision of 296 meeting (8-10th Sep, 2020): Deferred for updated status of GMP from QA & LT Division. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
5.	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	Rosulip 20mg Tablet
	Composition	Each Film Coated Tablet Contains: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
6.	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	Rosulip 40mg Tablet
	Composition	Each Film Coated Tablet Contains: 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.	

	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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
7.	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 100mg Capsules
	Composition	Each Capsule Contains: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
8.	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: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
9.	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: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
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	Gabreg 50mg Capsules
	Composition	Each Capsule Contains: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
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	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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
12.	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.	

	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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
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	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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
14.	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	Inezon 400mg Tablet
	Composition	Each Tablet Contains: 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) (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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
15.	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	Inezon 600mg Tablet
	Composition	Each Tablet Contains: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
16.	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: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	

	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
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	Temisart 40mg Tablet
	Composition	Each Tablet Contains: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
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	Temisart 80mg Tablet
	Composition	Each Tablet Contains: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
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	Viredo B Tablet 300mg
	Composition	Each Film Coated Tablet Contains: 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. **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. The reply should have been submitted till 31-12-2024 but the firm has submitted the reply after the valid period.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that	

	PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
20.	**Name and address of manufacturer / Applicant**	M/s Pearl Pharmaceuticals, Islamabad
	Brand Name +Dosage Form + Strength	Paradine Inj 250mg
	Composition	Each vial contains: Cephradine……250mg.
	Diary No. Date of R& I & fee	GRF Via Tracking ID HYP-ZVE-686R R & I dated 02-03-2011
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	1's vial, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Velosef Injection of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 1870)
	GMP status	
	Decision of 268th Meeting: Deferred for confirmation of approval status by reference regulatory authorities.	
	Firm's response: The firm has submitted the response vide online tracking ID HYP-ZVE-686R dated July 29th, 2025. The firm has submitted R&I receiving for the reply of the abovementioned deferred case dated 13-12-2024.	
	Remarks of Evaluator: **Decision of 320th meeting of Registration Board:** Registration Board deliberated the matter in detail and acknowledged the fact that the "Cephradine injection" has not been withdrawn from US market due to safety & efficacy reasons as evident from the above cited notice published in US Federal Register. Hence, Registration Board decided to consider pending registration applications in the light of aforementioned position. **Decision of 323rd meeting:** Accordingly, the label claim and specifications of the innovator's product and USP monograph have been reviewed and based upon the label claim of "Velosef Injection 250mg", "Velosef 500mg Injection" & "Velosef injection 1gm" registered vide registration no. 001870, 001866 & 001869 respectively, advised the PE&R division to issue registration letters as per following label claim for generic products. Each vial contains: Cephradine ……. 250mg (with L-arginine)	

	Each vial contains: Cephradine ……. 500mg (with L-arginine) Each vial contains: Cephradine ……. 1g (with L-arginine) **Specifications:** In 323rd meeting, the Board approved the cases with USP specs but now the official monograph of Cephradine for injection is not available in USP. **The firm shall submit applicable fee for revision of label claim and specifications (as per innovator's).**	
	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.	
21.	**Name and address of manufacturer / Applicant**	M/s Pearl Pharmaceuticals, Islamabad
	Brand Name +Dosage Form + Strength	Paradine Inj 500mg
	Composition	Each vial contains: Cephradine……500mg.
	Diary No. Date of R& I & fee	GRF Via Tracking ID HYP-ZVE-686R R & I dated 02-03-2011
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	1's vial, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Velosef Injection of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 1866)
	GMP status	
	Decision of 268th Meeting: Deferred for confirmation of approval status by reference regulatory authorities.	
	Firm's response: The firm has submitted the response vide online tracking ID HYP-ZVE-686R dated July 29th, 2025. The firm has submitted R&I receiving for the reply of the abovementioned deferred case dated 13-12-2024.	
	Remarks of Evaluator:	

	Decision of 320th meeting of Registration Board: Registration Board deliberated the matter in detail and acknowledged the fact that the "Cephradine injection" has not been withdrawn from US market due to safety & efficacy reasons as evident from the above cited notice published in US Federal Register. Hence, Registration Board decided to consider pending registration applications in the light of aforementioned position. **Decision of 323rd meeting:** Accordingly, the label claim and specifications of the innovator's product and USP monograph have been reviewed and based upon the label claim of "Velosef Injection 250mg", "Velosef 500mg Injection" & "Velosef injection 1gm" registered vide registration no. 001870, 001866 & 001869 respectively, advised the PE&R division to issue registration letters as per following label claim for generic products. Each vial contains: Cephradine ……. 250mg (with L-arginine) Each vial contains: Cephradine ……. 500mg (with L-arginine) Each vial contains: Cephradine ……. 1g (with L-arginine) **Specifications:** In 323rd meeting, the Board approved the cases with USP specs but now the official monograph of Cephradine for injection is not available in USP. **The firm shall submit applicable fee for revision of label claim and specifications (as per innovator's).**	
	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.	
22.	**Name and address of manufacturer / Applicant**	M/s Pearl Pharmaceuticals, Islamabad
	Brand Name +Dosage Form + Strength	Paradine Inj 1gm
	Composition	Each vial contains: Cephradine……1gm
	Diary No. Date of R& I & fee	GRF Via Tracking ID HYP-ZVE-686R R & I dated 02-03-2011
	Pharmacological Group	Cephalosporin

	Type of Form	Form 5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	1's vial, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Velosef Injection of M/s GlaxoSmithKline Pakistan Limited (Reg. No. 001869)
	GMP status	

Decision of 268th Meeting:
Deferred for confirmation of approval status by reference regulatory authorities.

Firm's response: The firm has submitted the response vide online tracking ID HYP-ZVE-686R dated July 29th, 2025. The firm has submitted R&I receiving for the reply of the abovementioned deferred case dated 13-12-2024.

Remarks of Evaluator:

Decision of 320th meeting of Registration Board:

Registration Board deliberated the matter in detail and acknowledged the fact that the "Cephradine injection" has not been withdrawn from US market due to safety & efficacy reasons as evident from the above cited notice published in US Federal Register. Hence, Registration Board decided to consider pending registration applications in the light of aforementioned position.

Decision of 323rd meeting:
Accordingly, the label claim and specifications of the innovator's product and USP monograph have been
reviewed and based upon the label claim of "Velosef Injection 250mg", "Velosef 500mg Injection" & "Velosef injection 1gm" registered vide registration no. 001870, 001866 & 001869 respectively, advised the PE&R division to issue registration letters as per following label claim for generic products.

Each vial contains:
Cephradine ……. 250mg
(with L-arginine)

Each vial contains:
Cephradine ……. 500mg
(with L-arginine)

Each vial contains:
Cephradine ……. 1g
(with L-arginine)

Specifications: In 323rd meeting, the Board approved the cases with USP specs but now the official monograph of Cephradine for injection is not available in USP.

The firm shall submit applicable fee for revision of label claim and specifications (as per innovator's).

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.

23.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Coxibex (Celecoxib) 400mg Capsule
	Composition	Each capsule contains: Celecoxib B.P…….400mg
	Diary No. Date of R& I & fee	Dy. No 20066 Dated 04-06-2018, Rs. 20,000/- 01-06-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	MS
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	CELEBREX (USFDA)
	Me-too status	
	GMP status	DML by way of formulation no. 000597 dated 05-07- 2016 renewal of DML letter issue dated 27th January 2017. GMP inspection by area FID dated 19-07-2017 concluded that firm was considered to be operating at good level of compliance with GMP guideline.
	Previous remarks of the Evaluator.	
	Previous Decision 291st meeting	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation of PEC-IX	Firm has submitted response on eapp CMS vide tracking ID 5V4-E8V-RSQA Initial reply submitted on 17.12.2024 Firm has submitted me-too reference of Celbexx plus 400mg Capsule M/s Getz Reg No. 053369
	Decision of 353rd meeting	Deferred for verification of submission of reply from R&I.
	Evaluation by PEC	The firm has submitted R&I receiving dated 20-12-2024 as a proof for submission of the reply vide online tracking ID No. 5V4-E8V-RSQA.

	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.

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.

24.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Sitalip DS 50/1000 mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Sitagliptin Phosphate Monohydrate…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	General Request Form Tracking ID PQ9-EJ3-6YP5 Dy No. 16021: 07-03-2019 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. • Revise your 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.
	Decision of 326th meeting: Deferred for following: • Latest GMP inspection report conducted within a period of last three years. • 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 of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
25.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Sitalip DS 50/500 mg Tablet
	Composition	Each Film Coated Extended Release Tablet Contains: Sitagliptin Phosphate Monohydrate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	General Request Form Tracking ID PQ9-EJ3-6YP5 Dy No. 16022: 07-03-2019 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. • Revise your 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.
	Decision of 326th meeting: Deferred for following: • Latest GMP inspection report conducted within a period of last three years. • 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.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
26.	Name and address of manufacturer / Applicant	M/s Medizan Laboratories (Pvt) Ltd, Plot No. 313, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Sitazan XR 50/850 mg Tablet
	Composition	Each Film Coated Extended Relase Tablet Contains: Sitagliptin Phosphate Monohydrate…50mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	General Request Form Tracking ID PQ9-EJ3-6YP5 Dy No. 16286: 07-03-2019 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. • Revise your 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.
	Decision of 326th meeting: Deferred for following: • Latest GMP inspection report conducted within a period of last three years. • 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.	

	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
27.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Profamed 5/500 XR Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin…5mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy.No 8428 dated 26-02-2019 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: 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 of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority.	

	Decision:- Deferred till the decision of the Authority.	
28.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Profamed 10/500 XR Tablet
	Composition	Each Film Coated Tablet Contains: Dapagliflozin…10mg Metformin Hcl…500mg
	Diary No. Date of R& I & fee	Dy.No 8429 dated 26-02-2019 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: 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 of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
29.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Profamed 10/1000 XR Tablet

	Composition	Each Film Coated Tablet Contains: Dapagliflozin…10mg Metformin Hcl…1000mg
	Diary No. Date of R& I & fee	Dy.No 8430 dated 26-02-2019 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: 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 of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
30.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Profazin Tablet 5mg
	Composition	Each Film Coated Tablet Contains: Dapagliflozin propanediol monohydrate eq to Dapagliflozin…5mg
	Diary No. Date of R& I & fee	Dy.No 8427 dated 26-02-2019 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: 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 of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
31.	Name and address of manufacturer / Applicant	**M/s MedPharm Research Lab.** 28-Km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	**Medadim A Dry Powder Injection 2.5gm**
	Diary No. Date of R& I & fee	Diary No: 12540, 05-04-2018, Rs: 20,000/-
	Composition	Each vial contains: Ceftazidime (as rate) …2000mg Avibactam (as sodium)… 500mg entahyd
	Pharmacological Group	3rd Generation Cephalosporin + beta-lactamase inhibitor
	Type of Form	Form-5
	Finished Product Specification	
	Pack size & Demanded Price	Innovator's specifications 1's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVYCAZ 2.5 grams single-dose vial by M/s Allergan USA, Inc (USFDA Approved)
	Me-too status	Not confirmed
	GMP status	12-01-2018 Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Me-too status not confirmed from available database.

	Decision of 281st meeting: 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-5D alongwith differential fee and submission of stability study data. **Reply by the firm:** The firm has submitted the reply vide online tracking ID No. **JWS-H54-6H5S dated 06-07-2026** and stated that me-too was not available at that time but now me-too is available. Avitazid 2.5gm Injection Reg. No.: 135513 By: M/s Air Pharmaceutcals (pvt) ltd.
	Decision: The Board discussed that the application was submitted on Form 5 whereas me-too of the applied product was not available at the time of submission of application. Moreover, the Board in its 281st meeting decided that the application shall be submitted on Form 5D and the deadline for submission of application on Form 5D has already been passed. Therefore, the Board decided to reject the application. **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. Analytical method of drug product and its verification/validation.

Cases of form 5 not considered in any meeting:

DRAP Authority in its 206th meeting, directed PE&R division to review and process all remaining cases of duplicate dossiers submitted by companies till 31st December, 2024 on form 5 or form 5D.

Below are the details of all such cases.

32.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, Plot No.224 & 225/1 Sector 23 Korangi Industrial area Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	**Mebever 200mg Capsule**
	Composition	Each modified release capsule contains: Mebeverine HCl as SR pellets…200 mg
	Diary No. Date of R& I & fee	Dy. No.:37 20-9-2017; Rs.20,000/- (19-09-2017)
	Pharmacological Group	Antispasmodics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 14's, 20's & 30's
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Sameb MR 200mg Capsule by Hilton Pharma
	GMP status	Not submitted.
	Remarks by evaluator The firm has submitted the reply vide online trackg ID No **M11-RMT-W6P7.**	

The firm has submitted R&I receiving of the initially submitted dossier. The diary no. 15720 dated 20-09-2017 has been verified from the available record. (Rs. 20,000/- fee dated 20-09-20217 Receipt No. 20170920

The firm was conveyed shortcomings vide letter No.F.1-1/2019/PEC-DRAP(AD PEC-VII) dated 06-11-2019.

The firm had submitted the reply of letter of the shortcomings vide R&I receiving dated 02-11-2024.

Following are the queries and the reply.

Query	**Response**
Source of pellets, in case of imported pellets differential fee and stability data of pellets along with valid GMP of manufacturer of pellets is needed.	Source of pellets: M/s Surge Laboratories (pvt) ltd., GMP certificate of Surge Laboratories issued on the basis on inspection conducted on 27-09-2024. 06 months accelerated and 36 months real time stability data of Mebeverin S Pellets is submitted.
Master formulation describing quantities of actives and inactives alongwith their justification/role of ingredients.	The SR pellets are manufactured and filled in capsules. No other excipient is added in capsule shell except SR pellet. The same formulation is submitted by the frm.

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.

33.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan (Pvt.) Ltd.** L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B industrial Area Karachi
	Brand Name +Dosage Form + Strength	Ledisof Tablet 400mg/90mg
	Composition	Eacch tablet contains: Sofosbuvir….400mg Ledipasvir…..90mg
	Diary No. Date of R& I & fee	GRF Via Tracking ID ZNQ-5XR-ZW4X Dy.No 698 dated 27-04-2016 Rs.20,000 dated 27-04-2016
	Pharmacological Group	Beta Blocker
	Type of Form	Form 5
	Finished Product Specification	

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Qunoten By Novartis
	Me-too status	
	GMP status	
	Remarks of the Evaluator.	
	Firm's response: The firm has submitted the response vide tracking Id ZNQ-5XR-ZW4X dated 30-08-2025	
	Evaluation by PEC: The applied formulation requires stability data whereas the firm has not submitted the required stability data vide letter requesting for consideration of the instant case for Board's meeting dated 04-11-2024. The last date for submission stability data was 30-06-2023.	
	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.	
34.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan (Pvt.) Ltd.** L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B industrial Area Karachi
	Brand Name +Dosage Form + Strength	Linzo Tablet 600mg
	Composition	Each film coated tablet contains: Linezolid…..600mg
	Diary No. Date of R& I & fee	GRF Via Tracking ID **RT1-PXM-XNLU** Dy. No. 379 dated 10-09-2015 Rs.20,000 dated 09-09-2015 (0298352)
	Pharmacological Group	Beta Blocker
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Available (Bionext)
	GMP status	GMP certificate issued on the basis of inspection conducted on 15-02-2024.
	Remarks of the Evaluator.	
	Firm's response: The firm has submitted the response vide tracking Id **RT1-PXM-XNLU** dated 30-08-2025, following documents are submitted: 1. Copy of R&I receiving of initially submitted dossier dated 10-09-2015. (Dy. No. 377 dated 10-09-2015 verified from the R&I section) 2. Copy of letter requesting for consideration of the applied product in Board's meeting (R&I receiving dated 04-11-2024) is submitted. 3. Copy of challan No. 0298351 Rs. 20,000/-.	
	Evaluation by PEC: The firm has submitted the complete dossier vide application ID No. **RT1-PXM-XNLU** dated 30-08-2025 but had requested for consideration of the case vide letter R&I dated 04-11-2024.	
	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.	
35.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan (Pvt.) Ltd.** L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B industrial Area Karachi
	Brand Name +Dosage Form + Strength	Linzo Suspension 100mg/5ml
	Composition	Each 5mL contains: Linezolid……100mg
	Diary No. Date of R& I & fee	GRF Via Tracking ID L1H-9E1-X25G Dy. No. 379 dated 10-09-2015 0298351 Rs. 20,000/-. 09-09-2015
	Pharmacological Group	Beta Blocker

	Type of Form	Form 5
	Finished Product Specification	Inhouse
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved. https://mhraproducts4853.blob.core.windows.net/docs/4c3186ca49926f8a67e9929e8372073f7b871487
	Me-too status	Available (Solaris)
	GMP status	GMP certificate issued on the basis of inspection conducted on 15-02-2024.
	Remarks of the Evaluator.	
	Firm's response: The firm has submitted the response vide tracking Id L1H-9E1-X25G dated 30-08-2025, following documents are submitted: 1. Copy of R&I receiving of initially submitted dossier dated 10-09-2015. (Dy. No. 379 dated 10-09-2015 verified from the R&I section) 2. Copy of letter requesting for consideration of the applied product in Boar's meeting (R&I receiving dated 04-11-2024) is submitted. 3. Copy of challan No. 0298351 Rs. 20,000/-.	
	Evaluation by PEC: The firm has submitted the complete dossier vide application ID No. L1H-9E1-X25G dated 30-08-2025 but had requested for consideration of the case vide letter R&I dated 04-11-2024.	
	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.	
36.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan (Pvt.) Ltd.** L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B industrial Area Karachi
	Brand Name +Dosage Form + Strength	Atenol 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Atenolol…50mg

Diary No. Date of R& I & fee	GRF Via Tracking ID WP8-568-N143 Dy.No 13660 dated 28-08-2017 Rs.20,000 dated 17-08-2017
Pharmacological Group	Beta Blocker
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 as uncoated tablet
Me-too status	Available
GMP status	GMP certificate issued on the basis of inspection conducted on 15-02-2024.
Remarks of the Evaluator.	

Firm's response: The firm has submitted the reply vide online tracking ID WP8-568-N143 dated 30-08-2025, following documents are submitted:

1. Copy of R&I receiving of initial submission of dossier dated 25-08-2017 (Dy. No. 13660) which has been verified from the R&I record.

2. Copy of letter requesting for consideration of Atenol 50mg tablet for Board's meeting (R&I dated 22-01-2020 is attached)

3. Fee challan No. 0700077 Rs. 20,000/-.

Evaluation by PEC:

The correct label claim of the product is:

Each tablet contains:

Atenolol…. 50mg

The firm shall submit fee for correction of label claim.

The firm has submitted the complete dossier vide application ID No. WP8-568-N143 dated 30-08-2025 but had requested for consideration of the case vide letter R&I dated 22-01-2020.

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.	
37.	**Name and address of manufacturer / Applicant**	**M/s Lisko Pakistan (Pvt.) Ltd.** L-10-D, Block no. 21, Shaheed Rashid Minhas Road, Federal B industrial Area Karachi
	Brand Name +Dosage Form + Strength	Cloprin tablet 75/75
	Composition	Each tablet contains: Clopidogrel as hydrogen bisulfate…..75mg Aspirin…….75mg
	Diary No. Date of R& I & fee	GRF Via Tracking ID BMT-YQ7-VU6E Dy.No 7973 dated 07-07-2017 Rs.20,000 dated 07-07-2017
	Pharmacological Group	Beta Blocker
	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.	EMA Approved
	Me-too status	Avilable
	GMP status	GMP certificate issued on the basis of inspection conducted on 15-02-2024.
	Remarks of the Evaluator.	
	Firm's response: The firm has submitted the reply vide online tracking ID BMT-YQ7-VU6E dated 30-08-2025, following documents are submitted: 1. Copy of R&I receiving of initial submission of dossier (Dy. No. 7973 07-07-2017) which has been verified from the R&I record. 2. Copy of letter requesting for consideration of the applied product for Board's meeting (R&I dated 04-11-2024 is attached) 3. Fee challan No. 0585289 Rs. 20,000/-.	
	Evaluation by PEC:	

	The firm has submitted the complete dossier vide application ID No. BMT-YQ7-VU6E dated 30-08-2025 but had requested for consideration of the case vide letter R&I dated 04-11-2024. The correct label claim is: Each film-coated bilayer tablet contains: Clopidogrel (as bisulphate)….75mg Aspirin (as enteric coated)……75mg The firm shall submit fee for correction of label claim as per reference product.
	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.

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.

38.	Name and address of manufacturer	M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore
	Brand Name +Dosage Form + Strength	Ultra tablet 120mg
	Diary No. Date of R& I & fee	Diary No. Nil. Dated 30-04-2010, Rs 8000/-
	Composition	Each film coated tablet contains: Orlistat…..120mg
	Pharmacological Group	Antiobesity (as provided by the fimr)
	Type of Form	Form 5
	Finished Product Specification	
	Pack size & Demanded Price	As per sro
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Could not be confirmed in tablet form.
	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: Copy of fee receipt of Rs. 12,000/- is submitted.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
39.	Name and address of manufacturer	M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore
	Brand Name +Dosage Form + Strength	OMC Suspension
	Diary No. Date of R& I & fee	Diary No. Nil. Dated 30-04-2010, Rs 8000/-
	Composition	Each tablet contains: Vitamin D3……400IU Ossein Mineral Complex 250mg Eq. to Calcium … 53.5mg Phosphorus … 24.8mg Residual Mineral Salt … 7.5.mg Collagen … 87.5mg Other Protein … 20mg
	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.	Could not be confirmed
	Me-too status	Could not be confirmed
	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) Details of trace elements have not been provided. Availability of atomic absorption spectrophotometer is not submitted	
	Evaluation by PEC: Copy of fee receipt of Rs. 12,000/- is submitted.	

	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
40.	Name and address of manufacturer	M/s Shrooq Pharmaceuticals (pvt) ltd., 21-km Ferozpur road, Lahore
	Brand Name +Dosage Form + Strength	Cinpride Syrup 1mg/5ml
	Diary No. Date of R& I & fee	Diary No. Nil. Dated 30-04-2010, Rs 8000/-
	Composition	Cinitapride as Tartrate
	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.	
	Me-too status	
	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) The firm has not submitted further details of the product.	
	Evaluation by PEC: Copy of fee receipt of Rs. 12,000/- is submitted.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
41.	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: 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: 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: Copy of fee receipt of Rs. 12,000/- is submitted. The firm shall submit the applicable fee for revision of formulation.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting**.**	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
42.	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: 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: Original fee receipt of Rs. 12,000/- No. 0823904 is submitted.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
43.	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: 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: Original fee receipt of Rs. 12,000/- No. 0823902 is submitted.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and	

	deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
44.	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: Sodium Chloride … 3.5gm Potassium Chloride … 1.50gm Sodium Citrate … 2.9gm 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= **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.** Sodium Chloride … 2.6gm Potassium Chloride … 1.50gm Sodium Citrate … 2.9gm 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: 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: Copy of fee receipt of Rs. 12,000/- without mentioning the name of the product is submitted.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
45.	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: Calcipotriol (hydrous) … 50mcg 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: 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: Original fee receipt of Rs. 12,000/- 819096 is submitted. The firm shall submit fee for revision of label claim as per reference product.	

	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
46.	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: 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: 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: Copy of fee receipt of Rs. 12,000/- is submitted. The firm shall submit fee for revision of label claim as per reference product.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
47.	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: Ossein Mineral Complex 830mg Eq. to Calcium … 177.6mg Phosphorus … 82.2mg Residual Mineral Salt … 24.8mg Collagen … 224mg Other Protein … 88.4mg 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 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: 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). The formulation is not as per me-too product.	
	Evaluation by PEC: Copy of fee receipt of Rs. 12,000/- is submitted. The firm shall submit fee for revision of label claim as per reference product.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting. **The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority.** **Decision:- Deferred till the decision of the Authority.**	
48.	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: Clindamycin Phosphate … 10mg/ml 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: 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: Copy of fee receipt of Rs. 12,000/- is submitted.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
49.	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: 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:	

	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: Copy of fee receipt of Rs. 12,000/- is submitted. The firm shall submit the applicable fee for revision of formulation (form film coated to uncoated)	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
50.	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: 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: 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: Copy of fee receipt of Rs. 12,000/- is submitted.	

	The firm shall submit the applicable fee for revision of formulation (form film coated to uncoated)	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	
51.	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: 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: 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: Copy of fee receipt of Rs. 12,000/- is submitted.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority.	

	Decision:- Deferred till the decision of the Authority.	
52.	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: Sodium Chloride … 1.3gm Potassium Chloride … 0.75gm Sodium Citrate … 1.45gm 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.	
	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: Copy of fee receipt of Rs. 12,000/- without mentioning the name of the product is submitted.	
	Decision of 360th meeting: 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 held all the decisions of the deferred the cases of Form 5 and deliberated that PPMA should approach DRAP Authority for extension of the timeline. The matter shall be taken up in the next Board's meeting.	
	The Board was informed that PPMA has submitted the request for extension in timelines for submission of replies of deferred cases of Form 5/Form 5D. Request of PPMA is under consideration of Authority. **Decision:- Deferred till the decision of the Authority.**	

Miscellaneous Cases:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date	Remarks
53.	M/s Werrick pharmaceuticals, Plot # 216-217, I-10/13, Industrial Area, Islamabad.	GLUSET PLUS XR TABLETS 50/1000mg Each extended release film .....coated tablet contains Metformin HCl .....1000mg Sitagliptin as phosphate monohydrate..50mg Anti-diabetic Manufacturer's specification	Form-5 Dy.No. 16553 dated 07-03-2019 Rs. 20,000/- dated 06-03-2019 14's, 20's & 30's; As per SRO	Janumet XR Tablet 50/1000mg of Merck & Co., (USFDA approved) Tagipmet XR Tablet 50/1000mg of M/s Highnoon Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance	The firm has revised the label claim from film coated tablet to extended release film coated tablet as per reference formulation. Fee challan of Rs. 5,000/- (Deposit slip # 1952504) dated 28-05-2019.

STABILITY STUDY DATA

Drug	Gluset Plus XR Tablets 50/1000mg
Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
Manufacturer of API	**Metformin HCl**: M/s AbhilashaPharma Pvt. Ltd. India **Sitagliptin Phosphate Monohydrate**: M/s Zhejiang Tianyu Pharmaceutical Co., China
API Lot No.	**Metformin HCl:** MET 121/16 **Sitagliptin Phosphate Monohydrate:** 12301-17030101
Description of Pack (Container closure system)	Alu Alu Blister Pack in Unit carton

Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real Time: 0,3, & 6 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	Trial# 01	Trial# 02	Trial# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	07/2018	07/2018	07/2018
Date of Initiation	01/08/2018	02/08/2018	03/08/2018
No. of Batches	03		
Date of Submission	16628 (07-03-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	**Metformin HCl:** Copy of COA (Batch #MET 121/16) from M/s Abhilasha Pharma Pvt. Ltd.India is submitted. **Sitagliptin phosphate monohydrate:** Copy of COA (Batch #12301-17030101) from M/s Zhejiang Tianyu Pharmaceuticals Co, Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate (certificate No. 1706138) issued by Food & Drugs Control Administration, India. It is valid until 01-06-2019. **Sitagliptin phosphate monohydrate:** Copy of GMP certificate (certificate No. ZJ20170020) issued by China Food & Drugs Administration, china. It is valid until 28-03-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the procurement of Metformin HCl attested by DRAP, Islamabad dated 27-12-2016. The firm has submitted copy of commercial invoice for the procurement of Sitagliptin Phosphate monohydrate attested by DRAP, Islamabad dated 23-06-2017.
6.	All provided documents will be attested (name,	Yes

	sign and stamp) for ensuring authenticity of data / documents.	
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
REMARKS OF EVALUATOR		
• The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.		
REQUEST OF EXEMPTION FROM ON SITE INSPECTION		
The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: Date of submission: 07-03-2019 vide diary no. 16628		
Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th &finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. **Date of inspection**: 20-11-2017 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of commercial invoice dated 08-12-2016 declaring 500Kgs quantity of API has been submitted which is attested by ADC, DRAP Islamabad. **Sitagliptin Phosphate Monohydrate:** Copy of commercial invoice dated 05-06-2017 declaring 2kgs quantity of API has been submitted which is attested by ADC, DRAP Islamabad.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of COA for following working standard & impurity Standards: For working standard: Metformin HCl : 98 % Sitagliptin Phosphate Monohydrate: 100% For Impurity standard: Dicyandiamide (Impurity A): 99.06%
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate (certificate No. 1706138) issued by Food & Drugs Control Administration, India. It is valid until 01/06/2019. **Sitagliptin phosphate monohydrate:** Copy of GMP

<table>
<tr><td></td><td></td><td>certificate (certificate No. ZJ20170020) issued by China Food & Drugs Administration, china. It is valid until 28-03-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for evaluation of vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA of Metformin HCl (Batch # MET 121/16) from M/s Abhilasha Pharma Pvt. Ltd, India has been submitted.
• Copy of COA of Sitagliptin Phosphate monohydrate (Batch # 12301 - 17030101) from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd, China has been submitted.</td></tr>
<tr><td></td><td></td><td>• Copy of COA of reference standard of Metformin HCl and Sitagliptin Phosphate Monohydrate has been submitted.
• Copy of COA of Metformin HCl impurity Standards A has been submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of “Gluset Plus XR Tablets 50/1000mg”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 01</td><td>1500 tablets</td><td>Jul-18</td></tr>
<tr><td>Trial # 02</td><td>1500 tablets</td><td>Jul-18</td></tr>
<tr><td>Trial # 03</td><td>1500 tablets</td><td>Jul-18</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>Trial # 01</td><td>1312 Tab (65 packs *20’s)</td><td>240 Tab (12 packs *20’s)</td><td>1060 Tab (53 packs *20’s)</td></tr>
<tr><td>Trial # 02</td><td>1309 Tab (65 packs *20’s)</td><td>220 Tab (11 packs *20’s)</td><td>1080 Tab (54 packs *20’s)</td></tr>
<tr><td>Trial # 03</td><td>1297 Tab (64 packs *20’s)</td><td>220 Tab (11 packs *20’s)</td><td>1060 Tab (53 packs *20’s)</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
</table>

12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-07-2018 to 13-02-2019.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Metformin HCl and Sitagliptin phosphate monohydrate.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Gluset Plus XR Tablets 50/1000mg" along with Stability Study Reports.
15.	Reports of stability studies of API from manufacturer.	**Metformin HCl:** The firm has submitted photocopy of 06 Months Accelerated and 60 Months Real Time Stability Study Data of 03 Batches from M/s AbhilashaPharma Pvt. Ltd, India according to zone IVA conditions. **Sitagliptin Phosphate Monohydrate:** The firm has submitted
		photocopy of 06 Months Accelerated and 24 Months Real Time Stability Study Data of 03 Batches from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd, China according to zone IVA conditions.
16.	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has used the excipients of innovator.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Janumet XR Tablets 50/1000mg manufactured by M/S Merck & CO., INC. with Lot No.R027476. The firm's product results are comparable to that of the competitor product.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of "Gluset Plus XR Tablets 50/1000mg" from 12-07-2018 to 12-01-2019.

Decision: Registration Board decided to constitute the panel for onsite verification for confirmation of following:

1) **Spray technique ensuring requisite quantity of API Sitagliptin being coated / incorporated on dosage form while using 100% quantity of API without loss compensation.**
2) **Results of dissolution analysis for Metformin performed by UV method were not interfered with the other API**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date	Remarks

54.	M/s Werrick pharmaceuticals, Plot # 216-217, I-10/13, Industrial Area, Islamabad.	Gluset Plus XR Tablets 50/500mg Each film .....coated tablet contains Metformin HCl .....500mg Sitagliptin as phosphate monohydrate .. 50mg Anti-diabetic Manufacturer's specification	Form-5 Dy.No. 16552 dated 07-03-2019 Rs. 20,000/- dated 06-03-2019 14's, 20's & 30's; As per SRO	Janumet XR Tablet 50/500mg of Merck & Co., (USFDA approved) Tagipmet XR Tablet 50/500mg of M/s Highnoon Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance	The firm has revised the label claim from film coated tablet to extended release film coated tablet as per reference formulation. Fee challan of Rs. 5,000/- (Deposit slip # 1952503) dated 28-05-2019.

STABILITY STUDY DATA

Drug	Gluset Plus XR Tablets 50/1000mg		
Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	**Metformin HCl**: M/s AbhilashaPharma Pvt. Ltd. India **Sitagliptin Phosphate Monohydrate**: M/s Zhejiang Tianyu Pharmaceutical Co., China		
API Lot No.	**Metformin HCl:** MET 121/16 **Sitagliptin Phosphate Monohydrate:** 12301-17030101		
Description of Pack (Container closure system)	Alu Alu Blister Pack in Unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C/75%±5% RH Real Time: 30˚C ± 2˚C/65%±5% RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real Time: 0,3, & 6 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	Trial# 01	Trial# 02	Trial# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	05/2018	05/2018	05/2018
Date of Initiation	13/07/2018	13/07/2018	13/07/2018
No. of Batches	03		
Date of Submission	16627 (07-03-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.	**Documents To Be Provided**	**Status**
1.	COA of API.	**Metformin HCl:** Copy of COA (Batch #MET 121/16) from M/s Abhilasha Pharma Pvt. Ltd.India is submitted. **Sitagliptin phosphate monohydrate:** Copy of COA (Batch #12301-17030101) from M/s Zhejiang Tianyu Pharmaceuticals Co, Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate (certificate No. 1706138) issued by Food & Drugs Control Administration, India. It is valid until 01-06-2019. **Sitagliptin phosphate monohydrate:** Copy of GMP certificate (certificate No. ZJ20170020) issued by China Food & Drugs Administration, china. It is valid until 28-03-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the procurement of Metformin HCl attested by DRAP, Islamabad dated 27-12-2016. The firm has submitted copy of commercial invoice for the procurement of Sitagliptin Phosphate monohydrate attested by DRAP, Islamabad dated 23-06-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 06 months Accelerated and 06 months Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 07-03-2019 vide diary no. 16627

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th &finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. **Date of inspection**: 20-11-2017 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software.
		• The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Metformin HCl:** Copy of commercial invoice dated 08-12-2016 declaring 500Kgs quantity of API has been submitted which is attested by ADC, DRAP Islamabad. **Sitagliptin Phosphate Monohydrate:** Copy of commercial invoice dated 05-06-2017 declaring 2kgs quantity of API has been submitted which is attested by ADC, DRAP Islamabad.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of COA for following working standard & impurity Standards: For working standard: Metformin HCl : 98 % Sitagliptin Phosphate Monohydrate: 100% For Impurity standard: Dicyandiamide (Impurity A): 99.06%
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Metformin HCl:** Copy of GMP certificate (certificate No. 1706138) issued by Food & Drugs Control Administration, India. It is valid until 01/06/2019. **Sitagliptin phosphate monohydrate:** Copy of GMP certificate (certificate No. ZJ20170020) issued by China Food & Drugs Administration, china. It is valid until 28-03-2022.
5.	Mechanism for Vendor pre-qualificatior	The firm has submitted SOP for evaluation of vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Copy of COA of Metformin HCl (Batch # MET 121/16) from M/s Abhilasha Pharma Pvt. Ltd, India has been submitted. • Copy of COA of Sitagliptin Phosphate monohydrate (Batch # 12301 - 17030101) from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd, China has been submitted. • Copy of COA of reference standard of Metformin HCl and Sitagliptin Phosphate Monohydrate has been submitted. • Copy of COA of Metformin HCl impurity Standards A has been submitted.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in product development department.

<table>
<tr><th colspan="3">Production Data</th></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of “Gluset Plus XR Tablets 50/500mg”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 01</td><td>1500 tablets</td><td>May-18</td></tr>
<tr><td>Trial # 02</td><td>1500 tablets</td><td>May-18</td></tr>
<tr><td>Trial # 03</td><td>1500 tablets</td><td>May-18</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>Trial # 01</td><td>1231 Tab (87 packs * 14’s)</td><td>238 (17 packs * 14’s)</td><td>980 (70 packs * 14’s)</td></tr>
<tr><td>Trial # 02</td><td>1234 Tab (88 packs * 14’s)</td><td>210 (15 packs * 14’s)</td><td>1022 (73 packs * 14’s)</td></tr>
<tr><td>Trial # 03</td><td>1229 Tab (87 packs * 14’s)</td><td>210 (15 packs * 14’s)</td><td>1008 (72 packs * 14’s)</td></tr>
</table></td></tr>
<tr><th colspan="3">QA / QC DATA</th></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-07-2018 to 13-02- 2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Metformin HCl and Sitagliptin phosphate monohydrate.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Gluset Plus XR Tablets 50/500mg” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Metformin HCl: The firm has submitted photocopy of 06 Months Accelerated and 60 Months Real Time Stability Study Data of 03 Batches from M/s AbhilashaPharma Pvt. Ltd, India according to zone IVA conditions.
Sitagliptin Phosphate Monohydrate: The firm has submitted photocopy of 06 Months Accelerated and 24 Months Real Time Stability Study Data of 03 Batches from M/s Zhejiang Tianyu Pharmaceutical Co., Ltd, China according to zone IVA conditions.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
</table>

17.	Drug-excipients compatibility studies.	The firm has used the excipients of innovator.
18.	Recor of comparative dissolution d data.	The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Janumet XR Tablets 50/500mg manufactured by M/s Merck & CO., INC. with Lot No.R027476. The firm's product results are comparable to that of the competitor product.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of "Gluset Plus XR Tablets 50/500mg" from 30-05-2018 to 09-01-2019.

Deficiencies /Observations	**Response by the Firm**
Since API Sitagliptin is being incorporated via coating solution so how it is possible to ensure that proper amount of active has been incorporated in dosage form while using 100% quantity in master formulation.	To ensure incorporation of desired quantity of Sitagliptin through film coating solution, % age increase in the weight of finished tablets is determined as per formulation. The limits of minimum and maximum increase of weight after film coating are set
	by quality control department and the finished product is tested accordingly. As per standard manufacturing norms all actives are calculated on the basis of 100% quantity unless required for specific material like vitamins etc. in case of variation in results of analysis, the quantities may be adjusted if so required which is not in this case.
Label claim of applied formulation is Film coated tablet while reference formulation is extended release film coated tablet. Revision of Form-5 with requisite fee is required.	Submitted
How it could be justified that the results of dissolution analysis for Metformin as performed by UV method have not been interfered with the other API i.e. Sitagliptin present in the same sample aliquot.	The result of dissolution analysis for Metformin HCl on UV has not been interfered with sitagliptin as absorption maxima of Metfomin HCl as per pharmacopoeia is at 232 ± 2nm and there is no absorbance observed for sitagliptin at 232 ± 2nm. For reference, the UV spectra for Metformin HCl and sitagliptin separately as well as in combination are also attached.

Decision: Registration Board decided to constitute the panel for onsite verification for confirmation of following:

1) **Spray technique ensuring requisite quantity of API Sitagliptin being coated / incorporated on dosage form while using 100% quantity of API without loss compensation.**
2) **Results of dissolution analysis for Metformin performed by UV method were not interfered with the other API**

Remarks:

The Products were applied on Form 5 with stability data. The firm had applied for exemption from onsite inspection for verification of submitted stability data and subsequently the cases were presented in 290th meeting and the Board deferred the cases for panel constitution for verification of genuineness of submitted stability data.

The applicant vide online application ID E5G-EQD-TD3U dated 26-01-2026 has requested for constitution of panel for the inspection.

It is submitted that the development data of another strength (100mg/1000mg) of the same formulation was approved in 321st meeting. Following are the details:

Application ID:

Dy. No. 20683, 20-08-2020

Form:

Form 5F

Brand name:

Gluset XR Tablet 100/1000mg

Label Claim:

Each Extended Release Film Coated Tablet Contains:

Sitagliptin (as Phosphate monohydrate)…..100mg

Metformin HCl……1000mg

Submitted for consideration by the Board whether the deferred the cases should be processed for panel constitution for verification of submitted stability data or otherwise.

Decision: The Board observed that the development data of different strength of the same formulation (Gluset Plus XR 100mg/1000mg) has already been approved on Form 5F in the name of the applicatn. Therefore, the Board decided to exempt the onsite inspection and approved Gluset Plus XR 50mg/1000mg and Guset Plus XR 50mg/500mg.

55. The case was rejected by the registration board in its 329th meeting on grounds that me-too and RRA reference was not available. The firm submitted an appeal in Appellate Board and the case was referred back to Registration Board for reconsideration.

The case was presented in 339th meeting after verification of me-too and RRA reference. The decision of 339th meeting is reproduced below:

"Registration decided to convey the decision of Appellate Board to the applicant for compliance."

ase Referred back by Drugs Appellate Board
Additional Director, Legal Affairs has forwarded the decision of 166th sitting of Drugs Appellate Board held on 5th June 2024. The case details are as under:

Appeal No	23/2024
Appellant	M/s Pharma Health Pakistan (Pvt.) Limited, Lahore
Appeal preferred against the decision of:	Registration Board
Decision Appealed Against:	Against the decision rendered by Drug Registration Board in its 329th held on 6th to 8th June, 2023 regarding product "E Dol 2mg Tablet"
Date of the issuance of the decision:	11/01/2024
Date of the Appeal received:	09/03/2024
Appellant represented by:	Ms. Samra Ahsan, Manager Regulatory, Affairs

1. The Drug Registration Board in its 329th Meeting held on 06th to 08th of June, 2023 ('Impugned Decision') rejected the Appellant's application for registration of 'E Dol 2mg Tablet' on the ground that "it is neither approved by any reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th Meeting nor approved previously by the Registration Board."

2. Ms. Samra Ahsan appearing on behalf of the Appellant contended that the Subject Drug is an international registered brand of Bayer PLC with the brand name Progynova 2mg, further that a generic of the said drug has already been registered by the Registration Board by the name and style of 'Progens Tablet 2mg in favor of Dson Research Laboratories Pvt. Limited, having Registration No. 071383. The Appellant further contended that the subject drug is approved by the MHRA and submitted documentary evidence in this regard.

3. The Board prima facie finds credence in Appellant's claim and is of the opinion that the matter should be reviewed afresh by the Registration Board in light of the Appellant's contentions which do not seem to have been taken into consideration by the Registration Board.

4. For the reasons as provided above, the instant Appeal is allowed and the matter is remanded back to the Registration Board. The Appellant is directed to file a detailed representation with the Registration Board, placing all details of Subject Drug's approval by Reference Regulatory Authorities and previous registration (if any) by the Registration Board. The Registration Board shall decide the application through a well-reasoned and speaking order and shall be free to seek all necessary information from the Appellant as it deems fit in accordance with the laws.

History of the case The case was presented in 329th meeting of Registration Board wherein the following decision was made

Name and address of manufacturer / Applicant	**M/s Pharma Health Pakistan Pvt Ltd. 17-Km, Ferozepur Road, Lahore**
Brand Name +Dosage Form + Strength	E Dol 2mg Tablet
Composition	Each Gram Contains: Estradiol Valerate…2mg
Diary No. Date of R& I & fee	Dy No. 17253: 07-03-2019

	PKR 20,000/-: 06-03-2019
Pharmacological Group	Estrogens
Type of Form	Form 5
Finished Product Specification	Firm has claimed in house specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
Me-too status	Could not be confirmed
GMP status	
Remarks of the Evaluator[3].	• Latest GMP inspection report conducted within a period of last three years. • Clarification is required since on some pages of Form 5, tablet dosage form is written while the label claim specifies that it is a topical dosage form. • Evidence of required manufacturing facility / section approval letter from Licensing Division. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
Decision: Registration Board decided to reject the application since the applied product is neither approved by any reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting nor approved previously by Registration Board. Moreover, firm has also not submitted any clinical evidence to establish safety and efficacy of the applied formulation.	

Evaluation:

As per the submissions of the firm, the reference of RRA approval has been verified from MHRA with following details:

- Name: Progynova® 2 mg Tablets
- Label claim: Each sugar coated tablet contains: Estradiol valerate… 2mg
- RRA: MHRA, UK

Moreover, following me-too status is also verified:

- Name: Progens Tablets 2mg
- Registration No: 71303
- Company: Dyson Research Laboratories (Pvt.) Ltd

Decision of 339th meeting of Registration Board:

Registration decided to convey the decision of Appellate Board to the applicant for compliance.

Remarks:

Submitted by consideration of Board.

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.

Registration Board 361 Meeting Minutes:

Sr. No	Title	Description
1	Case Category	Routine (Abdul Mughees)
	Name, address of Applicant.	**Zafa Pharmaceutical Laboratories (Pvt) Ltd.** L-1/B Block-22 Federal B Industrial Area, Karachi-75950 **(000513)**
	Application Form Dy. No / Tracking ID & date of submission	(AR4-D8N-QQU8, 2024-06-03)
	Detail of Fee Submitted	30000.0, 2024-04-19,
	The proposed proprietary name / brand name	**Epzin 10mg tablet**
	Label Claim	Each tablet contain 10mg empagliflozin
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30 deg
	For generic drugs (me-too Status)	EMPAA 10mg tablets , Horizon Pharmaceuticals Pvt. Ltd
	Pharmacotherapeutic Group of (API)	ATC code: A10BK03; Sodium-glucose co-transporter 2 (SGLT2) inhibitors
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	Approved from DRAP
	Detail of previous approval	
	Evaluation Remarks	
	The firm has submitted following evidence: It is imperative to mention here that Empagliflozin API imported in 2021 for trial/manufacturing purposes was also procured through Noshad Trading. Furthermore, the manufacturer of the API in both cases (2021 procurement and the API used for the recent CDP study-2026) is the same, namely Fuxin Long Rui Pharmaceutical Co. Ltd., China. To substantiate this claim, following documents are duly being submitted: Clearance/import documents related to the Empagliflozin API procured in 2021. Corresponding documents related to the API used for the CDP study (2026) Certificate of Analysis (CoA) of the API procured in 2021. Certificate of Analysis (CoA) of the API used for the CDP study (2026)	
	Decision	
	Deferred Registration Board deferred to devise a mechanism to dipose off such cases wherein active pharmaceutical ingredient was imported without import license and clearance certificate. However, submitted data fulfils codal formalities.	
2	Case Category	Contract Manufacturing (Adil Saeed)
	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	(RP3-B5E-RE2A, 2025-01-08)

	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Erixon 50mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100x10s-As per SRO,10x10s-As per SRO,1x10s-As per SRO,1x5s-As per SRO,2x10s-As per SRO,3x10s-As per SRO,4x7s-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	not applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical Pvt Ltd-Plot# 129, Sundar Industrial Estate, Lahore Pakistan.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Sildenafil Tablet, USP 50mg by Rubicon Research Private Limited, USFDA APPROVED
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has already been granted registration of same drug product vide Registration No. 133071. The firm has requested to withdraw this application.	
	Decision	
	Rejected	
3	Case Category	Contract Manufacturing (Adil Saeed)
	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	(4PP-L78-TRQA, 2025-01-08)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Erixon 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100x10s-As per SRO,10x10s-As per SRO,1x10s-As per SRO,1x5s-As per SRO,2x10s-As per SRO,3x10s-As per SRO,4x7s-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	not applicable
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical Pvt Ltd-Plot# 129, Sundar Industrial Estate, Lahore Pakistan.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Sildenafil Tablet, USP 20mg by Rubicon Research Private Limited, USFDA APPROVED
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has requested to withdraw their application.	
	Decision	
	Rejected	
4	Case Category	Contract Manufacturing (Adil Saeed)
	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	(3G5-P9R-GRBX, 2025-01-08)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Erixon 25mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100x10s-As per SRO,10x10s-As per SRO,1x10s-As per SRO,1x5s-As per SRO,2x10s-As per SRO,3x10s-As per SRO,4x7s-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	not applicable
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceutical Pvt Ltd-Plot# 129, Sundar Industrial Estate, Lahore Pakistan.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Sildenafil Tablet, USP 25mg by Rubicon Research Private Limited, USFDA APPROVED
	GMP status of the firm	

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Firm has been granted registration of same drug product vide Registration No. 133072. Further firm has requested to withdraw this application.	
	Decision	
	Rejected	
5	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(ZSW-S4Q-62RY, 2024-06-13)
	Detail of Fee Submitted	75000.0, 9400 2024-05-15, 2026-07-17
	The proposed proprietary name / brand name	**Feveren-F 500mg TABLET**
	Label Claim	Each Film Coated tablet contains: Paracetamol (B.P)..... 500mg (B.P specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x7's, 4x7s, 1 x 10'-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)	N02BE01 Anilides
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Paracetamol 500 mg Film-coated Tablets (Balkanpharma – Dupnitsa AD 3, Samokovsko Shosse Str., 2600 Dupnitsa Bulgaria)
	Detail of previous approval	PEramol 500mg Tablet 353rd meeting of RB
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs(LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
6	Case Category	Routine (Adil 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	(YL6-NXV-SYGD, 2025-01-15)
	Detail of Fee Submitted	300000.0, 2024-12-24,
	The proposed proprietary name / brand name	**Sildena Dry Powder for Oral Suspension 10mg/mL**
	Label Claim	Each reconstituted mL contains: Sildenafil Citrate equivalent to Sildenafil.....10mg.
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	112ml-As per SRO,30ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	24 Year(s)Do not store above 30°C.
	For generic drugs (me-too Status)	Silagro Powder for Oral Suspension 10mg/mL (Reg. No.: 123345) by M/s Nabiqasim Industries (Pvt.) Ltd., Karachi.
	Pharmacotherapeutic Group of (API)	PDE 5 inhibitor for Pulmonary hypertension
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Zhejiang Zhongtong Pharmaceutical Co., Ltd. (Ready-to-fill granules)
	Detail of stability batches of drug product	3 batches, 130 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug Import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Revatio 10mg/ml. B. No. B780303 M/s Upjohn UK ltd
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted.
	The status in reference regulatory authorities	REVATIO for Oral Suspension 10mg/mL by M/s Viatris Specialty LLC, USA. (USFDA approved)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 10.11.2023 is submitted.
	Evidence of approval of manufacturing facility	Renewal letter dated 30.10.2019 is submitted.
	Evaluation Remarks	
	Firm has requested to withdraw their application.	
	Decision	
	Rejected	
7	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	(RLJ-UGM-SYXU, 2025-01-15)
	Detail of Fee Submitted	75000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Vira 1.1.24mg/ml Injection**
	Label Claim	Each ml of solution contains: Sildenafil Citrate eq. to Sildenafil.....0.8mg.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store between 20°C to 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	PDE 5 inhibitor for Pulmonary hypertension
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED
	Detail of stability batches of drug product	3 batches, 520 vials 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	Revatio 10mg/12.5ml Injection B. No. 598651 M/s Pfizer

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Revatio Injection by Pfizer Inc
	GMP status of the firm	GMP certificate is submitted
	Evidence of approval of manufacturing facility	Section approval is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
8	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**AsianContinental (Pvt.) Ltd.** D-32, S.I.T.E II, Super Highway, Karachi **(000643)**
	Application Form Dy. No / Tracking ID & date of submission	(GR9-YPQ-J7QG, 2024-06-20)
	Detail of Fee Submitted	75000.0, 9400 2024-05-15, 2026-07-17
	The proposed proprietary name / brand name	**Acgut 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Acotiamide HCl Hydrate 100mg
	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 below 30 °C
	For generic drugs (me-too Status)	Dyspenal Tablet 100mg (Kaizen Pharma Pvt Ltd)
	Pharmacotherapeutic Group of (API)	A03FA10 Propulsives
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Acofide Tablets 100 mg (Acotiamide Hydrochloride Hydrate) Zeria Pharmaceutical Co., Ltd
	Detail of previous approval	Acogut 100mg Tablet. M-358. Reg Letter issued,
	Evaluation Remarks	
	Cross referred application. Product is already approved and registration letter is issued.	
	Decision	
	Approved	
9	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(U2W-J3E-UPQ7, 2025-01-23)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-07-22
	The proposed proprietary name / brand name	**Sargra 25mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 25mgAjanta Pharma USA Inc. Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	350th meeting of Registration Board.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs(LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
10	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(MZY-Q8Z-P362, 2025-01-23)
	Detail of Fee Submitted	93000.0, 9400 2024-11-28, 2026-07-22
	The proposed proprietary name / brand name	**Sargra 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 100mg, Ajanta Pharma USA Inc. Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	Approved in 351st meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs(LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
11	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)**

	Application Form Dy. No / Tracking ID & date of submission	(QJ6-L78-GVA3, 2025-09-15)
	Detail of Fee Submitted	75000.0, 2025-02-03,
	The proposed proprietary name / brand name	**Wnafil 50mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 400 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s WNSFeild. Material import verified in PSI.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 50mg Tablet B. No. VS094520
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IV-A Attached
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	Valid till 11th October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
12	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)**
	Application Form Dy. No / Tracking ID & date of submission	(XMW-UXW-2Y4G, 2025-09-15)
	Detail of Fee Submitted	75000.0, 2025-02-03,
	The proposed proprietary name / brand name	**Wnafil 100mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil Citrate eq. 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)Store below 25°C.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Century Pharmaceuticals Limited 103-106, GIDC, Halol Dist. Panchmahals
	Detail of stability batches of drug product	3 batches, 400 tablets each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from WNSFeild. Loan and import verified in PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viagra 100mg B. No. VS114726
	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	Valid till 11th October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section approved
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
13	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	(ZEV-7T2-U9DS, 2025-02-13)
	Detail of Fee Submitted	75000.0, 2025-01-13,
	The proposed proprietary name / brand name	**Luxado 75mg Tablet**
	Label Claim	Each film coated tablet contains: Eluxadoline.....75mg
	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. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, Antipropulsives, A07DA06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	JiangsuYongan Pharmaceutical Co.Limited
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viberzi 75mg Tablet B. No. 524851 Mfg Allergan Australia.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viberzi by Allergan USA, Inc. Madison, NJ 07940
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 27.12.2023 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	

	Approved	
14	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	(M4R-DRQ-733P, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-29,
	The proposed proprietary name / brand name	**ELUXADOL 100mg Tablet**
	Label Claim	Each film coated tablet contains: Eluxadoline.....100mg
	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. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, Antipropulsives, A07DA06
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	Name & address of API manufacturer	Jiangsu Yongan Pharmaceutical Co.Limited
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viberzi 100mg Tablet B. No. 526351 Mfg Allergan Australia.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viberzi by Allergan USA, Inc. Madison, NJ 07940
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 27.12.2023 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
15	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	(HGP-ENR-1VJW, 2025-05-08)
	Detail of Fee Submitted	75000.0, 2025-01-13,
	The proposed proprietary name / brand name	**Luxado 100mg Tablet**
	Label Claim	Each film coated tablet contains: Eluxadoline.....100mg

	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. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, Antipropulsives, A07DA06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangsu Yongan Pharmaceutical Co.Limited
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Viberzi 100mg Tablet B. No. 526351 Mfg Allergan Australia.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Viberzi by Allergan USA, Inc. Madison, NJ 07940
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 06.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 27.12.2023 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
16	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**shaheen pharmaceuticals** 3-KM Murghzar Road Saidu Sharif Swat **(000562)**
	Application Form Dy. No / Tracking ID & date of submission	(9NL-W7T-BTN3, 2026-03-09)
	Detail of Fee Submitted	38700, 2026-01-22,
	The proposed proprietary name / brand name	**Bigra 100mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Hilagra 100mg Tablet (Hilton Pharma) Reg. No. 128040
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) ATC code: G04BE03.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED 103 TO 106, GIDC, HALOL CITY, HALOL-

		389350, DIST-PANCHMAHAL, GUJARAT STATE India
	Detail of stability batches of drug product	3 batches 1666 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	Pharmaceutical Equivalence And Comparative Dissolution study with Hilagra 100mg Tablet manufactured by (Hilton Pharma) Reg. No. 128040
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	Sildenafil Mylan 100 mg film-coated tablets MHRA Approved
	GMP status of the firm	GMP Valid
	Evidence of approval of manufacturing facility	Approval letter is submitted
	Evaluation Remarks	
	Priority as per decision of authority on drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
17	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**shaheen pharmaceuticals** 3-KM Murghzar Road Saidu Sharif Swat **(000562)**
	Application Form Dy. No / Tracking ID & date of submission	(95L-Z4E-JBYU, 2026-03-09)
	Detail of Fee Submitted	38700, 2026-01-22,
	The proposed proprietary name / brand name	**Bigra 50mg Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at temperature 15 to 30 C away from sunlight
	For generic drugs (me-too Status)	Hilagra 50mg Tablet (Hilton Pharma) Reg. No. 128038
	Pharmacotherapeutic Group of (API)	Selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5) ATC code: G04BE03.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CENTURY PHARMACEUTICALS LIMITED 103 TO 106, GIDC, HALOL CITY, HALOL-389350, DIST-PANCHMAHAL, GUJARAT STATE India
	Detail of stability batches of drug product	3 batches 1500 Tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence And Comparative Dissolution study with Hilagra 50mg Tablet

		manufactured by (Hilton Pharma) Reg. No. 128038
	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	GMP Valid Submitted
	Evidence of approval of manufacturing facility	Section approval submitted
	Evaluation Remarks	
	Priority as per decision of authority on drugs used in ED. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
18	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(RAE-6NB-AS3R, 2025-04-09)
	Detail of Fee Submitted	75000.0, 2025-01-10,
	The proposed proprietary name / brand name	**Desleric Tablet 0.1mg**
	Label Claim	Each film-coated tablet contains: Pemafibrate.....0.1mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	LIPID MODIFYING AGENTS, PLAIN C10AB12
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Pvt. Ltd.
	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	Parmodia Tablets 0.1mg (Kowa Company, Ltd, Tokyo) B. No. PY4A
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as pe Zone IVb Conditions.
	The status in reference regulatory authorities	PMDA, Japan Approved (Parmordia Tablet 0.1mg by
	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
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
19	Case Category	Routine (Adil Saeed)

	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(M8W-PYL-ADV9, 2025-04-09)
	Detail of Fee Submitted	75000.0, 2025-01-30,
	The proposed proprietary name / brand name	**Minrone Tablet 1.25mg**
	Label Claim	Each tablet contains: Esaxerenone.....1.25mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	ALDOSTERONE ANTAGONISTS Used in treatment ofhypertension and diabetic nephropathy.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangsu Jingye Pharmaceutical Co., Ltd.
	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	Minnebro 1.25mg Tablet (Daiichi Sankyo Co. Ltd. 3-5-1 Nihonbashihoncho, Chuo-ku, Tokyo) B No. YEA0020
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA, Japan Approved (MINNEBRO Tablet 1.25mg by Daiichi Sankyo Co., Ltd., Japan)
	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
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
20	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(3RS-J5N-LTDN, 2025-04-09)
	Detail of Fee Submitted	75000.0, 2025-01-30,
	The proposed proprietary name / brand name	**Minrone Tablet 2.5mg**
	Label Claim	Each tablet contains: Esaxerenone.....2.5mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C

	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	ALDOSTERONE ANTAGONISTS Used in treatment ofhypertension and diabetic nephropathy.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangsu Jingye Pharmaceutical Co., Ltd.
	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	Minnebro 2.5mg Tablet (Daiichi Sankyo Co. Ltd. 3-5-1 Nihonbashihoncho, Chuo-ku, Tokyo) B No. YFA0135
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA, Japan Approved (MINNEBRO Tablet 2.5mg by Daiichi Sankyo Co., Ltd., Japan)
	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
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
21	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(1DE-3HL-JU34, 2025-04-09)
	Detail of Fee Submitted	75000.0, 2025-01-30,
	The proposed proprietary name / brand name	**Minrone Tablet 5mg**
	Label Claim	Each tablet contains: Esaxerenone.....5mg (Innovator’s Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 10’s, 14’s, 20’-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	ALDOSTERONE ANTAGONISTS Used in treatment of hypertension and diabetic nephropathy.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jiangsu Jingye Pharmaceutical Co., Ltd.
	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	Minnebro 5mg Tablet (Daiichi Sankyo Co. Ltd. 3-5-1 Nihonbashihoncho, Chuo-ku, Tokyo) B No. YGA0027

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA, Japan Approved (MINNEBRO Tablet 5mg by Daiichi Sankyo Co., Ltd., Japan)
	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
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
22	Case Category	Any Other (Adil 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	(2M1-5TW-5EM7, 2026-03-26)
	Detail of Fee Submitted	313500.0, 2025-08-20,
	The proposed proprietary name / brand name	**Variorelix ® 500mcg/1ml**
	Label Claim	Each Pre-filled syringe Contains: Ganirelix acetate ... Eq. to Ganirelix.....0.5 mg (per 1 ml) (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)Below 30ºC
	For generic drugs (me-too Status)	Orgalutran®
	Pharmacotherapeutic Group of (API)	Competitive gonadotropin-releasing hormone (GnRH) antagonist
	Name, address of Manufacturing site:	Vitane Pharmed-Tehran-Qazvin Highway, Nazarabad Industrial Town, Imam Khomeini Street, Vitane Pharmed Factory-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Orgalutran® 0.25mg/0.5ml B. No. U022644 Mfg NV ORganon Netherlands
	Name, address of Marketing Authorization Holder:	Varian Pharmed Co. , No. 1534, Golshid 2nd St., Golrokh 2nd St., West Ghazali Blvd., Eshtehard Industrial City, Alborz, I.R. Iran, Iran
	Details of Certificates (CoPP/FSC/cGMP):	Copy of GMP certificate is submitted.
	Details of Authorization Letter :	COPP and agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	upto 36 months
	The status in reference regulatory authorities	Orgalutran®
	Evaluation Remarks	
	Priority as per decision of Authority for applications of imported finished drug products. Firm has requested to withdraw their application.	
	Decision	
	Rejected	
23	Case Category	Any Other (Adil 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	(3J1-RZA-1P74, 2026-04-06)
	Detail of Fee Submitted	300000.0, 2025-05-09,
	The proposed proprietary name / brand name	**Variopeptyl 0.1**
	Label Claim	Each Prefilled Syringe (1ml) contains: Triptorelin acetate eq to Triptorelin... 0.1 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2's-As per SRO
	Shelf Life (Unit)	2 Year(s)2-8 °C
	For generic drugs (me-too Status)	Decapeptyl Injection
	Pharmacotherapeutic Group of (API)	L02AE04 Gonadotropin releasing hormone (GnRH) analogues
	Name, address of Manufacturing site:	Varian Pharmed Co.-No. 1534, Golshid 2nd St., Golrokh 2nd St., West Ghazali Blvd, Eshtehard Industrial City, Alborz, I.R. Iran-Iran
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Name, address of Marketing Authorization Holder:	Varian Pharmed Co., No. 1534, Golshid 2nd St., Golrokh 2nd St., West Ghazali Blvd, Eshtehard Industrial City, Alborz, I.R. Iran, Iran
	Details of Certificates (CoPP/FSC/cGMP):	GMP certificate valid till 12.2025 is submitted.
	Details of Authorization Letter :	Free Sale certificate and Agency agreement is submitted.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-20C upto 60 months.
	The status in reference regulatory authorities	Decapeptyl Injection
	Evaluation Remarks	
	Priority as per decision of authority for imported finished drug products. Firm has requested to withdraw their application.	
	Decision	
	Rejected	
24	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(881-MGP-54DP, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Eplespra 25mg Tablet**
	Label Claim	Each film-coated tablet contains: Eplerenone.....25mg (JP Pharmacopoeia)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	7’s, 10’s, 14’s, 20’-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Epliron Tablet 25mg Highnoon Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists C03DA04

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aurisco Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Epliron 25 Tablet B. No 240549 M/s Highnoon Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA Approved
	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	Section approval letter dated 27.04.2020 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
25	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(2DV-SP3-U3Q7, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Eplespra 50 mg tablet**
	Label Claim	Each film-coated tablet contains: Eplerenone .....25mg (JP Pharmacopoeia)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	7’s, 10’s, 14’s, 20’-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Epliron Tablet 50mg Highnoon Laboratories Ltd.
	Pharmacotherapeutic Group of (API)	Aldosterone antagonists C03DA04
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aurisco Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Epliron 50 Tablet B. No 232844 M/s Highnoon Laboratories.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA Approved
	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	Section approval letter dated 27.04.2020 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
26	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(85N-1DL-HSDT, 2025-04-04)
	Detail of Fee Submitted	75000.0, 2025-01-06,
	The proposed proprietary name / brand name	**Epalrest Tablet 50mg**
	Label Claim	Each film-coated tablet contains: Epalrestat .....50mg (JP Specification)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	7's, 10's 14's, 10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	aldose reductase inhibitors (ARIs). It is a carboxylic acid derivative used primarily as an oral medication to treat diabetic neuropathy
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Kaifeng Mingren Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	3 batches, 2000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kinedak Tablet 50mg (Alfresa Pharma, Japan) B. No. 249TB
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA, Japan Approved (Kinedak Tablets 50mg by Alfresa Pharma, Japan)
	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	Section approval letter dated 27.04.2020 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
27	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(R2M-8M5-RT3M, 2025-01-23)

	Detail of Fee Submitted	93000.0, 2024-11-28,
	The proposed proprietary name / brand name	**Sargra 50mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 MonthStore in a cool & Dry place below 30
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Sildenafil Tablet, USP 50mg, Ajanta Pharma USA Inc. Bridgewater, NJ 08807 (USFDA Approved)
	Detail of previous approval	350th meeting of Registration Board.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs(LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	
28	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Novamed Pharmaceuticals (Pvt.) Ltd** 28-KM, Ferozepur Road, Lahore **(000590)**
	Application Form Dy. No / Tracking ID & date of submission	(QHA-U4L-51XW, 2025-01-21)
	Detail of Fee Submitted	37000.0, 2025-01-14,
	The proposed proprietary name / brand name	**Panagra Dry Suspension Oral**
	Label Claim	Each ml Contains: Sildenafil as citrate.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's(112ml)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 86°F (30°C) in the original package
	For generic drugs (me-too Status)	Silagro
	Pharmacotherapeutic Group of (API)	PDE-5 inhibitor for Pulmonary Hypertension
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Pvt Ltd
	Detail of stability batches of drug product	3 batches, 25 packs 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	Sildenafil 10mg/ml oral suspension B. No. DJ16433 Mfg Ajanta USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	REVATIO ORAL SUSPENSION by FDA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 14.09.2021 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
29	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	(9P3-6WV-9YZ6, 2025-01-28)
	Detail of Fee Submitted	37000.0, 2025-01-24,
	The proposed proprietary name / brand name	**Seldin 10mg/ml Suspension**
	Label Claim	Each mL of reconstituted Suspension Contains: Sildenafil as Citrate .....10 mg (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 25°c
	For generic drugs (me-too Status)	Silagro Powder for Oral Suspension 10mg/ml by NabiQasim
	Pharmacotherapeutic Group of (API)	PDE 5 inhibitor for pulmonary hypertension.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 250 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Import of material was verified in PSI.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sildenafil Suspension B. No. SL5102 Mfg Amneal Pharmaceuticals LLC
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	UK MHRA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 11.06.2024 is submitted.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
30	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(PSE-16Q-Z331, 2024-10-09)

	Detail of Fee Submitted	30000.0, 2023-12-05,
	The proposed proprietary name / brand name	**Brivact 10mg tablet**
	Label Claim	Each film coated tablet contains: Brivaracetam.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's,1x10's,2x10's,-As per SRO
	Shelf Life (Unit)	2 Year(s)Should be stored at room temperature below 30
	For generic drugs (me-too Status)	Brivace 10mg tablet M/S Hilton Pharma
	Pharmacotherapeutic Group of (API)	N03AX23 Other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Lee pharma Limited
	Detail of stability batches of drug product	3 batches, 1050 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from Medisure, clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Briviact 10mg Tablet
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Briviact 10mg tablet M/S UCB Pharma S.A. (USFDA Approved),Belgium
	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	
31	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(P2R-WV6-X1BE, 2024-07-02)
	Detail of Fee Submitted	30000.0, 2024-05-14,
	The proposed proprietary name / brand name	**Agoniz 25mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Agomelatine .....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)Store below 25°c
	For generic drugs (me-too Status)	Agozit Tablet by Wnsfeild Pharma
	Pharmacotherapeutic Group of (API)	N06AX22 Other antidepressants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shanku's Pharmaceuticals Plot No 9,10,11 Milan Industrial Estate, Santej, Ta: Kalol, Dist: Gandhinagar - 382721, Gujarat
	Detail of stability batches of drug product	3 batches, 1200 tablets each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Agoviz 25mg Tablet B. No. 1G127 M/s PharmEvo
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 36 months.
	The status in reference regulatory authorities	TGA Australia Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Section approval letter dated 05.05.2010 is submited.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
32	Case Category	Routine (Adil Saeed)
	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	(5LB-9GE-QTZ6, 2025-04-29)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Fycom Oral Suspension**
	Label Claim	Each ml of oral suspension contains Perampanel (as hemi sesquihydrate)...0.5mg
	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 room temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals (Pvt) Ltd.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	US FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	In submitted data, stability chamber data logger graphs are totally identical to the one submitted in following applications of M/s Hamaz Pharmaceuticals. Further as per submitted data Model and S. No. of UV spectrophotometer is also similar (UV-1800 (A11635581124ML)). R&D Officer in both firms is Mr. Muhammad Bilal, and R&D Manager is Naheed Yousaf. Same persons have signed the data of both firm in dates of same month	
	YAR-MN7-WH62	
	G72-8XG-BEB3	

G72-8XG-BEB3	
9S8-Z57-V897	
2XX-U53-6U7E	
1R4-YSV-X3R4	
Both firms, M/s Hamaz and M/s Horizon are sister concerns, but still its not possible for two firms to use same stability chambers and same UV spectrophotometer for stability studies and batch analysis. Further same persons are R&D officer and R&D manager in both firms.	
Decision	
Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	

33	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(YAR-MN7-WH62, 2025-05-12)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Fycom 12mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel (as hemisesquihydrate) .....12 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 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NURAY CHEMICALS PRIVATE LIMITED
	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)	Taken loan from M/s Horizon. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 12mg tablet B. No..... Mfg Eisai USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US FDA as FYCOMPA (Perampanel 12mg Tablets), for ORAL Use.
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 13.04.2021 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.04.2024 is submitted
	Evaluation Remarks	

In submitted data, stability chamber data logger graphs are totally identical to the one submitted in following application of M/s Horizon Pharma. Further as per submitted data Model and S. No. of UV spectrophotometer is also similar (UV-1800 (A11635581124ML)). R&D Officer in both firms is Mr. Muhammad Bilal, and R&D Manager is Naheed Yousaf. Same persons have signed the data of both firm in dates of same month	
5LB-9GE-QTZ6	
Both firms, M/s Hamaz and M/s Horizon are sister concerns, but still its not possible for two firms to use same stability chambers and same UV spectrophotometer for stability studies and batch analysis. Further same persons are R&D officer and R&D manager in both firms.	
Decision	
Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager ((Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	

34	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(Y9H-61E-J1LS, 2025-05-12)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Fycom 8mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel (as hemisesquihydrate) .....8 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 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NURAY CHEMICALS PRIVATE LIMITED
	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)	Taken loan from M/s Horizon. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 8mg tablet B. No..... Mfg Eisai USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US FDA as FYCOMPA (Perampanel 8mg Tablets), for ORAL Use.
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 13.04.2021 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.04.2024 is submitted

	Evaluation Remarks	
	In submitted data, stability chamber data logger graphs are totally identical to the one submitted in following application of M/s Horizon Pharma. Further as per submitted data Model and S. No. of UV spectrophotometer is also similar (UV-1800 (A11635581124ML)). R&D Officer in both firms is Mr. Muhammad Bilal, and R&D Manager is Naheed Yousaf. Same persons have signed the data of both firm in dates of same month	
	5LB-9GE-QTZ6	
	Both firms, M/s Hamaz and M/s Horizon are sister concerns, but still its not possible for two firms to use same stability chambers and same UV spectrophotometer for stability studies and batch analysis. Further same persons are R&D officer and R&D manager in both firms.	
	Decision	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager ((Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
35	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(9S8-Z57-V897, 2025-04-29)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Fycom 10mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel (as hemisesquihydrate) .....10 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 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NURAY CHEMICALS PRIVATE LIMITED
	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)	Taken loan from M/s Horizon. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 10mg tablet B. No..... Mfg Eisai USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US FDA as FYCOMPA (Perampanel 10mg Tablets), for ORAL Use.
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 13.04.2021 is submitted.

	Evidence of approval of manufacturing facility	Section approval letter dated 30.04.2024 is submitted
	Evaluation Remarks	
	In submitted data, stability chamber data logger graphs are totally identical to the one submitted in following application of M/s Horizon Pharma. Further as per submitted data Model and S. No. of UV spectrophotometer is also similar (UV-1800 (A11635581124ML)). R&D Officer in both firms is Mr. Muhammad Bilal, and R&D Manager is Naheed Yousaf. Same persons have signed the data of both firm in dates of same month	
	5LB-9GE-QTZ6	
	Both firms, M/s Hamaz and M/s Horizon are sister concerns, but still its not possible for two firms to use same stability chambers and same UV spectrophotometer for stability studies and batch analysis. Further same persons are R&D officer and R&D manager in both firms.	
	Decision	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
36	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(G72-8XG-BEB3, 2025-04-29)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Fycom 6mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel (as hemi sesquihydrate) .....6 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 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NURAY CHEMICALS PRIVATE LIMITED
	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)	Taken loan from M/s Horizon. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 6mg tablet B. No..... Mfg Eisai USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US FDA as FYCOM (Perampanel 6mg Tablets), for ORAL Use.

	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 13.04.2021 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.04.2024 is submitted
	Evaluation Remarks	
	In submitted data, stability chamber data logger graphs are totally identical to the one submitted in following application of M/s Horizon Pharma. Further as per submitted data Model and S. No. of UV spectrophotometer is also similar (UV-1800 (A11635581124ML)). R&D Officer in both firms is Mr. Muhammad Bilal, and R&D Manager is Naheed Yousaf. Same persons have signed the data of both firm in dates of same month	
	5LB-9GE-QTZ6	
	Both firms, M/s Hamaz and M/s Horizon are sister concerns, but still its not possible for two firms to use same stability chambers and same UV spectrophotometer for stability studies and batch analysis. Further same persons are R&D officer and R&D manager in both firms.	
	Decision	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager ((Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
37	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(2XX-U53-6U7E, 2025-04-29)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Fycom 2mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel (as hemi sesquihydrate) .....2 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 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NURAY CHEMICALS PRIVATE LIMITED
	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)	Taken loan from M/s Horizon. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 2mg tablet B. No..... Mfg Eisai USA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	Registered drug by US FDA as FYCOM (Perampanel 2mg Tablets), for ORAL Use.
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 13.04.2021 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.04.2024 is submitted
	Evaluation Remarks	
	In submitted data, stability chamber data logger graphs are totally identical to the one submitted in following application of M/s Horizon Pharma. Further as per submitted data Model and S. No. of UV spectrophotometer is also similar (UV-1800 (A11635581124ML)). R&D Officer in both firms is Mr. Muhammad Bilal, and R&D Manager is Naheed Yousaf. Same persons have signed the data of both firm in dates of same month	
	5LB-9GE-QTZ6	
	Both firms, M/s Hamaz and M/s Horizon are sister concerns, but still its not possible for two firms to use same stability chambers and same UV spectrophotometer for stability studies and batch analysis. Further same persons are R&D officer and R&D manager in both firms.	
	Decision	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
38	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(1R4-YSV-X3R4, 2025-04-29)
	Detail of Fee Submitted	75000.0, 2025-03-19,
	The proposed proprietary name / brand name	**Fycom 4mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel (as hemisesquihydrate) .....4 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 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NURAY CHEMICALS PRIVATE LIMITED
	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)	Taken loan from M/s Horizon. Clearance certificate and loan letter is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 4mg tablet B. No..... Mfg Eisai USA

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	2 batches 5000 tablets each
	The status in reference regulatory authorities	Registered drug by US FDA as FYCOMPA (Perampanel 4mg Tablets), for ORAL Use.
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 13.04.2021 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.04.2024 is submitted
	Evaluation Remarks	
	In submitted data, stability chamber data logger graphs are totally identical to the one submitted in following application of M/s Horizon Pharma. Further as per submitted data Model and S. No. of UV spectrophotometer is also similar (UV-1800 (A11635581124ML)). R&D Officer in both firms is Mr. Muhammad Bilal, and R&D Manager is Naheed Yousaf. Same persons have signed the data of both firm in dates of same month	
	5LB-9GE-QTZ6	
	Both firms, M/s Hamaz and M/s Horizon are sister concerns, but still its not possible for two firms to use same stability chambers and same UV spectrophotometer for stability studies and batch analysis. Further same persons are R&D officer and R&D manager in both firms.	
	Decision	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
39	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**A'raf (Pvt) Ltd** 23 KM Raiwind Road Lahore **(000685)**
	Application Form Dy. No / Tracking ID & date of submission	(W39-U68-7R16, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-01-16,
	The proposed proprietary name / brand name	**Zopiraf 25mg oral Tablet**
	Label Claim	Each film coated Tablet Contain Topiramate ------ 25mg (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO,60's-As per SRO
	Shelf Life (Unit)	2 Year(s)NMT 30C
	For generic drugs (me-too Status)	Topiro 25mg Tablet (Adamjee Pharmaceuticalse
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX11
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	data of 3 batches, 3000 tablets each is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted

	Pharmaceutical Equivalence and Comparative Dissolution Profile	Topamax B. No. NAS1500 Mfg cilag Switzerland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Topamax (Janssen)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 27.08 2024 is submitted
	Evidence of approval of manufacturing facility	Regularization of layout letter 12.03.2021 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
40	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Global Pharmaceuticals Pakistan** Plot # 8, Street # S-8, RCCI, Industrial Estate Rawat, Islamabad-Pakistan **(000724)**
	Application Form Dy. No / Tracking ID & date of submission	(3JM-2Q5-41V8, 2025-04-09)
	Detail of Fee Submitted	37000.0, 2025-03-10,
	The proposed proprietary name / brand name	**Luzone cream 1% w/w**
	Label Claim	Each gram contains: Luliconazole.....10mg(1%w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm-As per SRO,15gm-As per SRO,30gm-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C - to 30°C (59°F to 86°F)
	For generic drugs (me-too Status)	Lunaz Cream 1% BY Winbrains Research Laboratories
	Pharmacotherapeutic Group of (API)	Imidazole and triazole derivatives D01AC18
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Precise Biopharma Private Limited ADDRESS: Plot No. C-384, T.T.C. Industrial Area, MIDC, Village Pawane, Navi Mumbai-400 703 Maharashtra (India)
	Detail of stability batches of drug product	3 batches, 102 tubes 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	Luzu 1% cream B. No. PHBP Mfg Bausch Health companies.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 19.01.2022 is submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	

	Decision	
	Approved	
41	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**SAMI Pharmaceuticals Pvt. Ltd.** F-95 Hub River Road S.I.T.E Karachi **(000072)**
	Application Form Dy. No / Tracking ID & date of submission	(RYP-4Q3-RJA5, 2025-02-07)
	Detail of Fee Submitted	75000.0, 2024-10-10,
	The proposed proprietary name / brand name	**LICONA**
	Label Claim	Each gram contains: Luliconazole.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De regulated-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store over 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Imidazole and triazole derivatives D01AC18
	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
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Luliconazole 1% cream B. No. 8147161 Mfg Bausch health Canada
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Luliconazole 1% Cream (USFDA)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 01.07.2024 is submitted
	Evidence of approval of manufacturing facility	Renewal letter dated 13.10.2023 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
42	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(YRV-PMT-DBXY, 2025-02-04)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Ramnel 10mg tablet**
	Label Claim	Each film-coated tablet contains: Perampanel.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s,14s, 20s, 28-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)	Not applicable
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals Pvt Ltd,
	Detail of stability batches of drug product	3 batches, 3500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 10mg Tablet B. No. 130999 Mfg Eisai Europe UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Fycompa 10mg by Catalyst Pharmaceuticals Inc
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 12.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
43	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(L5N-6ZX-65ZX, 2025-02-10)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Ramnel 8mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel.....8mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s,14s, 20s, 28-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)	Fycompa 8mg Tablet by Hilton Pharma (Pvt.), Ltd.
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals Pvt Ltd,
	Detail of stability batches of drug product	3 batches, 3500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 8mg Tablet B. No. 137214 Mfg Eisai Europe UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Fycompa 8mg by Catalyst Pharmaceuticals Inc
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 12.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 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.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(P18-JHP-NH2S, 2025-02-10)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Ramnel 12mg tablet**
	Label Claim	Each film-coated tablet contains: Perampanel.....12mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s,14s, 20s, 28-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)	Not applicable
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals Pvt Ltd,
	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)	Drug import license is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 12mg Tablet B. No. 132137 Mfg Eisai Europe UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Fycompa 12mg by Catalyst Pharmaceuticals Inc
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 12.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 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.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(A7P-JY9-S9MB, 2025-02-10)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Ramnel 2mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel 2mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	7s, 10s,14s, 20s, 28-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)	Fycompa 2mg Tablet by Hilton Pharma (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals Pvt Ltd,
	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)	Drug import license is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 2mg Tablet B. No. 140352 Mfg Eisai Europe UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Fycompa by Catalyst Pharmaceuticals Inc
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 12.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
46	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(4G2-XEZ-4RXU, 2025-02-10)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Ramnel 6mgTablet**
	Label Claim	Each film-coated tablet contains: Perampanel.....6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s,14s, 20s, 28-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)	Fycompa 6mg Tablet by Hilton Pharma (Pvt.), Ltd.
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals Pvt Ltd,
	Detail of stability batches of drug product	3 batches, 3500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 6mg Tablet B. No. 139135 Mfg Eisai Europe UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted

	The status in reference regulatory authorities	Fycompa 6mg Tablet by Catalyst Pharmaceuticals Inc
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 12.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
47	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(49G-DAG-DVQG, 2025-02-10)
	Detail of Fee Submitted	37000.0, 2024-12-05,
	The proposed proprietary name / brand name	**Ramnel 4mg Tablet**
	Label Claim	Each film-coated tablet contains: Perampanel.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7s, 10s,14s, 20s, 28-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)	Fycompa 4mg Tablet by Hilton Pharma (Pvt.), Ltd.
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX22
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nuray Chemicals Pvt Ltd,
	Detail of stability batches of drug product	3 batches, 3500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Fycompa 4mg Tablet B. No. 138580Mfg Eisai Europe UK
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Fycompa 4mg Tablet by Catalyst Pharmaceuticals Inc
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 12.06.2023 is submitted.
	Evidence of approval of manufacturing facility	Section approval letter dated 30.06.2020 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
48	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Polyfine Chempharma** 51 Industrial Estate Hayatabad Peshawar, Pakistan **(000216)**

	Application Form Dy. No / Tracking ID & date of submission	(6RU-EB1-73NQ, 2026-03-09)
	Detail of Fee Submitted	38700, 2026-03-04,
	The proposed proprietary name / brand name	**Sildfil 25mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Sildenafil Citrate eq to Sildenafil ..... 25 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 8-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature
	For generic drugs (me-too Status)	Getfil 25mg tablet
	Pharmacotherapeutic Group of (API)	PDE 5 inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Rakshit Drugs Private Limited
	Detail of stability batches of drug product	3 batches 10000 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	Getfil 25mg Tablet B. No. 001FS3 Mfg Getz Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Attached
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	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	
49	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi **(000333)**
	Application Form Dy. No / Tracking ID & date of submission	(8ZD-4QQ-PMME, 2026-05-11)
	Detail of Fee Submitted	75000, 2026-03-24,
	The proposed proprietary name / brand name	**PEPZYM-P PLUS 25000 CAPSULES**
	Label Claim	Each capsule contains: 300mg pancreatin corresponding to: 25,000 Ph. Eur. Units LIPASE 18,000 Ph. Eur. Units AMYLASE 1,000 Ph. Eur. Unit PROTEASE
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10x10's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Digestive Enzymes/Pancreatic Enzyme replacement therapies (PERT)
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Spansules Formulations India private limited (Office Address: 3rd Floor, MIG-57, Dharmareddy colony, Hydernagar, Hyderabad – 500072, INDIA)
	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)	Clearance certificate is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Creon 25000 Capsule B. No 64353 (Abbott Laboratories GmbH Hannover, Germany)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Creon 25000 Capsule (Abbott Laboratories GmbH Hannover, Germany)
	GMP status of the firm	20 February, 2024
	Evidence of approval of manufacturing facility	03 January 2000
	Evaluation Remarks	
	Priority as per approval of Director PE&R vide File (Ref. No: 10-1/2025-PEC / Subject: Non-routine / out of queue consideration) dated 18.08.2026 Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
50	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Shaigan Pharmaceuticals (Pvt) Ltd** 14Km Adyala Road Post office Dahgal Rawalpindi **(000333)**
	Application Form Dy. No / Tracking ID & date of submission	(MX4-3JE-NP3R, 2026-05-11)
	Detail of Fee Submitted	75000, 2026-03-24,
	The proposed proprietary name / brand name	**PEPZYM-P FORTE 35000 CAPSULES**
	Label Claim	Each capsule contains: 420mg pancreatin corresponding to: 35,000 Ph. Eur. Units LIPASE 25,200 Ph. Eur. Units AMYLASE 1,400 Ph. Eur. Unit PROTEASE
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10x10's -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Digestive Enzymes/Pancreatic Enzyme replacement therapies (PERT)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Spansules Formulations India private limited (Office Address: 3rd Floor, MIG-57, Dharmareddy colony, Hydernagar, Hyderabad – 500072, INDIA)
	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)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Kreon 35000 capsule (Viatris Healthcare Limited Dublin, Ireland). Lot 65821

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Kreon 35000 capsule (Viatris Healthcare Limited Dublin, Ireland).
	GMP status of the firm	20 February, 2024
	Evidence of approval of manufacturing facility	03 January 2000
	Evaluation Remarks	
	Priority as per approval of Director PE&R vide File (Ref. No: 10-1/2025-PEC / Subject: Non-routine / out of queue consideration) dated 18.08.2026 Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
51	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	**Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)**
	Application Form Dy. No / Tracking ID & date of submission	(UG9-2XQ-8LMW, 2026-02-19)
	Detail of Fee Submitted	38700, 2025-10-22,
	The proposed proprietary name / brand name	**SULPIRA 50MG TABLET**
	Label Claim	Each tablet contains: Levosulpiride 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Sulvorid 50mg (Reg.No 070485) - HIGH-Q PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Antipsychotics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	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	Sulvorid 50mg tablet 5SV156 M/s High-Q
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Levosulpiride Aristo 50mg TABLETS, Aristo Pharma, Germany, RRA 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	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
52	Case Category	Export Facilitation (Adil Saeed)

	Name, address of Applicant.	**Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)**
	Application Form Dy. No / Tracking ID & date of submission	(PVS-XTA-TDHJ, 2026-03-10)
	Detail of Fee Submitted	38700, 2025-10-22,
	The proposed proprietary name / brand name	**SULPIRA 25mg Tablet**
	Label Claim	Each tablet contains: Levosulpiride 25mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,3x10's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Sulvorid (Reg.No 070484) - HIGH-Q PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	Propulsive (Gastro-Prokinetic)
	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)	AD attested invoice and drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sulvorid 25mg tablet B. No. 25v308, M/s High-Q
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	LEVOGASTROL 25 mg TABLETS, Laboratorios Salvat S.A., SPAIN AEMPS 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	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
53	Case Category	Export Facilitation (Adil Saeed)
	Name, address of Applicant.	**Sante (Private) Limited** A-97, SITE Superhighway, Karachi. **(000702)**
	Application Form Dy. No / Tracking ID & date of submission	(981-US7-44J9, 2025-09-26)
	Detail of Fee Submitted	75000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Vislat-N Ophthalmic Solution**
	Label Claim	Each ml contains; Netarsudil Dimesylate eq. Netarsudil...0.2mg Latanoprost..... 0.05mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2.5-As per SRO
	Shelf Life (Unit)	24 Year(s)Store at 2°C to 8°C

	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Ophthalmologicals, antiglaucoma preparations and miotics, ATC code: S01EE51
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Data of 3 batches with real time at 5C is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate and AD attested invoice is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Roclanda Eye Drops (AERIE PHARMACEUTICALS IRELAND) B. No. 90645
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	ROCKLATAN® (netarsudil and latanoprost ophthalmic solution) Company: ALCON LABS INC (USA)
	GMP status of the firm	GMP certificate issued on basis of inspection dated 24.01.2024 is submitted.
	Evidence of approval of manufacturing facility	Sterile ophthalmic drops general section mentioned in renewal letter dated 20.09.2021
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
54	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(6R9-W3U-PU31, 2025-02-10)
	Detail of Fee Submitted	75000.0, 2024-12-19,
	The proposed proprietary name / brand name	**Dogest**
	Label Claim	Each film coated tablet contains: Dienogest.....2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 14's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Not Applicable.
	Pharmacotherapeutic Group of (API)	PROGESTOGENS G03DB08
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Chenghui Shuangda Pharmaceutical Co., Ltd., situated at Economic Development Zone, Pingyuan County?Dezhou City, Shandong, P.R. China.
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Visanne Tablet 2mg B. No. WEW87L Mfg bayer Germany

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Dienogest Stragen 2 mg Film-Coated tablets, approved by MHRA.
	GMP status of the firm	GMP certificate issued on basis of inspection dated 03.11.2022 is submitted
	Evidence of approval of manufacturing facility	Tablet Hormone section mentioned in Renewal letter dated 08.06.2021
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
55	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(DGG-VD5-S838, 2025-02-12)
	Detail of Fee Submitted	75000.0, 2024-07-29,
	The proposed proprietary name / brand name	**Imeglin 500mg Tablet**
	Label Claim	Each Film-Coated Tablet contains: Imeglimin HCL.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-De-Controlled
	Shelf Life (Unit)	24 Year(s)Real time 30 C
	For generic drugs (me-too Status)	Nil
	Pharmacotherapeutic Group of (API)	Other blood glucose lowering drugs, excl. insulins A10BX15
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Ltd., Block. no. 82/B, ECP road, AT & Post Karakhadi-391450, Taluka Padra, District Vadodara, Gujrat, India
	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)	Form 6 is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Twymeeg 500mg Tablet B. No. 1121C Mfg Sumitomo pharma Japan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Section approval letter is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
56	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan.

		(000644)
	Application Form Dy. No / Tracking ID & date of submission	(S5P-HPA-RPL9, 2025-09-30)
	Detail of Fee Submitted	75000, 2025-09-05,
	The proposed proprietary name / brand name	**Seagra 25mg Orodispersible Tablet**
	Label Claim	Each ORODISPERSIBLE Tablet Contains: Sildenafil Citrate eq. to Sildenafil.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	G04BE03 Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 450 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice or clearance certificate is not submitted. Firms film coated sildenafil is approved and its registration was issued on basis of PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vizarsin 25mg Tablet Batch No. 11320922
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per Zone-IV A
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Tablet General Section approved vide letter dated 05.05.2010
	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	
57	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(N9L-97D-8HQT, 2025-10-09)
	Detail of Fee Submitted	75000, 2025-09-05,
	The proposed proprietary name / brand name	**Seagra 50mg Chewable Tablet**
	Label Claim	Each Chewable Tablet Contains: Sildenafil as Citrate.....50mg (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 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	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.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from WNSfeild, loan verified in PSI.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	idoka 50mg Chewable tablets Lot No. CAB0268 M/s Stada
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone-IV A
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Valid till October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section approval 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	
58	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(9UG-J8J-L4DL, 2025-10-02)
	Detail of Fee Submitted	75000, 2025-09-05,
	The proposed proprietary name / brand name	**Seagra 50mg Orodispersible Tablet**
	Label Claim	Each ORODISPERSIBLE Tablet Contains: Sildenafil as Citrate 50MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	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
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M.s WNSFeild, loan verified in PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vizarsin 50mg Tablet Batch No. 34640112
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone-IV A
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Valid till October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section approval 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	
59	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(3Q8-W3X-18R7, 2025-10-14)
	Detail of Fee Submitted	75000, 2025-09-05,
	The proposed proprietary name / brand name	**Seagra 100mg Orodispersible Tablet**
	Label Claim	Each ORODISPERSIBLE Tablet Contains: Sildenafil as Citrate 100MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	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
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s WNSfeild. Loan verified in PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Vizarsin 100mg Tablet Batch No. 12620323
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone-IV A
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Valid till October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section approved
	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	
60	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(7MS-XEV-EY21, 2025-09-30)
	Detail of Fee Submitted	75000, 2025-09-05,
	The proposed proprietary name / brand name	**Seagra 25mg Chewable Tablet**
	Label Claim	Each Chewable Tablet Contains: Sildenafil as Citrate 25MG
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A

	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	T-16, T-17, T-18 data of 3 batches is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan, loan verified in PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Idoka 25mg tablet, B. No. CAB0786
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone-IV A
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Valid till October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section
	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	
61	Case Category	Any Other (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(5D5-1JE-DMES, 2025-09-30)
	Detail of Fee Submitted	75000, 2025-09-05,
	The proposed proprietary name / brand name	**Seagra 100mg Chewable Tablet**
	Label Claim	Each Chewable Tablet Contains: Sildenafil as Citrate 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	T-22, T-23, T-24 Data of 3 batches is submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan, loan verified in PSI
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Idoka 100mg Chewable tablets. B. No. CAB0587
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone-IV A
	The status in reference regulatory authorities	CIMA Spain Approved
	GMP status of the firm	Valid till October, 2025
	Evidence of approval of manufacturing facility	Tablet General Section approved
	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	
62	Case Category	Routine (Adil Saeed)
	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	(W2M-B91-Y8BE, 2024-06-25)
	Detail of Fee Submitted	30000.0, 2023-10-30,
	The proposed proprietary name / brand name	**TRIZOL 600MG/300ML INFUSION**
	Label Claim	Each 300ml vial contains: Linezolid.....600mg
	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 30oC
	For generic drugs (me-too Status)	Lezol 600mg/300ml Infusion by M/s Bosch Pharmaceuticals (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	J01XX08 Other antibacterials
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s SYMED LABS LIMITED
	Detail of stability batches of drug product	3 batches, 500 vials 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	Lezol 600mg/300ml Infusion M/s
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVA upto 60 months
	The status in reference regulatory authorities	Zyvox IV Infusion (Pfizer Limited. UK)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection report dated 11.01.2021 is submitted,
	Evidence of approval of manufacturing facility	Liquid Injection Vial (LVP) (general) section approved vide letter dated 20.06.2025
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
63	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, 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 (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 360th meeting of RB for submission of RMP. Now firm has submitted RMP. Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
64	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Winbrains Research Laboratories** Plot No. 69/1 Block B, Phase I-II Industrial Estate, Hattar, Pakistan **(000725)**
	Application Form Dy. No / Tracking ID & date of submission	(QHT-U39-S8WY, 2025-04-06)
	Detail of Fee Submitted	30000.0, 7000.0 2024-06-05, 2025-02-21
	The proposed proprietary name / brand name	**Person 50mg Tablet**
	Label Claim	Each Sugar Coated Tablet Contains: Eperisone Hydrochloride.....50mg
	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)	Peson Tablet by Regal Pharma
	Pharmacotherapeutic Group of (API)	Muscle relaxant, Other centrally acting agents M03BX09
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1200 Tablets each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Perispa 50mg Tablet B. No. 094 Mfg M/s Platinum Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	Tablet general section mentioned in letter dated 24.06.2011
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
65	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(5YN-1BV-L3SR, 2025-02-13)
	Detail of Fee Submitted	37000.0, 2024-12-30,
	The proposed proprietary name / brand name	**Epson 50mg Tablet**
	Label Claim	Each Sugar Coated Tablet Contains: Eperisone Hydrochloride.....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)Store below 25°c
	For generic drugs (me-too Status)	Peson Tablet by Regal Pharma
	Pharmacotherapeutic Group of (API)	Muscle relaxant, Other centrally acting agents M03BX09
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Eperon 50mg Tablets Batch No. 041
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA Japan
	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	

66	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(STB-PEW-TEZL, 2024-09-11)
	Detail of Fee Submitted	75000.0, 2024-07-12,
	The proposed proprietary name / brand name	**Calcidiol 15mg/100mL oral solution in drops**
	Label Claim	Each 100ml of solution contains: Calcifediol (as monohydrate)..... 15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mL-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)	A11CC06 Vitamin D and analogues
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CARBOGEN AMCIS B.V & Address: Nieuweweg 2A, Veenendaal, 3901BE, Netherlands
	Detail of stability batches of drug product	3 batches, 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Dedrogyl 0.15mg/ml oral solution for drops.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	National Agency for the, Safety of Medicine and Health Products (ANSM)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023

Evaluation Remarks

Firm is using 15% overage. Firm was asked to justify it.
Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.
Firm was further asked to give reference of international guidance allowing it.
Firm has quoted ICH Q8 (R2) guidelines section “2.2.2 Overages,” The quoted section states as under;
2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product’s shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).
Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.

Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.	
In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.	
Firm was asked about these differences.	
Firm stated that DS manufacturer has performed stability on both conditions.	
Firm has not submitted stability summary sheets of DS signed and stamped by the DS manufacturer	
The case was discussed in 357th meeting and was deferred with following decision Deferred for following; Submission of detailed analysis and quantification of degradation products in the finished drug product. Submission of signed stability datasheets of drug substance from drug substance manufacturer. Submission of clarification from drug substance manufacturer regarding performance of stability studies according to different climatic conditions.	
Regarding degradation products, firm has submitted quantification of degradation products in the Finished product. 10% drug substance has degraded and 10% total degradation products are measured. Total 4 degradation products are identified, Product 1- 3.03%, Product 2-2.88%, Product 3-0.14% and Product 4-4%. Further firm has stated that calcifediol is known to undergo isomerization, including formation of pre-calcifediol/isomeric forms and structurally related vitamin D metabolites, such as 3-epi-25-hydroxyvitamin D3. These compounds are structurally related to clacifediol and are not established as DNA-reactive/carcinogenic impurities.	
Signed stability datasheets of drug substance from drug substance manufacturer are submitted.	
Clarification from drug substance manufacturer is submitted stating: "We/I hereby declare that Stability studies for Calcifediol Monohydrate are conducted under both Climatic Zone II (25°C ± 2°C/60% RH ± 5% RH) and Climatic Zone IVa (30°C ± 2°C/65% RH ± 5% RH) The studies are performed under both climatic conditions to support regulatory submissions in different geographical regions and to demonstrate the stability of the drug substance under varying long-term storage conditions"	
Application fulfills codal formalities. Recommended for consideration of board.	
Decision	
Deferred Deferred for submission of innovator's method of analysis of degradation products in finished drug product.	

67	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(JQE-Y8Z-G52W, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	**Calcidiol 0.266mg oral solution**
	Label Claim	Each 1.5ml of solution contains: Calcifediol monohydrate..... 0.266mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.5mL (10 bottles pe-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)	A11CC06 Vitamin D and analogues
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	CARBOGEN AMCIS B.V & Address: Nieuweweg 2A, Veenendaal, 3901BE, Netherlands
Detail of stability batches of drug product	3 batches, 100 bottles each
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Hideroferol 0.266mg Oral solution B. No. 23023
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
The status in reference regulatory authorities	Spanish Agency for Medicines and Health Products (AEMPS)
GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023

Evaluation Remarks

Firm is using 15% overage. Firm was asked to justify it.
Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.
Firm was further asked to give reference of international guidance allowing it.
Firm has quoted ICH Q8 (R2) guidelines section “2.2.2 Overages,” The quoted section states as under;
2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product’s shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).
Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.
Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.
In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.
Firm was asked about these differences.
Firm stated that DS manufacturer has performed stability on both conditions.
Firm has not submitted stability summary sheets of DS signed and stamped by the DS manufacturer
The case was discussed in 357th meeting and was deferred with following decision Deferred for following; Submission of detailed analysis and quantification of degradation products in the finished drug product. Submission of signed stability datasheets of drug substance from drug substance manufacturer. Submission of clarification from drug substance manufacturer regarding performance of stability studies according to different climatic conditions.
Regarding degradation products, firm has submitted quantification of degradation products in the Finished product. 10% drug substance has degraded and 10% total degradation products are measured. Total 4 degradation products are identified, Product 1- 3.03%, Product 2-2.88%, Product 3-0.14% and Product 4-4%. Further firm has stated that calcifediol is known to undergo

isomerization, including formation of pre-calcifediol/isomeric forms and structurally related vitamin D metabolites, such as 3-epi-25-hydroxyvitamin D3. These compounds are structurally related to clacifediol and are not established as DNA-reactive/carcinogenic impurities.	
Signed stability datasheets of drug substance from drug substance manufacturer are submitted.	
Clarification from drug substance manufacturer is submitted stating: "We/I hereby declare that Stability studies for Calcifediol Monohydrate are conducted under both Climatic Zone II (25°C ± 2°C/60% RH ± 5% RH) and Climatic Zone IVa (30°C ± 2°C/65% RH ± 5% RH) The studies are performed under both climatic conditions to support regulatory submissions in different geographical regions and to demonstrate the stability of the drug substance under varying long-term storage conditions"	
Application fulfills codal formalities. Recommended for consideration of board.	
Decision	
Deferred Deferred for submission of innovator's method of analysis of degradation products in finished drug product.	

68	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port Qasim Authority, Karachi **(000755)**
	Application Form Dy. No / Tracking ID & date of submission	(HEH-38E-TX97, 2024-09-23)
	Detail of Fee Submitted	75000.0, 2024-08-07,
	The proposed proprietary name / brand name	**calcidiol 0.1mg/mL Oral drops in Solution**
	Label Claim	Each ml of solution contains Calcifediol monohydrate..... 0.1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10mL-As per SRO,20mL-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)	A11CC06 Vitamin D and analogues
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Nieuweweg 2A , Veenendaal ,3901 BE , Netherlands
	Detail of stability batches of drug product	3 batches, 100 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Hideroferol Choque 0.1mg Oral solution
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
	The status in reference regulatory authorities	Spanish Agency for Medicines and Health Products (AEMPS)
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
	Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023
	Evaluation Remarks	
	Firm is using 15% overage. Firm was asked to justify it.	

	Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.	
	Firm was further asked to give reference of international guidance allowing it.	
	Firm has quoted ICH Q8 (R2) guidelines section "2.2.2 Overages," The quoted section states as under;	
	2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product's shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).	
	Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.	
	Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.	
	In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.	
	Firm was asked about these differences.	
	Firm stated that DS manufacturer has performed stability on both conditions.	
	Firm has not submitted stability summary sheets of DS signed and stamped by the DS manufacturer	
	The case was discussed in 357th meeting and was deferred with following decision Deferred for following; Submission of detailed analysis and quantification of degradation products in the finished drug product. Submission of signed stability datasheets of drug substance from drug substance manufacturer. Submission of clarification from drug substance manufacturer regarding performance of stability studies according to different climatic conditions.	
	Regarding degradation products, firm has submitted quantification of degradation products in the Finished product. 10% drug substance has degraded and 10% total degradation products are measured. Total 4 degradation products are identified, Product 1- 3.03%, Product 2-2.88%, Product 3-0.14% and Product 4-4%. Further firm has stated that calcifediol is known to undergo isomerization, including formation of pre-calcifediol/isomeric forms and structurally related vitamin D metabolites, such as 3-epi-25-hydroxyvitamin D3. These compounds are structurally related to clacifediol and are not established as DNA-reactive/carcinogenic impurities.	
	Signed stability datasheets of drug substance from drug substance manufacturer are submitted.	
	Clarification from drug substance manufacturer is submitted stating: "We/I hereby declare that Stability studies for Calcifediol Monohydrate are conducted under both Climatic Zone II (25°C ± 2°C/60% RH ± 5% RH) and Climatic Zone IVa (30°C ± 2°C/65% RH ± 5% RH) The studies are performed under both climatic conditions to support regulatory submissions in different geographical regions and to demonstrate the stability of the drug substance under varying long-term storage conditions"	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Deferred Deferred for submission of innovator's method of analysis of degradation products in finished drug product.	
69	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Kaizen Pharmaceuticals (Pvt) Ltd** Plot No. E-127, E-128 & E-129, North Western Zone, Port

	Qasim Authority, Karachi **(000755)**
Application Form Dy. No / Tracking ID & date of submission	(18D-TED-RP2M, 2024-09-09)
Detail of Fee Submitted	75000.0, 2024-08-07,
The proposed proprietary name / brand name	**Calcidiol 3mg Oral Solution**
Label Claim	Each 1.5ml of solution contains Calcifediol Monohydrate..... 3mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1.5mL (1 bottle per -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)	A11CC06 Vitamin D and analogues
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	CARBOGEN AMCIS B.V & Address: Nieuweweg 2A, Veenendaal, 3901BE, Netherlands
Detail of stability batches of drug product	3 batches, 100 bottles each
Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	Hideroferol Choque 3mg Oral solution B. No. 23001
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Zone IVa, upto 60 months.
The status in reference regulatory authorities	Spanish Agency for Medicines and Health Products (AEMPS)
GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 03.01.2023 is submitted.
Evidence of approval of manufacturing facility	Liquid section approved vide letter dated 03.03.2023

Evaluation Remarks

Firm is using 15% overage. Firm was asked to justify it.
Firm has stated that its a vitamin D preparation so during manufacturing processes it losses 15% of its potency, thats why they have used 15% overage.
Firm was further asked to give reference of international guidance allowing it.
Firm has quoted ICH Q8 (R2) guidelines section “2.2.2 Overages,” The quoted section states as under;
2.2.2 OveragesIn general, use of an overage of a drug substance to compensate for degradation during manufacture or a product’s shelf life, or to extend shelf life, is discouraged. Any overages in the manufacture of the drug product, whether they appear in the final formulated product or not, should be justified considering the safety and efficacy of the product. Information should be provided on the 1) amount of overage, 2) reason for the overage (e.g., to compensate for expected and documented manufacturing losses), and 3) justification for the amount of overage. The overage should be included in the amount of drug substance listed in the batch formula (3.2.P.3.2).
Even if international guidelines permit overage in especial circumstances, international guidelines also instruct to perform impurity profiling of finished drug product, which local manufacturers don't perform. Due to this reason if 15% drug substance has degraded during formulation then it must have degraded into some degradation products, which are neither identified nor quantified.
Observation 2: in section 3.2.S.7 stability data was submitted in generic tables, it was neither on letter head of drug substance manufacturer nor was signed or stamped. Firm was asked to submit Signed and stamped stability data sheets from drug substance manufacturer.

In response firm submitted changes submitted by the drug substance manufacturer to EDQM. As per this document DS manufacturer had performed stability of DS as per Zone II conditions and in 2011 & 2018, and in initial submission data was as per Zone IVa and was of 2016.
Firm was asked about these differences.
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Regarding degradation products, firm has submitted quantification of degradation products in the Finished product. 10% drug substance has degraded and 10% total degradation products are measured. Total 4 degradation products are identified, Product 1- 3.03%, Product 2-2.88%, Product 3-0.14% and Product 4-4%. Further firm has stated that calcifediol is known to undergo isomerization, including formation of pre-calcifediol/isomeric forms and structurally related vitamin D metabolites, such as 3-epi-25-hydroxyvitamin D3. These compounds are structurally related to clacifediol and are not established as DNA-reactive/carcinogenic impurities.
Signed stability datasheets of drug substance from drug substance manufacturer are submitted.
Clarification from drug substance manufacturer is submitted stating: "We/I hereby declare that Stability studies for Calcifediol Monohydrate are conducted under both Climatic Zone II (25°C ± 2°C/60% RH ± 5% RH) and Climatic Zone IVa (30°C ± 2°C/65% RH ± 5% RH) The studies are performed under both climatic conditions to support regulatory submissions in different geographical regions and to demonstrate the stability of the drug substance under varying long-term storage conditions"
Application fulfills codal formalities. Recommended for consideration of board.

Decision

Deferred

Deferred for submission of innovator's method of analysis of degradation products in finished drug product.

70	Case Category	Routine (Adil Saeed)
	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	(SJD-3MY-TH2Z, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-02-20,
	The proposed proprietary name / brand name	**Tofanib Tablets 5mg**
	Label Claim	Each Film coated tablet contains: Tofacitinib Citrate eq. to Tofacitinib 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's; 14's; 28's; 10'-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 30C.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Janus-associated kinase (JAK) inhibitors L04AF01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SICHUAN KELUN 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 (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tofajak Tablet 5mg B No. 001 M/s Hiranis Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on basis of inspection dated 07.03.2024 is submitted
	Evidence of approval of manufacturing facility	Regularization of sections letter dated 28.12.2020 is submitted wherein Tablet General section is mentioned.
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
71	Case Category	Routine (Adil Saeed)
	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	(ATQ-TU1-2M28, 2025-06-19)
	Detail of Fee Submitted	37000.0, 2025-02-20,
	The proposed proprietary name / brand name	**Tofanib Tablets 10mg**
	Label Claim	Each Film coated tablet contains: Tofacitinib Citrate eq. to tofacitinib 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's; 14's; 28's; 10'-De-Controlled
	Shelf Life (Unit)	24 Month(s)Store below 30C.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Janus-associated kinase (JAK) inhibitors L04AF01
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	SICHUAN KELUN 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 (in case of Import)	Form 6 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Tofajak Tablet 10mg B No.041
	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	GMP certificate issued on basis of inspection dated 07.03.2024 is submitted
	Evidence of approval of manufacturing facility	Regularization of sections letter dated 28.12.2020 is submitted wherein Tablet General section is mentioned.
	Evaluation Remarks	

	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
72	Case Category	Routine (Adil Saeed)
	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	(E82-T4N-5WXN, 2025-03-04)
	Detail of Fee Submitted	75000.0, 2024-10-17,
	The proposed proprietary name / brand name	**XEROV Tablets 5mg**
	Label Claim	Each Film Coated Tablet Contains : Suvorexant 5mg
	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 Month(s)store below 30C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	N05CJ01 HYPNOTICS AND SEDATIVES Orexin receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Huainan Shunlong 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 (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Belsomra 5mg B. No. 2010701 Mfg Merck Sharp & Dohme Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	BELSOMRA® Tablets approved by USFDA for Merck & Co., Inc., USA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 07.03.2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet general section mentioned in regularization of layout letter dated 03.12.2024
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
73	Case Category	Routine (Adil Saeed)
	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	(Q7S-YBQ-T143, 2025-03-04)
	Detail of Fee Submitted	75000.0, 2024-10-17,
	The proposed proprietary name / brand name	**XEROV Tablets 10mg**

	Label Claim	Each Film Coated Tablet Contains: Suvorexant 10mg
	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)	Not Available
	Pharmacotherapeutic Group of (API)	N05CJ01 HYPNOTICS AND SEDATIVES Orexin receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Huainan Shunlong 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 (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Belsomra 5mg B. No. 2001939 Mfg Merck Sharp & Dohme Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	BELSOMRA® Tablets approved by USFDA for Merck & Co., Inc., USA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 07.03.2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet general section mentioned in regularization of layout letter dated 03.12.2024
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
74	Case Category	Routine (Adil Saeed)
	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	(1PH-6Y1-SR5R, 2025-03-04)
	Detail of Fee Submitted	75000.0, 2024-10-17,
	The proposed proprietary name / brand name	**XEROV Tablets 15mg**
	Label Claim	Each Film Coated Tablet Contains : Suvorexant 15mg
	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 Month(s)store below 30C
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	N05CJ01 HYPNOTICS AND SEDATIVES Orexin receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Huainan Shunlong 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 (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Belsomra 15mg B. No. 20023758 Mfg Merck Sharp & Dohme Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	BELSOMRA® Tablets approved by USFDA for Merck & Co., Inc., USA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 07.03.2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet general section mentioned in regularization of layout letter dated 03.12.2024
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
75	Case Category	Routine (Adil Saeed)
	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	(GTY-4NB-HJ5E, 2025-03-04)
	Detail of Fee Submitted	75000.0, 2024-10-17,
	The proposed proprietary name / brand name	**XEROV Tablets 20mg**
	Label Claim	Each Film Coated Tablet Contains : Suvorexant 20mg
	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)	Not Available
	Pharmacotherapeutic Group of (API)	N05CJ01 HYPNOTICS AND SEDATIVES Orexin receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Huainan Shunlong 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 (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Belsomra 20mg B. No. 2006905 Mfg Merck Sharp & Dohme Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	BELSOMRA® Tablets approved by USFDA for Merck & Co., Inc., USA
	GMP status of the firm	GMP certificate issued on basis of inspection dated 07.03.2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet general section mentioned in regularization of layout letter dated 03.12.2024
	Evaluation Remarks	

	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
76	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	(VLU-871-9VT8, 2025-02-13)
	Detail of Fee Submitted	37000.0, 2024-11-21,
	The proposed proprietary name / brand name	**Roxtin 20mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Roxadustat.....20mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Roxaget Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	Other antianemic preparations B03XA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches, 1200 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has stated that material was imported via FEDEx/DHL or through green channel, thats why there are no clearance documents. Firm has previouslt intimated about it and list of drugs also have sildenafil, tadalafil vardenafil etc (total 10 drug susbtances.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Evrenzo 20mg Tablets B No. 51HD961 Astellas Japan
	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	Renewal inspection in 2024
	Evidence of approval of manufacturing facility	Renewal letter dated 11.06.2024 is submitted wherein tablet general section is mentioned.
	Evaluation Remarks	
	Firm has imported material without any prior approval and same matter has been discussed for this firm in previous meetings also. Except this, application fulfills codal formalities, recommended for consideration of board.	
	Decision	
	Deferred Registration Board deferred to devise a mechanism to dipose off such cases wherein active pharmaceutical ingredient was imported without import license and clearance certificate. However, submitted data fulfils codal formalities.	
77	Case Category	Import (Adil Saeed)
	Name, address of Applicant.	**AMB HK ENTERPRISES (PVT) LTD, LAHORE** 2nd floor plaza 60, Commercial

		Block K, Phase-1 DHA, Lahore. **(05-352-0058-104514D)**
	Application Form Dy. No / Tracking ID & date of submission	(YXW-MU3-UBR8, 2026-02-12)
	Detail of Fee Submitted	300000.0, 13500 2025-07-18, 2025-09-24
	The proposed proprietary name / brand name	**Somarex**
	Label Claim	Each 1ml vial solution for injection contains 0.1mg of Octreotide Acetate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 Vials/box and/or as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in a refrigerator (2°C - 8°C).
	For generic drugs (me-too Status)	Generic Product
	Pharmacotherapeutic Group of (API)	Somatostatin and analogues
	Name, address of Manufacturing site:	Fuan Pharmaceutical Group Hubei Renmin Pharmaceuti-No.1 Qijiashan Road, Baiquan Town, Dongxihu District, Wuhan City, Hubei Province-China
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Sandostatin 0.1mg/1ml By Novartis Pharma Schweiz AG B. No. SWH44
	Name, address of Marketing Authorization Holder:	AMB HK ENTERPRISES (PVT) LTD, 2nd FLOOR,PLAZA 60, COMMERCIAL BLOCK-K, PHASE 1, DHA, LAHORE, Pakistan
	Details of Certificates (CoPP/FSC/cGMP):	GMP compliance notice issued by Hubei Medical products administration is submitted. Further COPP is also submitted where it is mentioned that facilities and operations conform to GMP as recommended by WHO
	Details of Authorization Letter :	NA
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached
	The status in reference regulatory authorities	FDA approved
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved As per policy for inspection abroad.	
78	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	(572-TGL-BW1D, 2025-01-30)
	Detail of Fee Submitted	75000.0, 2024-11-20,
	The proposed proprietary name / brand name	**Tics-G 25mg/ml Oral Solution**
	Label Claim	Each ml of oral solution contains: Topiramate.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml, 15ml, 20ml, 30-As per SRO
	Shelf Life (Unit)	2 Year(s) Store at 20°C to 25°C
	For generic drugs (me-too Status)	N/A

	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX11
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ambica Chemicals
	Detail of stability batches of drug product	3 batches, 100 bottles 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	Eprontia 25mg/ml solution B. No 602672 Mfg Tulex Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	EPRONTIA 25mg/ml oral solution USFDA Approved
	GMP status of the firm	GMP certificate issued on basis of inspection dated 06.06.2023
	Evidence of approval of manufacturing facility	Oral liquid general section mentioned in renewal letter dated 20.09.2021
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
79	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	(HXZ-EYY-33Z1, 2025-04-03)
	Detail of Fee Submitted	93000.0, 2024-11-27,
	The proposed proprietary name / brand name	**Migles 25mg/ml Oral Solution**
	Label Claim	Each ml of oral solution contains: Topiramate.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml, 15ml, 20ml, 30-As per SRO
	Shelf Life (Unit)	2 Year(s) Store at 20°C to 25°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antiepileptics N03AX11
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	Name & address of API manufacturer	Ambica Chemicals
	Detail of stability batches of drug product	3 batches, 100 bottles 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	Eprontia 25mg/ml solution B. No 602672 Mfg Tulex Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	submitted
	The status in reference regulatory authorities	EPRONTIA 25mg/ml oral solution USFDA Approved

	GMP status of the firm	GMP certificate issued on basis of inspection dated 06.06.2023
	Evidence of approval of manufacturing facility	Oral liquid general section mentioned in renewal letter dated 20.09.2021
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
80	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Dyson Research Laboratories (Pvt.) Ltd** 28-Km Ferozpur Road Lahore **(000559)**
	Application Form Dy. No / Tracking ID & date of submission	(YHA-QTE-EWW5, 2025-05-12)
	Detail of Fee Submitted	75000.0, 2025-02-06,
	The proposed proprietary name / brand name	**Prog-V 100mg**
	Label Claim	Each tablet contains: Progesterone.....100mg. (As per Innovator's Specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Alu x Alu packed in -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C.
	For generic drugs (me-too Status)	Luteina Vaginal Tablets 100mg, manufactured by Adamed Pharma S.A., situated at Ul. Marszalka Jozefa Pilsudskiego 5, 95-200 Pabianice, Poland and imported by Organs Pharma (Pvt.) Ltd., situated at Plot
	Pharmacotherapeutic Group of (API)	Progesteron
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symbiotec Pharmalab (Pvt.) Ltd., situated at Plot No. 5, 6, 7 & 8, Special Economic Zone, Phase-II, Pharma Zone, Pithampur, Dist. Dhar – 454 774, Madhya Pradesh, INDIA.
	Detail of stability batches of drug product	3 batches, 1000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Taken loan from M/s Venus, clearane certificate and loan documents are submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Endometrin 100mg Tablet B. No. ZK306A Qpharma AB Sweden for Ferring Germany
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Lutigest Vaginal Tablet 100mg., approved by Medicines and Healthcare Products Regulatory Agency (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	
81	Case Category	Routine (Adil Saeed)

	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	(TA2-25G-QBZJ, 2025-05-05)
	Detail of Fee Submitted	75000.0, 2025-03-04,
	The proposed proprietary name / brand name	**TRIFEN 0.005%W/W CREAM**
	Label Claim	Each gram contains: Trifarotene.....50mcg (0.005%w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30gm, As per SRO-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)	Retinoids for topical use in acne D10AD06
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. HENAN JIN HUAITANG BIOLOGICAL ENGINEERINGCO.,LTD. No.5329, Hesudadao RD street Aveue,Wuzhi County, Jiaozuo city, Henan, China
	Detail of stability batches of drug product	3 batches, 500 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Trifarotene 50mcg/g cream M/s Aklief/ Galderma B. No. 2710034
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	MHRA Approved; Aklief 50 microgram/g cream; Galderma (UK) Limited Evergreen House North Grafton Place London NW1 2DX United Kingdom
	GMP status of the firm	GMP certificate issued on basis of inspection dated 14.12.2023 is submitted
	Evidence of approval of manufacturing facility	section approval letter dated 07.02.2014 is submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
82	Case Category	Routine (Adil Saeed)
	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	(5YX-4MS-3UVN, 2025-03-06)
	Detail of Fee Submitted	75000.0, 2025-02-13,
	The proposed proprietary name / brand name	**Roxus 150mg Tablet**
	Label Claim	Each film coated tablet contains: Roxadustat.....150mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 30's, 100's, A-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30OC at a dry place, protect from light and heat.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	Other antianemic preparations B03XA05
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s Jiangxi LongLife Bio-pharmaceutical Co., Ltd. Address: 198 Industrial Avenue, Jinxian Industrial Park, Nanchang, Jiangxi Province, P.R. China.
	Detail of stability batches of drug product	3 batches, 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Evrenzo 150mg B. No. 20H0147 M/s Astellas
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	EMA Approved;EVRENZO 150 MG FILM-COATED TABLETSDelpharm Meppel B.V. Hogemaat 2 7942 JG Meppel The Netherlands
	GMP status of the firm	Copy of GMP certificate issued on basis of inspection dated 14.12.2023
	Evidence of approval of manufacturing facility	Tablet general section mentioned in section approval letter dated 07.02.2014
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
83	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(5WS-ZZW-JXLZ, 2024-08-09)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Diosone 500mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Micronized purified flavonoid fraction ..... 500 mg Corresponding to: Diosmin..... 450 mg 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 International
	Pharmacotherapeutic Group of (API)	VASCULOPROTECTANTS / CAPILLARY-ACTING DRUGS / BIOFLAVONOIDS, ATC code: C05CA53: cardiovascular system.

	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	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 (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	DAFLON 500mg Film coated tablet ANSM France 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	
84	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(T92-XDX-5P7V, 2025-05-13)
	Detail of Fee Submitted	93000.0, 9400 2025-02-28, 2026-08-24
	The proposed proprietary name / brand name	**Gestomit 70mcg/20mcg Tablet**
	Label Claim	Each Tablet Cotains: Gestodene.....0.075mg Ethinylestradiol 0.020mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 21's As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature below 30
	For generic drugs (me-too Status)	Meliane(Gestodene-Ethinylestradiol) Tablet Marketed by: Medipharm (Pvt.) Ltd., 108-kotlakhpat Industrial Estate, Lahore
	Pharmacotherapeutic Group of (API)	Progestogens and estrogens, sequential preparations G03AB06
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Millinette 20/75 microgram coated tablets of M/s Gedeon Richter (UK) Ltd, Add: 127 Shirland Road, London, W9 2EP, UK (MHRA Approved)
	Detail of previous approval	Approved in 347th meeting of RB
	Evaluation Remarks	
	Cross-referred product.	
	Decision	

	Approved	
85	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)**
	Application Form Dy. No / Tracking ID & date of submission	(T8N-XAU-LRZX, 2025-05-15)
	Detail of Fee Submitted	75000.0, 2025-03-05,
	The proposed proprietary name / brand name	**Daprostane 04mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Daprodustat.....4mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Stored at temperature 15-30 degree
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Other antianemic preparations B03XA07
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Jesduvroq 4mg Tablet Lot No. Jd119
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	GMP certificate issued on basis of inspection dated 11.11.2021 is submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
86	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)**
	Application Form Dy. No / Tracking ID & date of submission	(H8A-BY3-X57L, 2025-04-21)
	Detail of Fee Submitted	75000.0, 2025-02-21,
	The proposed proprietary name / brand name	**Daprostane 1mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Daprodustat 01mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Stored at temperature 15-30 degree
	For generic drugs (me-too Status)	Not Available

	Pharmacotherapeutic Group of (API)	Other antianemic preparations B03XA07
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Jesduvroq 1mg Tablet Lot No. Jd078
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	GMP certificate issued on basis of inspection dated 11.11.2021 is submitted
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
87	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**Welmark Pharmaceuticals** Plot No. 122, Block - B, Phase V, Industrial Estate Hattar, KPK, Pakistan **(000614)**
	Application Form Dy. No / Tracking ID & date of submission	(23G-S7U-4N7L, 2025-03-04)
	Detail of Fee Submitted	75000.0, 2025-02-28,
	The proposed proprietary name / brand name	**Daprostane 02mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Daprodustat.....2mg (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)Stored at temperature 15-30 degree
	For generic drugs (me-too Status)	Not Available
	Pharmacotherapeutic Group of (API)	Other antianemic preparations B03XA07
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	3 batches 1500 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Drug import license is submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Jesduvroq 2mg Tablet Lot No. Jd108
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	PMDA Japan Approved
	GMP status of the firm	GMP certificate issued on basis of inspection dated 11.11.2021 is submitted
	Evidence of approval of manufacturing facility	Submited
	Evaluation Remarks	

	Application fulfills codal formalities. Recommended for consideration of board.	
	Decision	
	Approved	
88	Case Category	Contract Manufacturing (Adil Saeed)
	Name, address of Applicant.	**MEDPHARM RESEARCH LAB** 28 KM FEROZPUR ROAD LAHORE **(000878)**
	Application Form Dy. No / Tracking ID & date of submission	(DSX-5Z3-6QLX, 2025-02-27)
	Detail of Fee Submitted	93000.0, 2024-11-15,
	The proposed proprietary name / brand name	**Rozemed 2/0.035mg Tablet**
	Label Claim	Each Sugar coated tablet contains Cyproterone acetate ..... 2 mg Ethinylestradiol 0.035mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO / DPC-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Diane 35 Tablet of M/s Bayer Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	DIANE-35 of M/s Bayer Australia, (TGA-Australian Approved)
	Detail of previous approval	approved in 343rd meeting of RB
	Evaluation Remarks	
	Cross referred product	
	Decision	
	Approved	
89	Case Category	Routine (Adil Saeed)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(P4N-QB5-9NVX, 2025-03-07)
	Detail of Fee Submitted	37000.0, 2025-01-23,
	The proposed proprietary name / brand name	**Oxole 1% Cream**
	Label Claim	Each gram contains: Oxiconazole as nitrate 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5g 10g 15g 30g 60g-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	xirconi 1% cream by ferozons laboratories limited.
	Pharmacotherapeutic Group of (API)	Imidazole and triazole derivatives D01AC11
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	harman finochem limited
	Detail of stability batches of drug product	3 batches, 200 tubes 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	Xirconi 1% cream B. NO. A011 M/s Ferozsons.
	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	GMP certificate issued on basis of inspection dated 08.08.2022 is submitted.
	Evidence of approval of manufacturing facility	Submitted
	Evaluation Remarks	
	Application fulfills codal formalities. recommended for consideration of board.	
	Decision	
	Approved	
90	Case Category	Contract Manufacturing (Adil Saeed)
	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	(SGZ-AEM-A82J, 2024-09-27)
	Detail of Fee Submitted	93000.0, 2024-09-23,
	The proposed proprietary name / brand name	**Resmet 100mg Tablet**
	Label Claim	Each Film-coated tablet contains: Resmetirom.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	A05BA11 REZDIFFRA is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).
	Name, address of Manufacturing site:	Hamaz pharmaceutical Pvt LTD-13-Km, Lutafabad Bosan Road, Multan.-
	Name & address of API manufacturer	Shandong Chenghui Shuangda Pharmaceuticals Co., Ltd
	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	Rezdiffra 100mg Lot No. 23C092B Madrigal pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US FDA as REZDIFFRA (Resmetirom 100mg Tablets), for oral use for ORAL Use.
	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	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager ((Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
91	Case Category	Contract Manufacturing (Adil Saeed)
	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	(BSS-S28-8RM4, 2024-09-27)
	Detail of Fee Submitted	93000.0, 2024-09-23,
	The proposed proprietary name / brand name	**Resmet 80mg Tablet**
	Label Claim	Each Film-coated tablet contains: Resmetirom.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Year(s)Store below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	A05BA11 REZDIFFRA is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).
	Name, address of Manufacturing site:	Hamaz pharmaceutical Pvt LTD-13-Km, Lutafabad Bosan Road, Multan.-
	Name & address of API manufacturer	Shandong Chenghui Shuangda Pharmaceuticals Co., Ltd
	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	REZDIFFRA 80mg TABLET Lot No. 22A315A M/s Madrigal Pharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Registered drug by US FDA as REZDIFFRA (Resmetirom 80mg Tablets), for oral use for ORAL Use.
	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	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
92	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Medipak Limited** 132, Industrial Estate, Kot Lakhpat **(000257)**
	Application Form Dy. No / Tracking ID & date of submission	(ZUL-A25-HQDS, 2024-07-18)
	Detail of Fee Submitted	30000.0, 45000 2024-06-04, 2026-07-08
	The proposed proprietary name / brand name	**Medvision Eye Drops**
	Label Claim	Each ml Contains: Pilocarpine HCl (USP) 12.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2.5ml -As per SRO
	Shelf Life (Unit)	2 Year(s)Store at 15°C to 25°C
	For generic drugs (me-too Status)	Pilocar Eye Drops By Ethical Labs
	Pharmacotherapeutic Group of (API)	Cholinergic Agonist
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sourcetech Quimica Ltd. Brazil
	Detail of stability batches of drug product	3 batches having batch size of 05 Litres (2000units) each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate issued dated 12-05-2022 specifying 100gm Pilocarpine HCl.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Vuity Eye Drops 1.25%
	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	Vuity (pilocarpine hydrochloride ophthalmic solution) 1.25%, for topical ophthalmic use USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate issued based on inspection dated 29-04-2026.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter for renewal of DML dated 08-06-2021 specifying Eye Drop Section (General).
	Evaluation Remarks	
	The instant application is priority as per decision of Authority taken in its 211th meeting held on 09th August, 2025.	
	Shortcomings	Firm’s Response

Submit evidence of me-too of applied product in applied strength as same could not be verified or submitted differential fee of new drug molecule	Firm has submitted differential fee Rs. 45000/- on deposit slip# 1824089951 for new strength of 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 copy of cGMP certificate of API manufacturer valid upto 22-01-2028

Decision

Approved

The Registration Board decided to approve the application, considering its priority status as per Authority decision and short availability of the molecule in the market, subject to submission of the following:

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

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	Case Category	Routine (Dr. Farhad Ullah)
	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	(WWX-T55-QAN8, 2024-07-13)
	Detail of Fee Submitted	30000.0, 2024-04-19,
	The proposed proprietary name / brand name	**Vefor**
	Label Claim	Each 5ml contains: Iron Sucrose complex eq.to Elemental Iron 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Do not store above 25°C
	For generic drugs (me-too Status)	Rubiject Injection by AGP Limited
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Global Calcium Private Limited
	Detail of stability batches of drug product	03 batches having batch size of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of form 6 dated 24-10-2022 specifying 25kg Iron Sucrose. Firm has also submitted copy of invoice, packing list, airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Venofer 100mg/5ml injection manufactured by Swiss iron Takeda Austria GmbH St. Peter-Strasse 25 4020 Linz/Austria; imported and marketed by Searle Pakistan
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 03 batches of drug substance as per zone IV

	The status in reference regulatory authorities	Venofer (Iron Sucrose) 20mg/ml, solution for injection MHRA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 26-09-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of Renewal of DML dated 11-04-2016 specifying Injection Liquid Ampoule (General) Section.
	Evaluation Remarks	

Shortcomings	Firm's Response
You have also submitted same formulation on contract manufacturing from M/s wimits pharma, clarify	We would like to clarify that we have submitted the same formulation from both our own site and on a contract manufacturing basis with M/s Wimits. This decision was made to meet market needs and ensure greater patient accessibility. The growing demand in the market necessitated multiple submissions to ensure continuous and uninterrupted supply from different manufacturing sites. Both submissions adhere have been made with the intention of ensuring timely availability of the product to meet the demands of healthcare professionals and patients. Same formulation of applicant has been approved on contract manufacturing from M/s Wimits Pharma in 345th meeting of Registration Board and registration letter has been issued with brand name Veniro Injection 100mg/5ml Reg. No#. 128169 and tracking ID#3AT-PSM-AESM

Decision

Rejected

The Registration Board decided to reject the instant application since registration of the same molecule has already been granted to the applicant through contract manufacturing.

94	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(6AQ-X4J-4PW6, 2025-04-08)
	Detail of Fee Submitted	93000.0, 2024-12-19,
	The proposed proprietary name / brand name	**FC Malt 500mg/10ml Injection**
	Label Claim	Each 10ml Vials contains: 500mg Iron as ferric carboxymaltose
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C. Excursions permitted between 15°C and 30°C.
	For generic drugs (me-too Status)	Ferotox 50mg/ml Injection by wilshire laboratories
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s MTI MEDICAL (Pvt.) Ltd.,-Plot# 586/587, Sundar Industrial Estate, Raiwind Road Lahore Pakistan.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	

	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Ferinject 50mg iron /ml, by Vifor Pharma UK Limited, approved by MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

Evaluation Remarks

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

Decision

Rejected

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

95	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(JY9-LJ5-93ZU, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-12,
	The proposed proprietary name / brand name	**Adapalene Cream 0.1% w/w**
	Label Claim	Label Claim: Each gram of cream contains: Adapalene..... 1mg (0.1% w/w) BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store at 25C

	For generic drugs (me-too Status)	Adapco cream by ATCO Laboratories
	Pharmacotherapeutic Group of (API)	Retinoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	GLENMARK LIFE SCIENCES LTD
	Detail of stability batches of drug product	2 batches having batch size of 500 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of commercial invoice cleared by AD DRAP dated 14-01-2020 specifying 0.2kg Adapalene.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Adapco Cream 0.1% w/w by M/s Atco Laboratories 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	Differin cream by GALDERMA LABORATORIES USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of renewal of DML dated 04-07-2022 specifying Cream/Ointment (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 DML of API manufacturer valid upto 31-12-2028. Firm has also submitted copy of cGMP certificate of API manufacturer valid upto 27-07-2028.
	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 studies has been submitted is required	Pictorial evidence of comparator's product is submitted Product name; Adapco cream 0.1% w/w; batch No#JK007J; Mfg date; 05/2022; Exp date; 04/2024 MAH name; Atco Laboratories
	Decision	
	Approved	
96	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(DRV-TBZ-5M8G, 2025-04-08)
	Detail of Fee Submitted	93000.0, 9400 2024-12-12, 2026-07-29
	The proposed proprietary name / brand name	**BECLO-FORM**
	Label Claim	Each metered dose (ex-valve) contains: 100 micrograms of beclomethasone dipropionate and 6 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (ex-actuator) of 84.6 micrograms of beclomethasone dipropionate and 5.0 micrograms of formoterol fumarate dihydrate
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120 actuations in 1 -As per SRO
	Shelf Life (Unit)	2 YearStore in a refrigerator (2-8°C)

	For generic drugs (me-too Status)	Foster Pressurized, Beclomethasone Dipropionate + Formoterol Fumarate Dihydrate 100mcg/6mcg, Chiesi Pharmaceutical (Pvt.) Ltd., Registration number: 066105
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan.-
	The status in reference regulatory authorities	Fostair 100 microgram/6 microgram per actuation pressurised inhalation solution, Chiesi Farmaceutici S.p.A., HPRA
	Detail of previous approval	FAMTROL BECLO MDI 100mcg/6mcg; Approved in 344th meeting of RB
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 344th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No#655522627 for correction of the status.
	Decision	
	Approved	
97	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(S69-NZ3-BMJZ, 2025-04-08)
	Detail of Fee Submitted	93000.0, 9400 2024-12-12, 2026-07-29
	The proposed proprietary name / brand name	**BECLO-FORM**
	Label Claim	Each metered dose (ex-valve) contains: 200 micrograms of beclomethasone dipropionate and 6 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (ex-

		actuator) of 177.7 micrograms of beclomethasone dipropionate and 5.1 micrograms of formoterol fumarate dihydrate.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120 actuations in 1 -As per SRO
	Shelf Life (Unit)	2 YearStore in a refrigerator (2-8°C)
	For generic drugs (me-too Status)	Foster Pressurized, Beclomethasone Dipropionate + Formoterol Fumarate Dihydrate 200mcg/6mcg, Chiesi Pharmaceutical (Pvt.) Ltd., Registration number: 095871
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan.-
	The status in reference regulatory authorities	Fostair 200 microgram/6 microgram per actuation pressurised inhalation solution, Chiesi Farmaceutici S.p.A., HPRA
	Detail of previous approval	FAMTROL BECLO MDI 200mcg/6mcg; Approved in 344th meeting of RB
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 344th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No#770730333 for correction of the status.

Decision	
Approved	

98	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(49G-BJW-DSUD, 2025-03-12)

	Detail of Fee Submitted	93000.0, 9400 2024-11-12, 2026-07-29
	The proposed proprietary name / brand name	**BECLO-FORM**
	Label Claim	Each dry powder inhalation capsule contains: 100 micrograms of beclomethasone dipropionate anhydrous and 6 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (the dose leaving the mouthpiece) of 81.9 micrograms of beclomethasone dipropionate anhydrous and 5.0 micrograms of formoterol fumarate dihydrate.
	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 YearStore below 30
	For generic drugs (me-too Status)	Foster Nexthaler DPI 100/6mcg, Manufacturer Chiesi Pharmaceutical (Pvt.) Ltd., Registration Number 095868
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan.-
	The status in reference regulatory authorities	Fostair NEXThaler 100 micrograms/6 micrograms, MHRA
	Detail of previous approval	Famtrol Beclo DPI Capsule 100mcg/6mcg; Approved in 344th of RB
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 344th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No. 8731837545 for correction of the status.

	Decision	
	Approved	
99	Case Category	Contract Manufacturing (Dr. Farhad Ullah)

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	(9MU-YP3-NNAQ, 2025-03-20)
Detail of Fee Submitted	93000.0, 9400 2024-11-27, 2026-07-29
The proposed proprietary name / brand name	**Incatrol-M**
Label Claim	Each dry powder inhaler capsule contains: Indacaterol (as Acetate)....150mcg Mometasone Furoate....80mcg Each delivered dose (dose that leaves the mouthpiece of inhaler) contains Indacaterol (as Acetate) ....125mcg Mometasone Furoate...62.5mcg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	7's,10's,14's,20's,2-As per SRO
Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
For generic drugs (me-too Status)	N/A
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
The status in reference regulatory authorities	ATECTURA ® BREEZHALER 150mcg/80mcg by Novartis Pharma AG, Basel, Switzerland
Detail of previous approval	Incaterol-M DPI Capsule 150mcg/80mcg; Approved in 344th RB meeting

Evaluation Remarks

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 344th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 8261711810 for correction of the status.

Decision

	Approved	
100	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(Y16-HXN-N3ES, 2025-03-20)
	Detail of Fee Submitted	93000.0, 9400 2024-11-27, 2026-07-29
	The proposed proprietary name / brand name	**Incatrol-M**
	Label Claim	Each dry powder inhaler capsule contains: Indacaterol (as Acetate)....150mcg Mometasone Furoate....160mcg Each delivered dose (dose that leaves the mouthpiece of inhaler) contains Indacaterol (as Acetate)....125mcg Mometasone Furoate.....127.5mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's28-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	ATECTURA ® BREEZHALER 150mcg/160mcg by Novartis Pharma AG, Basel, Switzerland
	Detail of previous approval	Incaterol-M DPI Capsule 150mcg/160mcg; Approved in 344th RB meeting
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 344th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 412044743405 for correction of the status.

	already approved' status of the cross-referred product of your application."	
	Decision	
	Approved	
101	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(5GY-T2G-Y8TE, 2025-04-07)
	Detail of Fee Submitted	93000.0, 9400 2024-11-27, 2026-07-29
	The proposed proprietary name / brand name	**Incatrol-MG**
	Label Claim	Each dry powder inhaler capsule contains: Indacaterol (as Acetate)....150mcg 63mcg of Glycopyrronium Bromide equivalent to 50mcg of Glycopyrronium Mometasone Furoate....160mcg Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains Indacaterol (as acetate)..... 114 mcg 58 mcg of glycopyrronium bromide equivalent to 46 mcg of glycopyrronium Mometasone furoate.....136mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's28-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C. Protect from heat, light & Moisture
	For generic drugs (me-too Status)	Ultivair-M by Highnoon Laboratories Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Enerzair Breezhaler 150mcg/50mcg/160mcg by Novartis Europharm Limited, Ireland
	Detail of previous approval	Incaterol-MG DPI Capsule 150mcg/50mcg/160mcg; Approved in 344th RB meeting
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3.	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 344th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 760899121 for correction of the status.

	Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	
	Decision	
	Approved	
102	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(EAM-D1J-JH7B, 2025-02-12)
	Detail of Fee Submitted	93000.0, 9400 2024-11-12, 2026-07-29
	The proposed proprietary name / brand name	**Incatrol-G**
	Label Claim	Each dry powder inhaler capsule contains: 143 micrograms of indacaterol maleate eqto110 micrograms of indacaterol base 63 micrograms of glycopyrronium bromide eq to 50 micrograms of glycopyrronium base Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains: 110 micrograms of indacaterol maleate equivalent to 85 micrograms of indacaterol base. 54 micrograms of glycopyrronium bromide equivalent to 43 micrograms of glycopyrronium base.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's,10's,14's,20's28-As per SRO
	Shelf Life (Unit)	2 Year(s)Store at room temperature between 15-25º C.
	For generic drugs (me-too Status)	Ultivair ,Highnoon Laboratories,Reg No:113986 Ltd,
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Limited-44, 45B, KORANGI CREEK ROAD,KARACHI. PAKISTAN-
	The status in reference regulatory authorities	Ulbitro Breezhaler,Novartis Pharmaceuticals UK Limited
	Detail of previous approval	Incaterol-G DPI Capsule 110mcg/50mcg; Approved in 348th RB meeting
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 348th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 3243573978 for correction of the status.

	from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	
	Decision	
	Approved	
103	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(VTT-X2W-R2H4, 2025-05-09)
	Detail of Fee Submitted	93000.0, 9400 2025-01-21, 2026-07-29
	The proposed proprietary name / brand name	**Vintro-UF**
	Label Claim	Each Capsule contains: Fluticasone Furoate ....100mcg Umeclidinium (as Bromide).....62.5mcg Vilanterol (as Trifenatate).....25mcg Each deliverable dose contains: Fluticasone Furoate.....92mcg Umeclidinium (as Bromide).....55mcg Vilanterol (as Trifenatate).....22mcg OR Capsule A blister strip contains: Fluticasone Furoate micronized....100mcg Capsule B blister strip contains: 74.2mcg of micronized Umeclidinium Bromideequivalent to Umeclidinium....62.5mcg 40mcg of micronized Vilanterol Trifenatate equivalent to Vilanterol...25mcg Each deliverable dose contains: 92mcg of Fluticasone Furoate, 55mcg of Umeclidinium 22mcg of Vilanterol.
	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 Store at 20°C to 25°C
	For generic drugs (me-too Status)	Vilanto-UF by Getz Pharma Pakistan Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd -44, 45B, KORANGI CREEK ROAD, KARACHI. PAKISTAN-
	The status in reference regulatory authorities	TRELEGY ELLIPTA BY GlaxoSmithKline Inc
	Detail of previous approval	VHAL-UF DPI Capsule 100mcg/62.5mcg/25mcg; Approved in 347th RB meeting
	Evaluation Remarks	

	Shortcomings	Firm's Response
	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 347th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 0830849985 for correction of the status.
	Decision	
	Approved	
104	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(PAX-G3S-D2U2, 2025-05-09)
	Detail of Fee Submitted	93000.0, 9400 2025-01-21, 2026-07-29
	The proposed proprietary name / brand name	**VINTRO-F**
	Label Claim	Each Capsule contains: Fluticasone Furoate..... 100 mcg Vilanterol as Trifenatate.....25 mcg Each deliverable dose contains: Fluticasone Furoate.....92 mcg Vilanterol.....22 mcg OR Capsule A blister strip contains: Micronized Fluticasone Furoate..... 100 mcg Capsule B blister strip contains: 40 mcg of micronized Vilanterol Trifenatate equivalent to Vilanterol .....25 mcg Each deliverable dose contains: Capsule A: 92 mcg of Fluticasone Furoate Capsule B: 22 mcg of Vilanterol
	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 YearStore at room temperature between (20°C - 25 °C)

	For generic drugs (me-too Status)	Relvar Ellipta (Fluticasone Furoate + Vilanterol Trifenatate) by Glaxo Smith Kline (GSK)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi -
	The status in reference regulatory authorities	BREO ELLIPTA 100mcg/25mcg (Fluticasone Furoate + Vilanterol Trifenatate) Inhalation powder by Glaxo Smith Kline
	Detail of previous approval	VHAL-F DPI Capsule 100mcg/25mcg; Approved in 347th RB meeting
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 347th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 7080755208 for correction of the status.

	Decision	
	Approved	
105	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(XAS-W3Z-W11Y, 2025-05-09)
	Detail of Fee Submitted	93000.0, 9400 2025-01-21, 2026-07-29
	The proposed proprietary name / brand name	**VINTRO-F**
	Label Claim	Each Capsule contains: Fluticasone Furoate..... 200 mcg Vilanterol as Trifenatate.....25 mcg Each deliverable dose contains: Fluticasone Furoate.....184 mcg Vilanterol.....22 mcg OR Capsule A blister

		strip contains: Micronized Fluticasone Furoate..... 200 mcg Capsule B blister strip contains: 40 mcg of micronized Vilanterol Trifenatate equivalent to Vilanterol .....25 mcg Each deliverable dose contains: Capsule A: 184 mcg of Fluticasone Furoate Capsule B: 22 mcg of Vilanterol
	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 YearStore at room temperature between (20°C - 25 °C)
	For generic drugs (me-too Status)	Relvar Ellipta (Fluticasone Furoate + Vilanterol Trifenatate) by Glaxo Smith Kline (GSK)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma (Pvt) Ltd-Plot No. 44-45-B, Korangi Creek Road, Karachi -
	The status in reference regulatory authorities	BREO ELLIPTA 200mcg/25mcg (Fluticasone Furoate + Vilanterol Trifenatate) Inhalation powder by Glaxo Smith Kline
	Detail of previous approval	VHAL-F DPI Capsule 200mcg/25mcg; Approved in 347th RB meeting
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 347th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 455070891416 for correction of the status.
	Decision	
	Approved	
106	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(VXA-12S-PJBW, 2025-05-09)
	Detail of Fee Submitted	93000.0, 9400 2025-01-29, 2026-07-29
	The proposed proprietary name / brand name	**Saltiflu**
	Label Claim	Each metered dose (ex valve) contains: Salmeterol (as salmeterol xinafoate) ---------- 25mcg Fluticasone propionate---------- 50 mcg This is equivalent to a delivered dose (ex actuator) of 21 micrograms of salmeterol and 44 micrograms of fluticasone propionate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	120 actuations in 1 -As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C
	For generic drugs (me-too Status)	Seretide inhaler, GlaxoSmithKline (GSK), registration number: 027381
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan.-
	The status in reference regulatory authorities	Seretide Evohaler pressurised inhalation suspension, GlaxoSmithKline (Ireland) Limited
	Detail of previous approval	Salmihale MDI 25mcg/50mcg; Approved in 347th RB meeting
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 347th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 50930106842 for correction of the status.

	Decision	
	Approved	
107	Case Category	Contract Manufacturing (Dr. Farhad Ullah)

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	(QAP-4AM-W9S1, 2025-05-09)
Detail of Fee Submitted	93000.0, 9400 2025-01-29, 2026-07-29
The proposed proprietary name / brand name	**Saltiflu**
Label Claim	Each metered dose (ex valve) contains: Salmeterol (as salmeterol xinafoate) ---------- 25mcg Fluticasone propionate---------- 125 mcg This is equivalent to a delivered dose (ex actuator) of 21 micrograms of salmeterol and 110 micrograms of fluticasone propionate.
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	120 actuations in 1 -As per SRO
Shelf Life (Unit)	2 YearDo not store above 25°C
For generic drugs (me-too Status)	Seretide inhaler, GlaxoSmithKline (GSK), registration number: 027382
Pharmacotherapeutic Group of (API)	
Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan.-
The status in reference regulatory authorities	Seretide Evohaler pressurised inhalation suspension, GlaxoSmithKline (Ireland) Limited
Detail of previous approval	Salmihale MDI 25mcg/125mcg; Approved in 347 RB meeting

Evaluation Remarks

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 347th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 07444995530 for correction of the status.

Decision

	Approved	
108	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(TUE-VYN-6PGV, 2025-05-09)
	Detail of Fee Submitted	93000.0, 9400 2025-01-29, 2026-07-29
	The proposed proprietary name / brand name	**Saltiflu**
	Label Claim	Each metered dose (ex valve) contains: Salmeterol (as salmeterol xinafoate) ---------- 25mcg Fluticasone propionate---------- 250 mcg This is equivalent to a delivered dose (ex actuator) of 21 micrograms of salmeterol and 220 micrograms of fluticasone propionate.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	120 actuations in 1 -As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C
	For generic drugs (me-too Status)	Seretide inhaler, GlaxoSmithKline (GSK), registration number: 027383
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Genix Pharma Private Limited-44, 45-B Korangi Creek Road, Karachi-75190, Pakistan.-
	The status in reference regulatory authorities	Seretide Evohaler pressurised inhalation suspension, GlaxoSmithKline (Ireland) Limited
	Detail of previous approval	Salmihale MDI 25mcg/250mcg; Approved in 347th RB meeting

Evaluation Remarks

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 347th Registration Board meeting and submitted undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 940455598 for correction of the status.

	already approved' status of the cross-referred product of your application."	
	Decision	
	Approved	
109	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(BJT-AH7-GQXA, 2025-05-07)
	Detail of Fee Submitted	75000.0, 18000.0 2024-06-24, 2025-04-22
	The proposed proprietary name / brand name	**HY-KOR 100mg Injection**
	Label Claim	Each Vial Contains: Hydrocortisone Sodium Succinate equivalent Hydrocortisone (USP).....100mg (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)20-25C
	For generic drugs (me-too Status)	CORTISONE 100MG INJECTION by VISION PHARMACEUTICALS
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wenovo Pharmaceuticals-PLOT No. 31-32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, Rawalpindi.-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	HYKOR 100MG Sterile powder for INJECTION; Approved in 339th RB meeting
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 339th Registration Board meeting and submitted Module I, undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 909543430970 for correction of the status.

	already approved' status of the cross-referred product of your application."	
	Decision	
	Approved	
110	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**Rogen Pharmaceuticals** Plot No. 30, S-4, National Industrial Zone Rawat, Islamabad. **(000692)**
	Application Form Dy. No / Tracking ID & date of submission	(8AD-4NE-XHN8, 2025-06-16)
	Detail of Fee Submitted	93000.0, 9400 2025-02-13, 2026-06-24
	The proposed proprietary name / brand name	**ISOTON**
	Label Claim	EACH SOFT GEL CAPSULE CONTAINS ISOTRETINOIN 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	30'S-As per SRO
	Shelf Life (Unit)	2 YearROOM TEMPRATURE
	For generic drugs (me-too Status)	ORATANE 20mg CAPSULES
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	BIOGEN PHARMACEUTICALS-8 KM CHAKBELI ROAD RAWAT,RAWALPINDI.-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	BIOTAN 20mg Capsule; Approved in 312th RB meeting
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 312th Registration Board meeting and submitted Module I, undertaking, relevant RB minutes, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 385526639381 for correction of the status.
	Decision	

	Approved	
111	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, 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 (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.
	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	
	Deferred in 360th meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by the Registration Board in its 275th meeting.	Firm has submitted evidence of approval of applied formulation in RRA. Zitromax 1000mg powder for oral suspension in sachet, CIMA Spain Approved.
	Decision	
	Approved	
112	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra **(000440)**
	Application Form Dy. No / Tracking ID & date of submission	(Z9S-YX8-R7R9, 2024-06-28)

	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**ONGLIP**
	Label Claim	Each Film Coated Tablet containing: Trelagliptin Succinate eq. to Trelagliptin.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	TRELAGET TABLET BY GETZ PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd.No. 21 Huancheng West Road Anqing Anhui 246000 China.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	ZAFATEC TABLET BY TEIJIN PHARMA LTD.
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application Q7R-63Y-GT2E.	
	Decision	
	Rejected The Registration Board decided to reject the application due to the submission of identical analytical data previously submitted by another applicant, indicating the submission of falsified data.	
113	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra **(000440)**
	Application Form Dy. No / Tracking ID & date of submission	(SZD-QSP-YQHM, 2024-06-28)
	Detail of Fee Submitted	75000.0, 2024-06-25,
	The proposed proprietary name / brand name	**ONGLIP**
	Label Claim	Each Film Coated Tablet containing: Trelagliptin Succinate eq. to Trelagliptin.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearRoom Temperature.
	For generic drugs (me-too Status)	TRELAGET TABLET BY GETZ PHARMA
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	Bio-Mark Pharmaceuticals-Plot # 527, Sundar Industrial Estate, Lahore-
	Name & address of API manufacturer	Anhui Haikang Pharmaceutical Co., Ltd.No. 21 Huancheng West Road Anqing Anhui 246000 China.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	ZAFATEC TABLET BY TEIJIN PHARMA LTD.,Japan
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application U2Y-7NY-DSLZ.	
	Decision	
	Rejected The Registration Board decided to reject the application due to the submission of identical analytical data previously submitted by another applicant, indicating the submission of falsified data.	
114	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Bio-Mark Pharmaceuticals** Plot # 527, Sundar Industrial Estate Lahore **(000863)**
	Application Form Dy. No / Tracking ID & date of submission	(P9B-RGL-5XBL, 2024-05-23)
	Detail of Fee Submitted	30000.0, 2024-05-03,
	The proposed proprietary name / brand name	**TRELAMARK 100mg tablet**
	Label Claim	Each film coated tablet contains: Trelagliptin Succinate eq. to Trelagliptin.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x4's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Temperature.
	For generic drugs (me-too Status)	TRELAGET 100mg TABLET BY GETZ PHARMA
	Pharmacotherapeutic Group of (API)	Anti-Diabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	ANHUI HAIKANG PHARMACEUTICAL CO. LTD
	Detail of stability batches of drug product	2 batches having batch size of 5000 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has also submitted copy of commercial invoice dated 28-11-2023 specifying 2.1kg Tralgliptin Succinate. However, invoice is not attested by AD/DD (I&E) DRAP field office
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies performed against Trelaget 100mg tablet by Getz Pharma

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per Zone IV-A
	The status in reference regulatory authorities	Zafatec Tablet 100mg By Teijin Pharma Ltd. Japan PMDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 18-01-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of issuance of DML dated 12-06-2017 specifying Tablet-I and Tablet-II (General) section.
	Evaluation Remarks	
	The data submitted in the present application, including CDP, AMV, stability studies, chromatograms (same file name, retention time, peak area, date and time), and other analytical records, are identical to those submitted by another applicant in application U2Y-7NY-DSLZ.	
	Decision	
	Rejected The Registration Board decided to reject the application due to the submission of identical analytical data previously submitted by another applicant, indicating the submission of falsified data.	
115	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, 2024-05-29,
	The proposed proprietary name / brand name	**Thiowel 4mg Capsules**
	Label Claim	Each Capsule Contains; Thiocolchicoside.....4mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)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	
	Deferred in 360th meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for verification of employment of analyst details present in the chromatograms submitted with the dossier	With reference to the minutes of Meeting of the Registration Board, it is hereby clarified that the technical staff list submitted during the inquiry Thiowel 4mg Capsules represented the technical staff currently engaged in the Production, Quality Control, and R&D departments. It is further clarified that Ms. Faiqa Ashfaq, the analyst who performed the testing of Thiowel 4mg Capsules during her tenure in 2024, remained employed with Solaris Life Sciences from 18 August 2023 to 13 March 2024. Accordingly, she was a duly authorized Quality Control Analyst for the testing of the above-mentioned products she analyzed. Furthermore, Ms. Faiqa Ashfaq was also present during the Drug Manufacturing License (DML) inspection conducted by DRAP. Her name appears in the technical staff list submitted during the DML inspection and can be verified from the DML Inspection Report duly signed by the DRAP inspection officials. Complete employment record of Ms. Faiqa Ashfaq and copy of the DML Inspection Report is submitted herewith for your kind consideration and verification. It is submitted for the information of the Registration Board that Ms. Faiqa Ashfaq resigned from M/s Solaris Pharma with immediate effect on 14.03.2024 and was issued an experience certificate covering the period from 18.08.2023 to 13.03.2024. However, the submitted stability data indicate that the 3rd-month testing of the applied product was performed on 27.05.2024 under the name of the same analyst, despite her resignation more than two months earlier. This discrepancy raises concerns regarding the authenticity and integrity of the submitted data.
	Decision	
	Rejected Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete; however, the HPLC system is not 21 CFR complaint.	
116	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, 2024-05-20,
	The proposed proprietary name / brand name	**Sofosbuvir 400mg film coated Tablet**

	Label Claim	Each film coated Tablet contains: 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 (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	
	Deferred in 360th meeting of RB;	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin	Firm has submitted copy of DML of API manufacturer valid upto 30-10-2028
	Stability study data of three batches of API as per zone IV till claimed shelf life	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A till 36th months
	Decision	
	Approved	
117	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	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	(EM4-T4P-8S8V, 2025-06-26)
	Detail of Fee Submitted	93000.0, 2025-05-19,
	The proposed proprietary name / brand name	**Nalbu 10mg/ml Injection**
	Label Claim	Each ml contains; Nalbuphine hydrochloride 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearAt room temperature

	For generic drugs (me-too Status)	Bunail 10mg/ml injection Bosch pharmaceuticals (pvt) ltd.
	Pharmacotherapeutic Group of (API)	Nalbuphine is an Opioid Agonist/Antagonist. It is a Competitive Opioid Antagonist, and Partial Opioid Agonist
	Name, address of Manufacturing site:	M/s SERAPH PHARMACEUTICAL -Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan -
	The status in reference regulatory authorities	NUBAIN Injection…..10mg/ml Par Pharmacutical USA, Approved in FDA.
	Detail of previous approval	Sernaib 10mg/ml (Reg#111997) in 119th PRV meeting
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 119th PRVC meeting and that another application based on the same data was approved in 351st meeting of RB. The firm submitted Module I, undertaking, registration letter, and fee of Rs. 9,400/- vide Deposit Slip No# 68643865 for correction of the status.

	Decision	
	Approved	
118	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**CUREXA HEALTH (PVT.) LIMITED** 517 SUNDER INDUSTRIAL ESTSTE **(000864)**
	Application Form Dy. No / Tracking ID & date of submission	(NQ5-AAW-4JBB, 2025-04-07)
	Detail of Fee Submitted	93000.0, 2024-11-22,
	The proposed proprietary name / brand name	**Kydor Ampoule 30mg**
	Label Claim	Each 1ml ampoule contains: Ketorolac Tromethamine 30mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5's-As per SRO

	Shelf Life (Unit)	2 YearDo not store above 30°C. Keep in a dry place. Protect from light.
	For generic drugs (me-too Status)	Ketoroget Injection 30mg/ml (by Getz Pharma)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Bio-Labs (Pvt.) Ltd.-Plot # 145, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Ketorolac Tromethamine (by HOSPIRA) USFDA Approved
	Detail of previous approval	Unilac 30mg Injection in 353rd RB meeting
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 353rd Registration Board meeting and submitted Module I, undertaking, relevant RB minutes, and fee of Rs. 9,400/- vide Deposit Slip No# 67665182 for correction of the status.

	Decision	
	Approved	
119	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**Wezen Pharmaceuticals** Industrial Estate Rawat **(000882)**
	Application Form Dy. No / Tracking ID & date of submission	(TD8-J1X-EEQ9, 2024-08-20)
	Detail of Fee Submitted	75000.0, 9400 2024-01-05, 2026-08-12
	The proposed proprietary name / brand name	**Ferrina 500mg Injection**
	Label Claim	Each 10ml Vial Contains: Iron as Ferric Carboxymaltose.....500mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c

	For generic drugs (me-too Status)	FERINJECT 500mg/10ml INJECTION by RG Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	FERRINA 500mg/10ml Injection in 343rd RB meeting
	Evaluation Remarks	

Shortcomings	Firm's Response
Registration Board in its 324th meeting decided to consider cross-referred approved products on Form 5-F in contract manufacturing. This decision was notified vide F.No.1-2/2022-DMC dated 13th June, 2023, In 250th meeting, the Board decided that Applicant shall refer along with extract of relevant minutes of Registration Board / Post-Registration Variation Approval, whichever the case may be, for the previous approval of the applied drug product on Form 5F from same manufacturer. Therefore, you are advised to inform regarding status of your application. In case your cross-referenced product has already been approved by the Registration Board on Form-5 F or in PRVC on Form 5F, please provide the following and your application will be considered accordingly: 1. Module 1, 2. Extract of the minutes of the relevant meeting of Registration Board and 3. Undertaking to adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification 4. If the product is approved, submit the pre-registration variation fee of Rs. 9,400/- for correction of the 'data already approved' status of the cross-referred product of your application."	Initially, the firm selected "No" for "Data Already Approved." Upon query, the firm informed that the applied product data had already been approved on Form 5F in the 343rd Registration Board meeting and submitted Module I, undertaking, relevant RB minutes, and fee of Rs. 9,400/- vide Deposit Slip No# 2151818312 for correction of the status.

Decision	
Approved	

120	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, 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
	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	
	Deferred in 360th meeting of RB;	
	Deferment Reason	Firm's Response
	Deferred for submission of comparative dissolution profile (CDP) data	Firm has submitted comparative dissolution profile (CDP) data of applied product
	Decision	
	Approved	
121	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**Neutro Pharma (Pvt.) Ltd.,** 9.5-Km, Sheikhupura Road, Lahore **(000576)**
	Application Form Dy. No / Tracking ID & date of submission	(MQW-R86-XG6A, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-12,
	The proposed proprietary name / brand name	**Adapalene gel 0.1% w/w**
	Label Claim	Each gram of gel contains: Adapalene..... 1mg (0.1% w/w) BP Specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store at 25C
	For generic drugs (me-too Status)	Adapco gel by ATCO Laboratories
	Pharmacotherapeutic Group of (API)	Retinoid
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	2 batches having batch size of 500 tubes each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of invoice cleared by AD (I&E) DRAP dated 14-01-2020 specifying 0.200kg Adapelene.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Adaferin gel 0.1% by M/s Laboratories Galderma, France
	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	Differin gel by GALDERMA LABORATORIES USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 04-08-2025.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 04-07-2022 specifying Cream/Ointment (General)-section.
	Evaluation Remarks	

Shortcomings	Firm's Response
Evidence of required manufacturing facility (GEL section) from licensing division is required	Not submitted
Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of DML of API manufacturer valid upto 31-12-2028. Firm has also submitted copy of cGMP certificate of API manufacturer valid upto 27-07-2028.
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 studies has been submitted is required	Pictorial evidence of comparator's/refernce product is submitted Product name; Adaferin gel 0.1%; batch No#1051272A; Mfg date; 10/2021; Exp date; 09/2024 MAH name; Galderma India Private Limited, Manufacturer; Laboratories Galderma, Zone Industrielle Monidesit74540 Alby Sur Cheran-FRANCE

	Decision
	Approved Approved subject to regularization of section name by the Licensing Division.

122	Case Category	Routine (Dr. Farhad Ullah)
	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	(S9G-SVV-G1V8, 2024-06-14)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	**Atropine Sulfate 1mg/1ml Injection**
	Label Claim	Each 1ml contains Atropine Sulfate 1mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10x1ml Ampoules-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Atropine Injection 1mg/1ml by P.D.H Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Anticholinergic agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Minsheng Group Shaoxing Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	03 batches having batch size of 05Litres each

	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of proforma invoice cleared dated 21-10-2021 specifying 01kg Atropine sulphate
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Atropine Sulfate Injection 1mg/1ml by M/s MaCarthys Laboratories Ltd T/A Martindale Pharma, Bampton Road, Harold Hill, Romford, RM3 8UG United Kingdom
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 03 batches of drug substance as per zone IV-B
	The status in reference regulatory authorities	Atropine Sulfate Injection 1mg in 1ml by MaCarthys Laboratories Ltd.UK-MHRA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 12-10-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 24-06-2019 specifying SVP (General) Section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Valid copy of cGMP certificate / DML of the Drug Substance manufacturer issued by relevant regulatory authority of country of origin is required	cGMP certificate of API from M/s Saurav Chemicals Ltd, is submitted while drug substance manufacturer is Minsheng Group Shaoxing Pharmaceutical Co., Ltd., clarify
	cGMP certificate of API from M/s Saurav Chemicals Ltd, is submitted while drug substance manufacturer is Minsheng Group Shaoxing Pharmaceutical Co., Ltd., clarify	We would like to clarify that Pacific has received API from two different suppliers. The dossier submitted was prepared based on the API manufactured by Minsheng Group Shaoxing Pharmaceutical Co., Ltd., China. However, at the time of responding to the query, we mistakenly attached the cGMP certificate and stability study data of M/s Saurav Chemicals Ltd., India. This was an inadvertent error. We confirm that the actual manufacturer of the API used in our product is Minsheng Group Shaoxing Pharmaceutical Co., Ltd., and the submitted dossier reflects this. Available GMP is attached for your reference (Attachment 1). The updated stability data and GMP relevant to Minsheng have been requested and will be shared accordingly (Declaration is attached as Attachment 2). Firm has submitted copy of DML of API manufacturer valid upto 24-05-2028
	Decision	
	Approved	
123	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(BS4-Z5G-8EV2, 2025-02-12)
	Detail of Fee Submitted	37000.0, 2024-10-11,
	The proposed proprietary name / brand name	**Virovir 500mg Tablet**
	Label Claim	Each film-coated tablet contains Famciclovir..... 500mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Famciclovir 500mg tablet by Amson vaccines & Pharma (pvt) Ltd
	Pharmacotherapeutic Group of (API)	Famciclovir is used to treat infections caused by certain types of viruses.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shanghai pharma Group Changzhou Kony Pharmaceuticals Co.,Ltd
	Detail of stability batches of drug product	3 batches having batch size of 600 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 17-08-2022 specifying 10kg Famciclovir.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Viracure DS 500mg tablet by Atco 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 IV-A
	The status in reference regulatory authorities	Famciclovir 500mg Film-coated Tablets MHRA Approved
	GMP status of the firm	FFirm has submitted copy of cGMP certificate of the firm based on inspection dated 16-12-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 30-08-2013 specifying Tablet (General) Section.
	Evaluation Remarks	

Shortcomings	Firm's Response
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 comparator's product is submitted Product name; Viracure DS; batch No#QZ002J; Mfg date; 12/2023; Exp date; 11/2025 MAH name; Atco Laboratories

	Decision	
	Approved	
124	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(EEV-JVD-V59Z, 2025-05-08)
	Detail of Fee Submitted	37000.0, 2025-01-02,
	The proposed proprietary name / brand name	**Vectin 6mg tablet**
	Label Claim	Each tablet contains: Ivermectin 6mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	ivermite 6mg tablet by Atco laboratories limited
	Pharmacotherapeutic Group of (API)	Indicated for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients
	Name, address of Manufacturing site:	Self Manufacturing

	Name & address of API manufacturer	Zhejiang Hisun Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 600 tablets each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 02-11-2023 specifying 100gm Ivermectin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Ivermite 6mg Tablet by Atco 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 IV-A
	The status in reference regulatory authorities	STROMECTOL 6mg tablet USFDA Approved Discontinued**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-12-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 30-08-2013 specifying Tablet (General) Section.
	Evaluation Remarks	
	Shortcomings	Firm's Response
	Clarification is required for difference in formulation than innovator's product or submit drug excipient compatibility study	Drug excipient compatibility study is submitted
	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 reference/comparator's product is submitted Product name; Ivermite 6mg tablets; batch No#MM005K; Mfg date; 11/2023; Exp date; 11/2025 MAH name; Atco Labs
	The pharmacopoeial monograph specifies that the assay and dissolution of Ivermectin Tablets is based on the sum of components H_2B1a and H_2B1b. However, the stability study chromatograms show only a single peak. Please clarify and submit justification, along with supporting data, demonstrating the suitability of the analytical method for the determination of both components.	The Ivermectin drug substance has been completely characterized for both the components of H2B1a & H2B1b as reported in the CoA of Drug substance wherein the quantity of component H2B1b found negligible i-e, 0.42%. Since the H2B1b has been controlled in API and the stability conditions does not result into interconversion of the components and also the finished product monograph does not require separate determination of individual components hence the reported results of Ivermectin are sufficient for establishing the drug product stability. As per USP General Notice "8.100" Negligible indicate quantity not exceeding 0.5mg. For Ivermectin tablet 6mg, it becomes: 6mg x 0.42% = 0.025mg That impact no or negligible effect in assay of ivermectin determination by major component H2B1a.
	Decision	
	Approved	
125	Case Category	Contract Manufacturing (Dr. Farhad Ullah)
	Name, address of Applicant.	**High-Q Pharmaceuticals** Plot# 224 and 225/1, sector 23, Korangi Industrial area, Karachi **(000597)**
	Application Form Dy. No / Tracking ID & date of submission	(9JU-8Z1-YZUJ, 2024-10-22)
	Detail of Fee Submitted	93000.0, 2024-09-30,

	The proposed proprietary name / brand name	**Hifer**
	Label Claim	Each 5ml contains: Iron sucrose eq. to elemental iron.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled,2's-De-Controlled,5mlx5's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Ferris 100mg/5ml Injection by Hudson Pharma
	Pharmacotherapeutic Group of (API)	Iron replacement Products
	Name, address of Manufacturing site:	M/s. NovaMed Pharmaceuticals-28-KM, Ferozepur Road, Lahore-
	Name & address of API manufacturer	Nanjing Hencer Pharmaceutical
	Detail of stability batches of drug product	3 batches having batch size of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 13-07-2022 specifying 375+125kg Iron Sucrose.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Hifer injection by M/s Nabiqasim Industries
	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	Venofer 20 mg iron / mL, solution for injection or concentrate for solution for infusion MHRA approved
	GMP status of the firm	High-Q Pharma Firm has submitted copy of cGMP certificate of the firm based on inspection dated 26-02-2025. Novamed Pharma Firm has submitted copy of cGMP certificate of the firm based on inspection dated 07-11-2023.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal/regularization of DML dated 14-09-2021 specifying Liquid Injectable Ampoule/Vial (General)-revised.
	Evaluation Remarks	

Shortcomings	Firm's Response
Valid copy of cGMP certificate or DML of API manufacturer issued by relevant regulatory authority of country of origin is required	Firm has submitted copy of DML of API manufacturer valid upto 28-11-2030
COA of the primary / secondary reference standards (sucrose and ferrous ammonium Sulfate) used in product testing, including details of the source and lot number shall be submitted	Submitted
Compliance Record of HPLC Software 21CFR, audit trail and system logs are required	Audit trail report is submitted

	Decision	
	Approved	
126	Case Category	Routine (Dr. Farhad Ullah)
	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	(AN9-4JS-VRGH, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-25,

The proposed proprietary name / brand name	**NeoQuel 300mg tablet**
Label Claim	NeoQuel 300mg tablet Each film coated tablet contains: Quetiapine Fumarate Eq to Quetiapine.....300mg (USP Specs)
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	3x10's-As per SRO
Shelf Life (Unit)	2 Year(s)At room temperature
For generic drugs (me-too Status)	Qutia 300mg tablet
Pharmacotherapeutic Group of (API)	Antipsychotic
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Name: M/S: Hema Pharmaceuticals Private Limited Address: Plot No.: - 6201/A&B, Opp. Ewac Alloys Ltd., GIDC Estate, Ankleshwar□393002.Gujarat, India.
Detail of stability batches of drug product	03 batches having batch size of 1500 tablets each
Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 24-01-2022 specifying 200kg Quetiapine Fumarate .
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE & CDP studies performed against Qutia 300mg tablets
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV
The status in reference regulatory authorities	MHRA approved
GMP status of the firm	The firm has submitted a cGMP inspection report dated 28-10-2024, wherein the panel has recommended issuance of the GMP certificate.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of renewal of DML dated 11-05-2022 specifying Tablet (General) Section.

Evaluation Remarks

Shortcomings	Firm's Response
The name in eApp is different than submitted application, clarify	The old name of Applicant is Siam Pharmaceutical, which is changed to new name Cell Health Sciences. Letter of change of name is submitted.
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 comparator's product is submitted Product name; Qutia 300mg tablet; batch No#8916; Mfg date; 08/2023; Exp date; 07/2025 MAH name; Glitz Pharma
Analytical record including chromatograms for submitted PE and CDP studies for drug product is required	Analytical record for PE and CDP studies for drug product is submitted
Stability study data at both real time and accelerated conditions contain same storage conditions of 30°C ± 2°C/65% ± 5% RH, clarify	There is a typographical error in the stability data sheets, where the same storage condition (30°C ± 2°C / 65% ± 5% RH) was inadvertently mentioned for both real-time and accelerated studies. The corrected stability summary sheets, indicating the appropriate storage conditions for real time and accelerated studies, are submitted
Compliance Record of HPLC Software 21CFR & Audit Trail Reports on Product Testing is required	Audit trail report is submitted

Decision

Approved

Registration Board further decided that applicant shall submit pre-registration variation fee Rs. 9400/- for correction of applicant details in module I

127	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(Z7A-5Z6-N84U, 2025-02-04)
	Detail of Fee Submitted	37000.0, 2024-11-29,
	The proposed proprietary name / brand name	**Vection 0.5% Lotion**
	Label Claim	Each gram of lotion contains: Ivermectin 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15ml, 20ml, 30ml, 60-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	Ivermite lotion 0.5%w/v by Atco laboratories limited
	Pharmacotherapeutic Group of (API)	Indicated for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hisun Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 150 bottles each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 02-11-2023 specifying 100gm Ivermectin.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Sklice 0.5% Lotion by Topaz pharmaceuticals, USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Firm has submitted stability study data of 3 batches of drug substance as per zone IV-A
	The status in reference regulatory authorities	SKLICE (ivermectin) lotion 0.5%, USFDA Approved
	GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-12-2024.
	Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 30-08-2013 specifying Lotion (General) Section.

Evaluation Remarks

Shortcomings	Firm's Response
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 reference/comparator's product is submitted Product name; Sklice Lotion 0.5%; batch No#3414201; Exp date; 01/2025 Manufactured by; Delpharm Montreal Inc. 3535 Route Trans Canada Highway Pointe- Claire, Quebec, Canada H9R 1B4
You have claimed for USP monograph for applied product while monograph for applied product is not available in USP, Clarify	The HPLC assay method for this product adopted the chromatographic conditions (column, mobile phase, flow rate, injection volume, and detection wavelength) sourced from the USP Ivermectin Topical Solution monograph as a referenced for analytical framework, the product's actual acceptance criteria and specifications comply with the Innovator's Standards. Updated Finish product specs and procedure are attached as

		annexure VII. Fee challan is already generated (challan # 096251166) but challan is not submitted today because link is down, once the challan submitted it will be shown on DRAP record and we will also submit the paid challan to DRAP.
	The submitted USP analytical method pertains to a veterinary topical solution, whereas the applied product is a lotion intended for human use. Clarify the applicability of the submitted USP method or provide the appropriate analytical method for the applied product.	The analytical assay method is designed to quantify the active pharmaceutical ingredient (API). Assay of Ivermectin Topical Solution USP is a reverse phased HPLC method therefore when adopted and applied on same active "ivermectin" quantification in Lotion Formulation found accurate, precise and Validated for use in analysis.
	The pharmacopoeial monograph defines ivermectin API as mixture of avermectin H_2B1a and H_2B1b. However, the chromatograms submitted in the drug product stability study show only a single peak. Please clarify and submit justification, along with supporting data, demonstrating the suitability of the analytical method for the determination of both components.	The Ivermectin drug substance has been completely characterized for both the components of H2B1a & H2B1b as reported in the CoA of Drug substance wherein the quantity of component H2B1b found negligible i-e, 0.42%. Since the H2B1b has been controlled in API and the stability conditions does not result into interconversion of the components and also the finished product monograph does not require separate determination of individual components hence the reported results of Ivermectin are sufficient for establishing the drug product stability. As per USP General Notice "8.100" Negligible indicate quantity not exceeding 0.5mg. For Ivermectin Cream 10mg/g, it becomes: 10mg x 0.42% = 0.042mg That impact no or negligible effect in assay of ivermectin determination by major component H2B1a.
	Decision	
	Approved	
128	Case Category	Routine (Dr. Farhad Ullah)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(LP5-2U7-E8PV, 2025-02-10)
	Detail of Fee Submitted	75000.0, 2024-11-11,
	The proposed proprietary name / brand name	**Vectin 1% Cream**
	Label Claim	Each gram contains: Ivermectin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 g,5g, 15 g, 30 g, -As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	No local reference is available
	Pharmacotherapeutic Group of (API)	Indicated for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Hisun Pharmaceutical CO., Ltd
	Detail of stability batches of drug product	3 batches having batch size of 200 tubes each
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted copy of clearance certificate dated 02-11-2023 specifying 100gm Ivermectin.

Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies performed against Soolantra 1% cream by Laboratories golderma Z.I. Montdesir, France
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	SOOLANTRA (ivermectin) cream, 1%, for topical use USFDA Approved
GMP status of the firm	Firm has submitted copy of cGMP certificate of the firm based on inspection dated 16-12-2024.
Evidence of approval of manufacturing facility	Firm has submitted copy of letter of issuance of DML dated 30-08-2013 specifying Cream/Ointment (General) Section.

Evaluation Remarks

Shortcomings	Firm's Response
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 reference/comparator's product is submitted Product name; Soolantra 10mg/g cream; batch No#3414201; Mfg date; 01/2023; Exp date; 01/2025 MAH name; Galderma International Tour Europlaza, 20 avenue André Prothin 92927 La Défense Cedex, France. Manufacturer; : Laboratories Galderma Z.I. Montdésir, 74540 Alby sur Chéran, France
Justification is required for not including the test for preservative content and viscosity test in finished product specifications as per innovator's product	Preservative content: With reference to the query raised by the honorable authority, we respectfully clarify that Preservative Efficacy Testing were successfully performed during product release (Finish) and at the 6th-Month stability testing interval. Reports along with updated Finish Product Specification (FPS) are attached as Annex-VII. Furthermore, as per the ICH Q1A(R2) Guidelines for Stability Testing, multi-dose topical formulations require verification of antimicrobial preservative effectiveness primarily at initial release and the end of shelflife, rather than at every short-term intermediate interval, while the test was performed as required to validate the preservative system, its inclusion in the initial Finished Product Specifications was omitted due to an oversight. The FPS has now been updated to include this parameter permanently. Viscosity: Initially during development of batches, Viscosity was performed on Finish stage and was in compliance with the viscosity of innovator product but was not added in the Finish product specs because as per British Pharmacopoeia (BP) General Monograph for Topical Semi-Solid Preparations, the BP explicitly outlines that viscosity is a nonmandatory test that may be carried out only where deemed appropriate. However, in compliance with the Authority's valuable feedback and to align with public assessment data for this product, we accept this recommendation. We commit to continue the viscosity test in commercial batches after grant of registration. Updated Finish Product
The pharmacopoeial monograph defines ivermectin API as mixture of avermectin H_2B1a and H_2B1b. However, the chromatograms submitted in the drug product stability study show only a single peak. Please clarify and submit justification, along with supporting data, demonstrating the suitability of the analytical	The Ivermectin drug substance has been completely characterized for both the components of H2B1a & H2B1b as reported in the CoA of Drug substance wherein the quantity of component H2B1b found negligible i-e, 0.42%. Since the H2B1b has been controlled in API and the stability conditions does not result

	method for the determination of both components.	into interconversion of the components and also the finished product monograph does not require separate determination of individual components hence the reported results of Ivermectin are sufficient for establishing the drug product stability. As per USP General Notice "8.100" Negligible indicate quantity not exceeding 0.5mg. For Ivermectin Cream 10mg/g, it becomes: 10mg x 0.42% = 0.042mg That impact no or negligible effect in assay of ivermectin determination by major component H2B1a.
	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 for Registration Holders, Document No. PHSR/GL/PV/07 is required	Submitted
	Evidence confirming establishment of pharmacovigilance unit by the applicant and notification of pharmacovigilance officer to the Pharmacy Services Division is required	Submitted
	Decision	
	Approved	

129	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(MNR-GM5-M8MQ, 2025-01-15)
	Detail of Fee Submitted	37000.0, 2024-10-24,
	The proposed proprietary name / brand name	**Sylor 500mg Capsule**
	Label Claim	Each Capsule contains: Cefaclor as Cefaclor Monohydrate 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x12's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Centigrade.
	For generic drugs (me-too Status)	CECLOR 500mg Capsule (AGP Pharmaceutical Islamabad)
	Pharmacotherapeutic Group of (API)	
	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	
	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	Cefaclor 500mg Capsule (MHRA Approved)
	GMP status of the firm	

	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms as submitted by another firm in applicaton ID No. GSW-JZN-2A3L.	
	Decision	
	Rejected The firm has submitted same chromatograms as submitted by another firm in applicaton ID No. GSW-JZN-2A3L.	
130	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(1NJ-2HM-6PLR, 2025-01-20)
	Detail of Fee Submitted	37000.0, 2024-11-19,
	The proposed proprietary name / brand name	**Dloran 10mg**
	Label Claim	Each film coated tablets contains: Loratadine.....10mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Softin 10mg Tablets Manufactured by Werrick Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories 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	Ireland Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted stability data of drug product which was submitted by another firm vide application ID No. X73-JTB-3BP1 (already approved).	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
131	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(EAQ-Q3M-NGNV, 2024-11-13)

	Detail of Fee Submitted	37000.0, 2024-09-13,
	The proposed proprietary name / brand name	**Mefno**
	Label Claim	Each Film Coated Tablet Contains: (Ondansetron as hydrochloride dihydrate.....8mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 tablets-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Ontiv Tablet by Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate , Doddaballapur, Bengaluru Rural District-561203. Tel : +919845939733 / +91-8277389023 Fax : 080-28563081 E-Mail : info@anugrahachemicals.in
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has applied for: D4J-BHY-M2RX (4mg Ondansetron tablet) EAQ-Q3M-NGNV (4mg Ondansetron tablet) 1T5-67T-MBEZ (Ondansetron Syrup)	
	The firm has submitted chromatograms having exactly the same retention time and in some of the chromatograms, height at corresponding time points (i.e. initial testing, 3rd month time point etc). In some of the chromatograms, the height is exactly of the same value (for standard runs)	
	Retention time for some of the sample run is also of the same value in some of the chromatograms in 03 dossiers.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
132	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(1T5-67T-MBEZ, 2024-11-13)
	Detail of Fee Submitted	37000.0, 2024-09-13,
	The proposed proprietary name / brand name	**Mefno**
	Label Claim	Each 5 ml Contains: (Ondansetron as hydrochloride dihydrate.....4mg (USP

		Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Zofran Syrup
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate , Doddaballapur, Bengaluru Rural District-561203. Tel : +919845939733 / +91-8277389023 Fax : 080-28563081 E-Mail : info@anugrahachemicals.in
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has applied for: D4J-BHY-M2RX (4mg Ondansetron tablet) EAQ-Q3M-NGNV (4mg Ondansetron tablet) 1T5-67T-MBEZ (Ondansetron Syrup)	
	The firm has submitted chromatograms having exactly the same retention time and in some of the chromatograms, height at corresponding time points (i.e. initial testing, 3rd month time point etc). In some of the chromatograms, the height is exactly of the same value (for standard runs)	
	Retention time for some of the sample run is also of the same value in some of the chromatograms in 03 dossiers.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
133	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Dr. Raza Pharma** 44-C Hayatabad Industrial Estate Peshawar **(000387)**
	Application Form Dy. No / Tracking ID & date of submission	(D4J-BHY-M2RX, 2025-01-15)
	Detail of Fee Submitted	37000.0, 2024-11-19,
	The proposed proprietary name / brand name	**Mefno**
	Label Claim	Each Film Coated Tablet Contains: (Ondansetron as hydrochloride dihydrate.....4mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 tablets-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Ontiv Tablet by Sami Pharmaceuticals

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate , Doddaballapur, Bengaluru Rural District-561203. Tel : +919845939733 / +91-8277389023 Fax : 080-28563081 E-Mail : info@anugrahachemicals.in
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has applied for: D4J-BHY-M2RX (4mg Ondansetron tablet) EAQ-Q3M-NGNV (4mg Ondansetron tablet) 1T5-67T-MBEZ (Ondansetron Syrup)	
	The firm has submitted chromatograms having exactly the same retention time and in some of the chromatograms, height at corresponding time points (i.e. initial testing, 3rd month time point etc). In some of the chromatograms, the height is exactly of the same value (for standard runs)	
	Retention time for some of the sample run is also of the same value in some of the chromatograms in 03 dossiers.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
134	Case Category	Routine (Farooq Aslam)
	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	(773-X43-5UJE, 2025-01-20)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Destron 4mg**
	Label Claim	Each Film Coated Tablet Contains: (Ondansetron as hydrochloride dihydrate.....4mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Ontiv Tablet by Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate ,

		Doddaballapur, Bengaluru Rural 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	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms for stability data of drug product which was submitted by another firm vide application ID No. D4J-BHY-M2RX.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
135	Case Category	Routine (Farooq Aslam)
	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	(DUE-Z1X-LW4P, 2025-01-20)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Destron**
	Label Claim	Each 5 ml Contains: (Ondansetron as hydrochloride dihydrate.....4mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Zofran Syrup
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate , Doddaballapur, Bengaluru Rural 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	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	The firm has submitted same chromatograms for stability data of drug product which was submitted by another firm vide application ID No. 1T5-67T-MBEZ.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
136	Case Category	Routine (Farooq Aslam)
	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	(N4J-H2H-4XNE, 2025-01-20)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Destron 8mg**
	Label Claim	Each Film Coated Tablet Contains: (Ondansetron as hydrochloride dihydrate.....8mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Ontiv Tablet by Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. ANUGRAHA CHEMICALS No D-47 to D-50 & C-62 to C-63, KSSIDC Industrial Estate , Doddaballapur, Bengaluru Rural 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	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms for stability data of drug product which was submitted by another firm vide application ID No. EAQ-Q3M-NGNV.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
137	Case Category	Routine (Farooq Aslam)
	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	(N6H-ZLZ-S5V4, 2025-01-20)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Finelid**
	Label Claim	Each film coated tablet Contains: Linezolid.....400mg (Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x6's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Centigrade.
	For generic drugs (me-too Status)	Barizold 400mg Tablets By M/s Barrett Hodgson Pakistan (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	OPTRIX LABORATORIES 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	Zyvox 400mg Tablets (Pfizer US)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms in application ID Nos. N6H-ZLZ-S5V4 (400mg tablet) and YE9-MXR-V3AP(600mg tablet) having same values of different parameters by changing the batch number.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
138	Case Category	Routine (Farooq Aslam)
	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	(YE9-MXR-V3AP, 2025-01-20)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Finelid Tablet 600mg**
	Label Claim	Each film coated tablet Contains: Linezolid.....600mg (Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x6's-As per SRO

	Shelf Life (Unit)	2 YearStore below 30 Degree Centigrade.
	For generic drugs (me-too Status)	Barizold 600mg Tablets By M/s Barrett Hodgson Pakistan (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	OPTRIX LABORATORIES 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	Zyvox 600mg Tablets (Pfizer USA)
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms in application ID Nos. N6H-ZLZ-S5V4 (400mg tablet) and YE9-MXR-V3AP(600mg tablet) having same values of different parameters by changing on the batch number.	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
139	Case Category	Routine (Farooq Aslam)
	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	(JVT-D4N-Q4WG, 2025-01-20)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Damadol Plus**
	Label Claim	Each film coated tablet Contains: Tramadol HCl USP.....37.5mg Paracetamol USP.....325mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearBelow 30 degree C°
	For generic drugs (me-too Status)	Pantra Plus by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CITI Pharma Pvt Ltd,Lucent drugs Pvt Ltd Factory: Sy No 10, Gaddapotharam Village,Jinnaram Mandal Sangarddy District, Telangana State,
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP	

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted same chromatograms for stability data of drug product which was submitted by another firm vide application ID No. JVT-D4N-Q4WG (rejected in 359th meeting).	
	Decision	
	Rejected The Board rejected the application because the applicant has submitted the same data, which was previously submitted by the another manufacturer.	
140	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	(E4Q-YQG-38A2, 2026-01-29)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	**TADALO TABLET 10MG**
	Label Claim	Each Film coated tablet contains Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4’s,7’s,10's,14’s, 20's, 25’s, 30's, 40's & 50's,60’s, 10x10’s ,4x7’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 10mg Tablet Registration Number: 132219
	Pharmacotherapeutic Group of (API)	Phosphodiesterase inhibitor
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batch No TC004 Date of Mfg 05-2025, Batch No TC005 Date of Mfg 05-2025, Batch No TC006 Date of Mfg 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 (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 10mg 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 (℃, %RH) 40°C±2°C & 75% ±5%RH, Storage Condition (℃, %RH) 30°C ±2°C & 75%±5%RH 06 months accelerated and 60 months real time.
	The status in reference regulatory authorities	Tadalafil Tablet 10mg Abbreviated New Drug Application (ANDA): 090141 Company: TEVA PHARMA USA USFDA approved
	GMP status of the firm	Last inspection report dated 27-29th May and 16th July, 2025 is submitted for renewal of DML.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The application has been processed on priority in compliance to the decision of DRAP Authority regarding ED drugs.	
	Decision	
	Approved	
141	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**Getz Pharma (Pvt) Limited** 29-30/27,Korangi Industrial Area karachi **(000284)**
	Application Form Dy. No / Tracking ID & date of submission	(GXZ-26D-Y29R, 2026-02-16)
	Detail of Fee Submitted	75000, 2025-04-17,
	The proposed proprietary name / brand name	**Vibex Tablets 75mg**
	Label Claim	Each film-coated tablet contains: Vibegron ... 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
	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)	Urologicals (Drugs for urinary frequency and incontinence)
	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 (in case of Import)	Documents for the procurement of API (Form 6, Invoice, Airway Bill and GD) has been submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Firm has submitted Pharmaceutical Equivalence Study against comparator product Gemtesa Tablets 75mg by M/s Sumitomo Pharma America, Inc. USFDA approved
	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	Gemtesa Tablets 75mg by M/s Sumitomo Pharma America, Inc. (USFDA Approved)
	GMP status of the firm	Valid GMP of FPP manufacturer is submitted.

	Evidence of approval of manufacturing facility	Firm has submitted Drug Manufacturing License (License No.: 000284) along with DML renewal receipt as the evidence of manufacturing facility.
	Evaluation Remarks	
	The firm was asked to clarify since the tests for Diastereoisomerism were included in the specifications of drug substance and enantiomeric purity for desired isomer were determined as per submitted dossier but the content estimation for other 03 isomers was not done.	
	Reply: In reply the firm has submitted another COA of drug substance with an additional test for isomeric contents of 03 isomers (mentioning the status of COA as "recertified) for batch number VDP25001 manufactured on Dec, 2025.	
	Decision	
	Approved	
142	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**May and Baker (Pvt.) Ltd** 23-Ghouri Block, Bahria Town, Lahore **(000953)**
	Application Form Dy. No / Tracking ID & date of submission	(QXD-PMP-5HXB, 2026-03-02)
	Detail of Fee Submitted	37000, 1700 2024-09-19, 2026-02-27
	The proposed proprietary name / brand name	**Bakolast 4mg sachet**
	Label Claim	Each sachet contains: Montelukast sodium eq. to montelukast.....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	7's,14's, 30's, 50's, 100's-As per SRO
	Shelf Life (Unit)	2 Year(s)below 24 degree
	For generic drugs (me-too Status)	myteka 4mg sachet by M/s Hilton
	Pharmacotherapeutic Group of (API)	Other Systemic Drugs for Obstructive Airway Diseases, Leukotriene receptor antagonists
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Metrochem API Private Limited, Unit-I, Plot No. 62/C/6, Pipeline Road, Phase – I, IDA, Jeedimetla, Quthbullapur (M), Medchal – Malkajgiri (Dist) – 500 055 Telangana State, India.
	Detail of stability batches of drug product	03 batches : 1500 sachet 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s GT Pharma pvt Ltd., dated 15-10-2022 for 30grams of material. Clearance certificate dated 06-07-2022 is submitted (GT Pharma).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been submitted against the comparator's product i.e Myteka Sachet by M/s Hilton.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	zoneII
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	NEW License issued w.e.f 29-04-2022
	Evidence of approval of manufacturing facility	Sachet Section General is approved
	Evaluation Remarks	

	The firm was asked to submit Audit trail report. The firm has stated that "Audit trail report/system log for submitted stability data of the drug product. As the HPLC is manual, the audit trail is not available." Analytical record for submitted PE and AMV studies has not been submitted.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases, wherein, the data is complete, however, the HPLC system is not 21 CFR compliant.	
143	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**FRONTIER DEXTROSE LIMITED** PLOT NO. 18/3 PHASE-1 INDUSTRIAL ESTATE HATTAR **(000633)**
	Application Form Dy. No / Tracking ID & date of submission	(LR5-T2N-LAL2, 2024-07-11)
	Detail of Fee Submitted	30000.0, 2024-04-29,
	The proposed proprietary name / brand name	**Sterifluid DS Infusion 250ml**
	Label Claim	Each 100ml Contains: Dextrose Anhydrous BP..... 5gm Sodium Chloride..... 0.9 gm
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	250ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Tempreture
	For generic drugs (me-too Status)	Medisol S (Reg # 106340) by Medipak Limited
	Pharmacotherapeutic Group of (API)	Carbohydrates & Electrolytes
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	.,K+S, Minerals & Agricuture GmBH, ,Weifang Shenghai Medicine Co., Ltd.
	Detail of stability batches of drug product	03 batches : 8000 infusion bottles 06 months accelerated and 06 months real time stability data according to zone IV-aA
	Documents for the procurement of API with approval from DRAP (in case of Import)	Dextrose: Clearance certificate dated 14-04-2023 is submitted. NaCl: Clearance certificate dated 20-03-2023 is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against the comparator's product i.e Medisol-S by M/s Medipak.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Dextrose: 06 months accelerated and 36 months real time stability data of 03 batches according t zone IV-A. NaCl: 06 months accelerated and 72 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Dextrose & Sodium Chloride Injections is approved in USFDA (01924435)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-12-2023.
	Evidence of approval of manufacturing facility	LVP General section s approved as per submitted GMP certificate.
	Evaluation Remarks	
	Decision	
	Approved	
144	Case Category	Routine (Farooq Aslam)

	Name, address of Applicant.	**gulfpharmaceuticals** Plot No.49,Street No. S-5,Rawalpindi Industrial Zone (RIZ),Islamabad. **(000750)**
	Application Form Dy. No / Tracking ID & date of submission	(PH4-MUM-TR81, 2025-01-13)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**Gufxime 100mg/5ml Dry suspension**
	Label Claim	Each 5ml of suspension contains: Cefixime trihydrate equivalent to Cefixime .....100 mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml suspension afte-De-Controlled
	Shelf Life (Unit)	2 Year15°C to 25°C
	For generic drugs (me-too Status)	Zixpro 100mg/5ml Dry suspension
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Linta Pharmaceuticals-Plot No.3,Street S-5, RCCI, Rawat-
	The status in reference regulatory authorities	Suprax Oral Suspension USP, of Lupin Pharmaceuticals Inc Manufactured by: Lupin Pharmaceuticals, Inc. Harborplace Tower 111 S. Calvert Street, 21st Floor Baltimore, MD 21202 Phone: 866-587-4617 Fax: 866-587-4627 Email: customerservice@lupinusa.com (for US marketed products only
	Detail of previous approval	Zix 100mg/5ml Dry powder suspension
	Evaluation Remarks	
	The data is already approved in 358th meeting of registration Board vide application ID (JNQ-MNH-E8X6, 2024-08-28).	
	At the time of submission of application, the data was not approved on Form 5F (manufacturer: Linta Pharma), but in 358th meeting the data was approved by the Board for an application submitted by Gilman Pharmaceuticals on contract manufacturing by Ms/ Linta Pharma. Therefore, the firm shall submit the applicable.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
145	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Helix Pharma (Pvt)., Ltd.** Hakimsons House, A-56, S.I.T.E, Manghopir Road, Karachi-75700 **(000030)**
	Application Form Dy. No / Tracking ID & date of submission	(7R8-85H-8YY1, 2025-09-30)

	Detail of Fee Submitted	37000.0, 2025-06-25,
	The proposed proprietary name / brand name	**APTIOM Oral Suspension 50mg/mL**
	Label Claim	Each mL of oral suspension contains: Eslicarbazepine Acetate 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,120ml-De-Controlled,30ml-De-Controlled,50ml-De-Controlled,60ml-De-Controlled,90ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)20°C to 25°C (68°F-77°F); excursions are permitted between 15°C and 30°C (59°F and 86°F)
	For generic drugs (me-too Status)	Available (Hiranis)
	Pharmacotherapeutic Group of (API)	anticonvulsants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s CTX Lifesciences Pvt. Ltd. - India
	Detail of stability batches of drug product	03 batches : 33 bottles (60mL each) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 14-11-2024 for 75kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Carlep by M/s Genix.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Zebinix Oral Suspension 50mg/mL as approved by EMA for BIAL - Portela & C^{a} , SA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-03-2024.
	Evidence of approval of manufacturing facility	Oral Solution/Liquid Syrup (General) Section is approved.
	Evaluation Remarks	
	The shelf life after opening of the container is 2 months as per SmPC of reference country (MHRA).	
	Decision	
	Approved	
146	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hoechst Pakistan Limited** Plot 23, Sector 22, Korangi Industrial Area, **(000007)**
	Application Form Dy. No / Tracking ID & date of submission	(VM2-RZJ-HZAW, 2025-01-13)
	Detail of Fee Submitted	75000.0, 18000.0 2024-08-26, 2024-09-05
	The proposed proprietary name / brand name	**EMJARD (Empagliflozin) 10mg Tablets**
	Label Claim	Each film coated tablet contains: Empagliflozin 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30

	For generic drugs (me-too Status)	Empagen Tablet 10mg by M/s Ferozsons Laboratories
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Ferozsons Laboratories Limited-P.O. Ferozsons Amangarh, Nowshera, Khyber Pakhtunkhwa - Pakistan-
	Name & address of API manufacturer	Fuxin Long Rui Pharmaceutical Co. Ltd.
	Detail of stability batches of drug product	02 batches : 13.669 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 23-06-2022 for 25kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Jardiance.
	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	Jardiance 10mg Tablets by M/s Boehringer Ingelheim Pharmaceutical Inc.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 15-06-2023 (Ferozsons)
	Evidence of approval of manufacturing facility	Tablet general section is approved as per submitted GMP certificate.
	Evaluation Remarks	
	Decision	
	Approved	
147	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**
	Application Form Dy. No / Tracking ID & date of submission	(J42-WZW-EY3R, 2025-01-15)
	Detail of Fee Submitted	93000.0, 2025-01-03,
	The proposed proprietary name / brand name	**Zeal 10mg Tablets**
	Label Claim	Each film-coated tablet contains: Vardenafil Hydrochloride eq. to Vardenafil 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2x5's ; 1x4's-As per SRO
	Shelf Life (Unit)	2 YearStore at Room Temperature
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-Plot No 313 Industrial Triangle Kahuta Road Islamabad -
	The status in reference regulatory authorities	GSK GlaxoSmithKline - USFDA Approved - https://www.accessdata.fda.gov/drugsatfda_docs/n400_Levitra.cfm
	Detail of previous approval	
	Evaluation Remarks	
	The product was approved in 351st meeting on Form 5F.	

	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
148	Case Category	Routine (Farooq Aslam)
	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	(TZ1-4RT-22RV, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2024-12-13,
	The proposed proprietary name / brand name	**Tadala 5mg**
	Label Claim	Each film Coated tablet contains; Tadalafil 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-De-Controlled,12's-De-Controlled,14'-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearNot more than 30C
	For generic drugs (me-too Status)	Not available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot no. 129 Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The product was approved in 351st meeting.	
	Decision	
	Approved	
149	Case Category	Routine (Farooq Aslam)
	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	(NXX-BJ5-3MZT, 2024-09-11)
	Detail of Fee Submitted	30000.0, 2024-07-05,
	The proposed proprietary name / brand name	**Rosupro EZ 20mg/10mg Tablets**
	Label Claim	Each bilayer film coated tablet contains: Rosuvastatin as Calcium ..... 20mg Ezetimibe l0mg
	Reference to Finished product specifications	As per Innovators Specification

Proposed Pack Size	10s -As per SRO
Shelf Life (Unit)	2 Year(s)Shelf Life only applies under appropriate conditions of storage specified
For generic drugs (me-too Status)	RolipEze 20mg/10mg Tablet by Hilton Pharma Pakistan Pvt Ltd
Pharmacotherapeutic Group of (API)	Lipid lowering agents
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Glenmark Life Sciences Limited Address Glenmark House A Wing B D Sawant No 74 A J N Pharmacity Thanam village Parawada Mandal Visakhapatnam 531019 India ,Nantong Chanyoo Pharmatech Co Ltd Address No 518 Laodong East Road Changzhou Jiangsu Province213018 P R China
Detail of stability batches of drug product	Batches: T244, T245, T246 (Batch size: 3000 tablets) 06 months accelerated and 06 months real time stability data according to zone IV-B.
Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: Form 5 dated 24-10-2023 along with GD No. KPAF-10308-08112023 Date: 08-11-2023 and airway bill is submitted. Ezetimibe: AD attested invoice issued on 29-11-2021 for 03kg material is submitted.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. RolipEze 20/10 by M/s Hilton Pharma.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 06 months accelerated and 48 months real time stability data of 03 batches according to zone IV-B. Ezetimibe: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-B.
The status in reference regulatory authorities	Roszet Tablets 20mg/10mg by Food and Drug Administration FDA
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-224 is submitted.
Evidence of approval of manufacturing facility	Tablet General Section is approved.

Evaluation Remarks

The firm shall submit applicable fee for correction of label claim from Film Coated Tablet to Bilayer Film coated Tablet.

The firm was asked to provide documents confirming import of drug substance (Rosuvastatin). The firm had submitted Form 5 (Drug import License) which is issued for commercial consignment for manufacturing of commercial batches. The firm was again asked for submission of clearance certificate.

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 Import License (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

	Approved The firm shall submit applicable fee for correction of label claim from Film Coated Tablet to Bilayer Film coated Tablet.	
150	Case Category	Routine (Farooq Aslam)
	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	(X77-EJ2-MJ3P, 2024-10-08)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-05, 2024-09-09
	The proposed proprietary name / brand name	**Rosupro EZ 10mg/10mg Tablets**
	Label Claim	Each film coated tablet bilayer contains: Rosuvastatin as Calcium.....10mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s -As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf Life only applies under appropriate conditions of storage specified
	For generic drugs (me-too Status)	RolipEze 10mg/10mg Tablet by Hilton Pharma Pakistan Pvt Ltd
	Pharmacotherapeutic Group of (API)	Lipid lowering agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Life Sciences Limited Address Glenmark House A Wing B D Sawant No 74 A J N Pharmacity Thanam village Parawada Mandal Visakhapatnam 531019 India ,Nantong Chanyoo Pharmatech Co Ltd Address No 518 Laodong East Road Changzhou Jiangsu Province 213018 P R China
	Detail of stability batches of drug product	Batches: T247, T248, T249 (Batch size: 1666 tablets) 06 months accelerated and 06 months real time stability data according to zone IV-B.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Rosuvastatin: Form 5 dated 24-10-2023 along with GD No. KPAF-10308-08112023 Date: 08-11-2023 and airway bill is submitted. Ezetimibe: AD attested invoice issued on 29-11-2021 for 03kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. RolipEze 10/10 by M/s Hilton Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 48 months real and 6 months accelerate stability data of 03 batches according to zone IV-A. Ezetimibe: 24 months real and 6 months accelerate stability data of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	Roszet Tablets 10mg/10mg by Food and Drug Administration FDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-224 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	

	The firm was asked to provide documents confirming import of drug substance (Rosuvastatin). The firm had submitted Form 5 (Drug import License) which is issued for commercial consignment for manufacturing of commercial batches. The firm was again asked for submission of clearance certificate.	
	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 Import License (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	
	Approved The firm shall submit applicable fee for correction of label claim from Film Coated Tablet to Bilayer Film coated Tablet.	
151	Case Category	Routine (Farooq Aslam)
	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	(H7T-B3V-QUYL, 2024-09-10)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-12, 2024-09-09
	The proposed proprietary name / brand name	**Rosupro EZ 5mg/10mg Tablets**
	Label Claim	Each film coated bilayer tablet contains: Rosuvastatin as Calcium .....5mg Ezetimibe .... 10mg The firm shall submit applicable fee for correction of label claim from Film Coated Tablet to Bilayer Film coated Tablet.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10s-As per SRO,20s-As per SRO
	Shelf Life (Unit)	2 Year(s)Shelf Life only applies under appropriate conditions of storage specified
	For generic drugs (me-too Status)	RolipEze 5mg/10mg Tablet by Hilton Pharma Pakistan Pvt Ltd
	Pharmacotherapeutic Group of (API)	Lipid lowering agents
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Glenmark Life Sciences Limited Address Glenmark House A Wing B D Sawant No 74 A J N Pharmacity Thanam village Parawada Mandal Visakhapatnam 531019 India ,Nantong Chanyoo Pharmatech Co Ltd Address No518 Laodong East Road Changzhou Jiangsu Province 213018 P R China
	Detail of stability batches of drug product	Batches: T255, T256, T257 (Batch size: 1666 tablets) 06 months accelerated and 06 months real time stability data according to zone IV-B.

	Documents for the procurement of API with approval from DRAP (in case of Import)	:Rosuvastatin: Form 5 dated 24-10-2023 along with GD No. KPAF-10308-08112023 Date: 08-11-2023 and airway bill is submitted. Ezetimibe: AD attested invoice issued on 29-11-2021 for 03kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. RolipEze 5/10 by M/s Hilton Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Rosuvastatin: 06 months accelerated and 48 months real time stability data of 03 batches according to zone IV-B. Ezetimibe: 06 months accelerated and 24 months real time stability data of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	Roszet Tablets 5mg/10mg by Food and Drug Administration FDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-224 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The firm was asked to provide documents confirming import of drug substance (Rosuvastatin). The firm had submitted Form 5 (Drug import License) which is issued for commercial consignment for manufacturing of commercial batches. The firm was again asked for submission of clearance certificate.	
	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 Import License (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	
	Approved The firm shall submit applicable fee for correction of label claim from Film Coated Tablet to Bilayer Film coated Tablet.	
152	Case Category	Routine (Farooq Aslam)
	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	(85P-GBJ-ZGPX, 2024-11-14)
	Detail of Fee Submitted	37000.0, 2024-10-25,
	The proposed proprietary name / brand name	**Valdosar HCT 10mg-160mg-12.5mg Tablets**
	Label Claim	Each film coated tablet contains: Amlodipine as Besylate .....10mg Valsartan.....160mg Hydrochlorothiazide.....12.5mg
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	10s 14s 20s 28s-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)	Triforge 10mg-160mg-12.5mg Tablets by Highnoon
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma Chem ,Suzhou Lixin Pharmaceutical Co Ltd,Zhuhai Rundu Pharmaceutical Co Ltd
	Detail of stability batches of drug product	03 batches (Batch size: 1500 tab) 06 months real time and 06 months accelerated stability data of 03 batches according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	HCT: Form 6 dated 27-04-2023 for 3kg material. Amlodipine: Form 5 dated 9th Sep, 2022 along with GD NO. KPAF-7338-20092022 Date: 20-09-2022 and airway bill. Valsartan: Form 6 dated 29-11-2021 for 4 kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Triforge by M/s Highnon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Amlodipine: 06 months accelerated and 60 months real time stability data according to zone IV-A. Valsartan: 06 months accelerated and 60 months real time stability data according to zone IV-B. HCT: 06 months accelerated and 48 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	Exforge HCT 10mg-160mg-12.5mg Tablets by Food and Drug Regulatory Authority USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm was asked to provide documents confirming import of drug substance. The firm had submitted Form 5 (Drug import License) which is issued for commercial consignment for manufacturing of commercial batches. The firm was again asked for submission of clearance certificate.	
	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 Import License (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	
	Approved	
153	Case Category	Routine (Farooq Aslam)

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	(P35-SE4-D4AW, 2024-11-05)
Detail of Fee Submitted	37000.0, 2024-09-24,
The proposed proprietary name / brand name	**Valdosar HCT 10mg-160mg-25mg Tablets**
Label Claim	Each film coated tablet contains: Amlodipine as Besylate .....10mg Valsartan.....160mg Hydrochlorothiazide.....25mg
Reference to Finished product specifications	United States Pharmacopeia
Proposed Pack Size	5s 10s 14s 28s-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)	Triforge 10mg-160mg-25mg Tablets by Highnoon
Pharmacotherapeutic Group of (API)	Antihypertensive
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Prudence Pharma Chem ,Suzhou Lixin Pharmaceutical Co Ltd,Zhuhai Rundu Pharmaceutical Co Ltd
Detail of stability batches of drug product	03 batches (Batch size: 1500 tab) 06 months real time and 06 months accelerated stability data of 03 batches according to zone IV-A.
Documents for the procurement of API with approval from DRAP (in case of Import)	HCT: Form 6 dated 27-04-2023 for 3kg material. Amlodipine: Form 5 dated 9th Sep, 2022 along with GD NO. KPAF-7338-20092022 Date: 20-09-2022 and airway bill. Valsartan: Form 6 dated 29-11-2021 for 4 kg material.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Triforge by M/s Highnon.
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Amlodipine: 06 months accelerated and 60 months real time stability data according to zone IV-A. Valsartan: 06 months accelerated and 60 months real time stability data according to zone IV-B. HCT: 06 months accelerated and 48 months real time stability data according to zone IV-A.
The status in reference regulatory authorities	Exforge HCT 10mg-160mg-25mg Tablets by Food and Drug Regulatory Authority USA
GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-2024 is submitted.
Evidence of approval of manufacturing facility	Tablet General Section is approved

Evaluation Remarks

The firm was asked to provide documents confirming import of drug substance. The firm had submitted Form 5 (Drug import License) which is issued for commercial consignment for manufacturing of commercial batches. The firm was again asked for submission of clearance certificate.
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 Import License (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	
	Approved	
154	Case Category	Routine (Farooq Aslam)
	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	(H9B-TBX-3BTL, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**Valdosar HCT 5mg-160mg-25mg Tablets**
	Label Claim	Each film coated tablet contains: Amlodipine as Besylate .....5mg Valsartan.....160mg Hydrochlorothiazide.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s, 14s and 28s-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)	Triforge 5mg-160mg-25mg Tablets by Highnoon
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma Chem ,Suzhou Lixin Pharmaceutical Co. Ltd ,Zhuhai Rundu Pharmaceutical Co. Ltd
	Detail of stability batches of drug product	03 batches (Batch size: 1500 tab) 06 months real time and 06 months accelerated stability data of 03 batches according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	HCT: Form 6 dated 27-04-2023 for 3kg material. Amlodipine: Form 5 dated 9th Sep, 2022 along with GD NO. KPAF-7338-20092022 Date: 20-09-2022 and airway bill. Valsartan: Form 6 dated 29-11-2021 for 4 kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Triforge by M/s Highnon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Amlodipine: 06 months accelerated and 60 months real time stability data according to zone IV-A. Valsartan: 06 months accelerated and 60 months real time stability data according to zone IV-B. HCT: 06 months accelerated and 48 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	Exforge HCT 5mg-160mg-25mg Tablets by Food and Drug Regulatory Authority USA

	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm was asked to provide documents confirming import of drug substance. The firm had submitted Form 5 (Drug import License) which is issued for commercial consignment for manufacturing of commercial batches. The firm was again asked for submission of clearance certificate.	
	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 Import License (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	
	Approved	
155	Case Category	Routine (Farooq Aslam)
	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	(6VS-XWR-LM8N, 2024-10-31)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**Valdosar HCT 5mg-160mg-12.5mg Tablets**
	Label Claim	Each film coated tablet contains: Amlodipine as Besylate .....5mg Valsartan.....160mg Hydrochlorothiazide.....12.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	28s and 30s -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)	Triforge 5mg-160mg-12.5mg Tablets by Highnoon
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Prudence Pharma Chem ,Suzhou Lixin Pharmaceutical Co Ltd.,Zhuhai Rundu Pharmaceutical Co Ltd
	Detail of stability batches of drug product	03 batches (Batch size: 1500 tab) 06 months real time and 06 months accelerated stability data of 03 batches according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	HCT: Form 6 dated 27-04-2023 for 3kg material. Amlodipine: Form 5 dated 9th Sep, 2022 along with GD NO. KPAF-7338-20092022 Date: 20-

		09-2022 and airway bill. Valsartan: Form 6 dated 29-11-2021 for 4 kg material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Triforge by M/s Highnon.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Amlodipine: 06 months accelerated and 60 months real time stability data according to zone IV-A. Valsartan: 06 months accelerated and 608 months real time stability data according to zone IV-B. HCT: 06 months accelerated and 48 months real time stability data according to zone IV-A.
	The status in reference regulatory authorities	Exforge HCT Tablets by Food and Drug Regulatory Authority USA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-05-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	The firm was asked to provide documents confirming import of drug substance. The firm had submitted Form 5 (Drug import License) which is issued for commercial consignment for manufacturing of commercial batches. The firm was again asked for submission of clearance certificate.	
	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 Import License (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	
	Approved	
156	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Jenner Pharmceuticals Pvt. Ltd** Plot No. 03, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura **(000823)**
	Application Form Dy. No / Tracking ID & date of submission	(TPG-7BM-Z63X, 2025-01-13)
	Detail of Fee Submitted	93000.0, 2024-12-20,
	The proposed proprietary name / brand name	**Trollius Lotion 1%**
	Label Claim	Each ml contains: Terbinafine Hydrochloride.....10mg JP specifications
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30C
	For generic drugs (me-too Status)	Terbisil lotion 1% by saffron pharmaceuticals pvt. ltd
	Pharmacotherapeutic Group of (API)	Anti fungal

	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd,-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN-
	Name & address of API manufacturer	N/A
	Detail of stability batches of drug product	03 batches of 1L
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan of API from M/s Seraph by M/s Solaris Lifescience.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	against terbiderm by M/s Atco
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	as per zone IV_A
	The status in reference regulatory authorities	Lamisil Once TM 1% cutaneous solution by Haleon Ireland Limited
	GMP status of the firm	NEW DML was granted in 2024
	Evidence of approval of manufacturing facility	.
	Evaluation Remarks	
	The stability data was approved on form 5F in 360th meeting.	
	The firm shall submit declaration of adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufactruer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products.	
	The firm shall submit the applicable fee for cross referring the approved product since at the time of submission of application, the data was not approved.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
157	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	(DYX-AEV-L37P, 2024-10-21)
	Detail of Fee Submitted	75000.0, 2024-09-16,
	The proposed proprietary name / brand name	**Roxtin 150mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Roxadustat.....150mg
	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.
	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	
	Form 6 is not submitted.	
	Decision	
	Deferred Deferred for a mechanism to dispose off such cases wherein the API was imported without Import License and Clearance certificate from DRAP.	
158	Case Category	Routine (Farooq Aslam)
	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	(2ZW-J7D-N6SM, 2024-08-21)
	Detail of Fee Submitted	75000.0, 2024-06-25,
	The proposed proprietary name / brand name	**Rozimibe 5mg + 10mg Tablet**
	Label Claim	Each Film Coated bilayer Tablet contains: Rosuvastatin as Calcium Salt (USP).....5MG 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 Year(s)Store below 25°C.
	For generic drugs (me-too Status)	Rovista EZ 5mg+10mg Tablet by Getz Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	

	The product was approved 352nd meeting (ID No. HQT-1RE-PXDZ). the firm shall submit applicable fee for correction of label claim.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
159	Case Category	Routine (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	(RRB-UA4-7U72, 2024-08-28)
	Detail of Fee Submitted	75000.0, 2024-07-24,
	The proposed proprietary name / brand name	**CAPRI 1.5MG Capsule**
	Label Claim	Each Capsule Contains: Cariprazine as Cariprazine Hydrochloride (USP).....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 YearReal time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH
	For generic drugs (me-too Status)	Caripra 1.5MG Capsule (Genix Pharma) 1.5mg / 3mg / 4.5mg / 6mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s WELCOME PAKISTAN TRADING PHARMA (PRIVATE) LTD-CHAKRI INTERCHANGE, MAIN ROAD, GANGANWALA, RAWALPINDI-
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	336
	Evaluation Remarks	
	The product was approved in 336th meeting vide ID No. Form 5F: Track ID: E99-D9Q-UJJA Dated: 03-06-2024 submitted by M/s Welcome Pakistan. Initially, the product was not approved on form 5F, therefore the firm shall submit fee for changing the status of data approved from No to Yes.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products.	

	2. Applicable fee for changing the status of data approved already.	
160	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(H5Q-4EX-M8QH, 2024-11-23)
	Detail of Fee Submitted	93000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Lyno-M 2.5mg/500mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Linagliptin.....2.5MG Metformin Hydrochloride (USP).....500MG (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The product was approved in 348th meeting vide ID No. 7ML-VTZ-6BBV submitted by M/s Wnsfeild. Initially, the product was not approved on form 5F, therefore the firm shall submit fee for changing the status of data approved from No to Yes.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
161	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(P5R-NV4-NS8N, 2024-11-23)
	Detail of Fee Submitted	93000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Lyno-M 2.5mg/1000mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Linagliptin.....2.5MG Metformin Hydrochloride (USP).....1000mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The product was approved in 348th meeting vide ID No. HTY-JPW-HZUS submitted by M/s Wnsfeild. Initially, the product was not approved on form 5F, therefore the firm shall submit fee for changing the status of data approved from No to Yes.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
162	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(XLJ-Y7W-XXGT, 2024-11-23)
	Detail of Fee Submitted	93000.0, 2024-11-08,
	The proposed proprietary name / brand name	**Lyno-M 2.5mg/850mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Linagliptin.....2.5MG Metformin Hydrochloride (USP).....850mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The product was approved in 336th meeting vide ID No. B2R-XVX-5P8D submitted by M/s Wnsfeild. Initially, the product was not approved on form 5F, therefore the firm shall submit fee for changing the status of data approved from No to Yes.	
	Decision	
	Approved Subject to submission of:	

	1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
163	Case Category	Routine (Farooq Aslam)
	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	(ZB1-Y55-BJUJ, 2025-01-23)
	Detail of Fee Submitted	93000.0, 2025-01-10,
	The proposed proprietary name / brand name	**Finen 10mg Tablet**
	Label Claim	Each film coated tablet contains: Finerenone ..... 10mg Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,2x10's-De-Controlled,3x10's-De-Controlled,4x7's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30oC
	For generic drugs (me-too Status)	None
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt). Ltd.-Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore-
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	KERENDIA 10mg TABLET Bayer Healthcare Pharmaceutical Inc. USFDA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has requested to withdraw the application.	
	Decision	
	Rejected The Board acceded the request of the firm and rejected the case.	
164	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(QLV-M26-TRZ7, 2025-01-23)

	Detail of Fee Submitted	93000.0, 2024-11-29,
	The proposed proprietary name / brand name	**Tadila 5mg Tablet**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 YearStore in a Cool & dry place below 30ºC.
	For generic drugs (me-too Status)	No Me-Too available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Tadalafil Tablets, USP 5mg (Ajanta Pharma USA Inc., Bridgewater, NJ 08807)
	Detail of previous approval	
	Evaluation Remarks	
	The product was approved in 351st meeting vide ID No. 9LG-5U5-JQ74, 2025-07-28 submitted by M/s Wimits. Initially, the product was not approved on form 5F, therefore the firm shall submit fee for changing the status of data approved from No to Yes.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
165	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(JDS-Q26-7DLU, 2025-01-09)
	Detail of Fee Submitted	93000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Roxanix 100mg Tablets**
	Label Claim	Each Film Coated Tablet contains: Roxadustat.....100mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 12's, 14's, 20-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade
	For generic drugs (me-too Status)	Approved by Getz, CCL, Kaizen and Horizon.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. WnsFeild Pharmaceuticls-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	UK MHRA Approved.
	Detail of previous approval	
	Evaluation Remarks	

	The product was approved in 360th meeting vide ID No. B2R-XVX-5P8D submitted by M/s 1AZ-LQ6-2LP8, 2024-10-23. Initially, the product was not approved on form 5F, therefore the firm shall submit fee for changing the status of data approved from No to Yes.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
166	Case Category	Routine (Farooq Aslam)
	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	(ATN-QQ6-WUGV, 2024-08-21)
	Detail of Fee Submitted	30000.0, 2024-07-19,
	The proposed proprietary name / brand name	**Glifzon-M**
	Label Claim	Each film coated tablet contains: Empagliflozin.....12.5mg metformin HCl..... 500 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)room temprature
	For generic drugs (me-too Status)	Diampa-M
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches : 1000 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 certificates for Metformin and empagliflozin for commercial import are submitted imported for manufacturing of other products.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Diampa-M tablet by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Metformin: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Empagliflozin: 06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Empagliflozn/Metformin HCl tablet, manufactured by Boehringer Ingelheim Pharma, Germany

	GMP status of the firm	GMP Certificate issued on the basis of inspection conducted on 21-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Clearance certificates for Metformin and empagliflozin for commercial import are submitted imported for manufacturing of other products.	
	Decision	
	Approved	
167	Case Category	Routine (Farooq Aslam)
	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	(T3X-BRL-NE4E, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2024-07-19,
	The proposed proprietary name / brand name	**Glifzon-M**
	Label Claim	Each film coated tablet contains: Empagliflozin..... 12.5mg, Metformin HCl..... 850mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 Year(s)room temprature
	For generic drugs (me-too Status)	Diampa-M
	Pharmacotherapeutic Group of (API)	Antidiabetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NA
	Detail of stability batches of drug product	03 batches : 1000 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 certificates for Metformin and empagliflozin for commercial import are submitted imported for manufacturing of other products.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product i.e. Diampa-M tablet by M/s Getz Pharma.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Metformin: 06 months accelerated and 60 months real time stability data of 03 batches according to zone IV-A. Empagliflozin: 06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Empagliflozn/Metformin HCl tablet, manufactured by Boehringer Ingelheim Pharma, Germany
	GMP status of the firm	GMP Certificate issued on the basis of inspection conducted on 21-12-2023.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Clearance certificates for Metformin and empagliflozin for commercial import are submitted imported for manufacturing of other products.	
	Decision	

	Approved	
168	Case Category	Routine (Farooq Aslam)
	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	(3XW-TA4-W4PE, 2025-09-30)
	Detail of Fee Submitted	37000.0, 2025-06-16,
	The proposed proprietary name / brand name	**AZY-F Nasal Spray**
	Label Claim	Each spray contains: Azelastine Hydrochloride .....137 mcg Fluticasone Propionate .....50 mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	23g-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 20°C-25°C.
	For generic drugs (me-too Status)	Ticovate Plus Nasal Spray by M/s Saffron
	Pharmacotherapeutic Group of (API)	Decongestants and other nasal preparations for topical use corticosteroids/ fluticasone, combinations
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Aurisco Pharmaceutical Co. Ltd,Coral Drugs Private Limited
	Detail of stability batches of drug product	03 batches : 5litres 06 months accelerated and 06 months real time stability data.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 27-Sep-2024 specifies 20g import of Fluticasone Propionate & Clearance certificate dated 09-Oct-2024 specifies 25g of Azelastine Hydrochloride has been imported.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE study is conducted against Dymista Nasal Spray (Batch No.:IC30936, MFG Date: 08/2023, EXP Date:07/2025) manufactured by MEDA Pharma GmbH & Co. KG Germany.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Azelastine HCl: 06 months accelerated and 60 months real time stability data according to zone IV-A for 03 batches. Fluticasone propionate: 06 months accelerated and 60 months real time stability data according to zone IV-B for 03 batches.
	The status in reference regulatory authorities	USFDA
	GMP status of the firm	GMP Certificate issued on the basis of inspection dated 31.01.2025.
	Evidence of approval of manufacturing facility	Ear, Nose & Throat Section (General & Steroid) Solution/Suspension (EAR, DROPS/Nasal Spray) section is approved.
	Evaluation Remarks	
	Routine case.	
	Decision	
	Approved	
169	Case Category	Routine (Farooq Aslam)

	Name, address of Applicant.	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)**
	Application Form Dy. No / Tracking ID & date of submission	(ZBW-LL2-PYWS, 2024-11-05)
	Detail of Fee Submitted	37000.0, 2024-10-31,
	The proposed proprietary name / brand name	**CLOG 75mg Tablet**
	Label Claim	Each Film-Coated Tablet Contains: Clopidogrel (as Bisulfate) 75mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and protect from light
	For generic drugs (me-too Status)	Plavix 75mg Tablet
	Pharmacotherapeutic Group of (API)	antiplatelet medication
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	AARTI DRUGS LIMITED.
	Detail of stability batches of drug product	03 batches : 1500 tablets 06 months accelerated and 06 months real time stability data of 03 batches according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 13-10-2023 for 500grams material.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Plavix 75mg tablet by M/s Sanofi Winthrop industrie, France.
	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	Approved in EMA, HPRA, EMC, FDA regulatory authorities.
	GMP status of the firm	Tablet General Section is approved.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The firm has not submitted System suitability testing of AMV studies as described by USP monograph.	
	Decision	
	Deferred for submission of System suitability testing of AMV studies for drug substance and drug product as described by USP monograph.	
170	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(Z21-N9L-32VD, 2024-06-13)
	Detail of Fee Submitted	30000.0, 2023-12-15,
	The proposed proprietary name / brand name	**ITOSCOT OD TABLET 150 MG**
	Label Claim	Each extended-release tablet contains: Itopride hydrochloride 150mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	10s,20s,30s,7s,14s,2-As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 15-30°C at dry place.
	For generic drugs (me-too Status)	GANATON OD TABLET ABBOTT LABORATORIES
	Pharmacotherapeutic Group of (API)	Dopamine D2 antagonist and acetylcholinesterase inhibitor.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Ami Lifesciences Private Limited. Address: 2nd Floor, Prestige Plaza, 40, Urmi Society, Nr.Urmi Cross Road, BPC Road, Akota, Vadodara-390020, Gujarat, INDIA.
	Detail of stability batches of drug product	.
	Documents for the procurement of API with approval from DRAP (in case of Import)	.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	.
	The status in reference regulatory authorities	GANATON OD TABLET MANUFACTURED BY ABBOTT
	GMP status of the firm	Last inspection report for renewal of DML dated 22-02-2024 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	The RRA reference for the applied product could not be confirmed from any reference regulatory authority. The firm has submitted a research article in support. https://www.kobayashi.co.jp/newsrelease/2022/otc_1/	
	Irakuna" is the first product in Japan to switch to OTC for the medical ingredient "Itoprid Hydrochloride," used to treat decreased gastric motility, marking the first time in 12 years that a new ingredient has switched to OTC in the gastrointestinal medicine market.	
	The same could not be confirmed from official website of PMDA Japan.	
	Decision	
	Deferred for evidence of approval of the applied product in reference regulatory authorities as determined by Registration Board in its 275th meeting.	
171	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	(LTQ-T4P-5H9R, 2024-07-10)
	Detail of Fee Submitted	30000.0, 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 (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.	
	The case was deferred in 360th meeting for submission of employment details of analyst mention in the submitted chromatograms.	
	With reference to the minutes of Meeting of the Registration Board, it is hereby clarified that the technical staff list submitted during the inquiry Paroxetine tablet represented the technical staff currently engaged in the Production, Quality Control, and R&D departments. It is further clarified that Ms. Faiqa Ashfaq, the analyst who performed the testing of Paroxetine tablet during her tenure in 2024, remained employed with Solaris Life Sciences from 18 August 2023 to 13 March 2024. Accordingly, she was a duly authorized Quality Control Analyst for the testing of the above-mentioned products she analyzed. Furthermore, Ms. Faiqa Ashfaq was also present during the Drug Manufacturing License (DML) inspection conducted by DRAP. Her name appears in the technical staff list submitted during the DML inspection and can be verified from the DML Inspection Report duly signed by the DRAP inspection officials. Complete employment record of Ms. Faiqa Ashfaq and copy of the DML Inspection Report is submitted herewith for your kind consideration and verification.	
	It is submitted for the information of the Registration Board that Ms. Faiqa Ashfaq resigned from M/s Solaris Pharma with immediate effect on 14.03.2024 and was issued an experience certificate covering the period from 18.08.2023 to 13.03.2024. However, the submitted stability data indicate that the 3rd-month testing of the applied product was performed on 17.05.2024 under the name of the same analyst, despite her resignation more than two months earlier. This discrepancy raises concerns regarding the authenticity and integrity of the submitted data.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
172	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, 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 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.

The case was deferred in 360th meeting for submission of employment details of analyst mention in the submitted chromatograms.
With reference to the minutes of Meeting of the Registration Board, it is hereby clarified that the technical staff list submitted during the inquiry Paroxetine tablet represented the technical staff currently engaged in the Production, Quality Control, and R&D departments. It is further clarified that Ms. Faiqa Ashfaq, the analyst who performed the testing of Paroxetine tablet during her tenure in 2024, remained employed with Solaris Life Sciences from 18 August 2023 to 13 March 2024. Accordingly, she was a duly authorized Quality Control Analyst for the testing of the above-mentioned products she analyzed. Furthermore, Ms. Faiqa Ashfaq was also present during the Drug Manufacturing License (DML) inspection conducted by DRAP. Her name appears in the technical staff list submitted during the DML inspection and can be verified from the DML Inspection Report duly signed by the DRAP inspection officials. Complete employment record of Ms. Faiqa Ashfaq and copy of the DML Inspection Report is submitted herewith for your kind consideration and verification.

	It is submitted for the information of the Registration Board that Ms. Faiqa Ashfaq resigned from M/s Solaris Pharma with immediate effect on 14.03.2024 and was issued an experience certificate covering the period from 18.08.2023 to 13.03.2024. However, the submitted stability data indicate that the 3rd-month testing of the applied product was performed on 19.05.2024 under the name of the same analyst, despite her resignation more than two months earlier. This discrepancy raises concerns regarding the authenticity and integrity of the submitted data.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
173	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, 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 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 360th meeting. The submitted real time stability data is at 25oC and accelerated stability data is at 40oC whereas the innovator has mentioned the storage conditions as -20oC which reflects that the real time stability studies should have been performed at -20oC.	
	The firm has submitted declaration from drug substance manufacturer. The firm has stated that theyare manufacturing proprietary novel polymorphic form SB. The crystal structure is different fromthe innovator; it is not required to adopt the same storage conditions. 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 firm has referred USFDA's document "Guidance for Industry: ANDAs: Pharmaceutical Solid Polymorphism", polymorphic forms of drug substance differ in internal solid state structure but not in chemical structure. Each ANDA applicant is required to demonstrate that, among ither things, the drug product exhibits sufficient stability and is bioequivalent to RLD. While the polymorphic form can affect drug product stability and bioequivalence, these performance characteristics are also dependent on formulation, the manufacturing process and other physiological properties of both drug substance and formulation excipients. Moreover, according to the same document, using a drug substance polymorphic form that is different from that of RLD may not preclude an ANDA applicant from formulating a generic drug product that exhibits bioequivalence and stability and the drug substance in the generic drug product need not have the polymorphic form as the drug substance in the RLD.	
	The firm has submitted CoPP No. TF2k-36x9 valid till 11-07-2027 issued by USFDA according to which the applied product is available in free sale in US.	
	Decision	
	Approved The Board deliberated polymorphic form is different in internal solid state structure and the chemical structure is same. Therefore, a different polymorphic form from innovator's/reference drug product, can used for formulating a generic drug product as described by USFDA. The Board accepted the justification submitted by the applicant and decided to approve the product subject to import policy for inspection of manufacturer abroad.	
174	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Zeta Pharmaceuticals** 494-A Sundar Industrial Estate Lahore **(000818)**
	Application Form Dy. No / Tracking ID & date of submission	(NTM-3TW-JURE, 2025-01-13)

	Detail of Fee Submitted	30000.0, 2023-11-15,
	The proposed proprietary name / brand name	**Gabipro 150mg Capsule**
	Label Claim	Each Capsule contains pregabalin.....150mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1*14-As per SRO
	Shelf Life (Unit)	2 Year(s)Ambient
	For generic drugs (me-too Status)	Zeegab Cap by Hilton
	Pharmacotherapeutic Group of (API)	Anticonvulsant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life Science 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	Lyrica Cap, USFDA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-06-2022.
	Evidence of approval of manufacturing facility	Capsule General Section is approved as per submitted GMP certificate.
	Evaluation Remarks	
	Stability summary sheets were not submitted initially with the application. The query was generated and application was sent back to applicant. The applicant submitted the stability summary sheets along with the chromatograms on 10-01-2026.	
	Remarks: The Chromatograms of standard runs (in the initially submitted module III and stability data of drug product submitted on 10-01-2026) dated 19-04-2023, 19-07-2023, 19-10-2023 have exactly the same values of RT, area & height, and the date acquired has been changed in chromatograms. Squiggly red line appearing under different chromatograms of stability of drug product which submitted initially that the chromatograms are made up in Microsoft word. Header of HPLC software (lab solution, shimadzu, empower etc) is also missing.	
	Decision	
	Rejected The Board discussed the evaluator remarks and decided to reject the application on following grounds:- 1. The Chromatograms of standard runs (in the initially submitted module III and stability data of drug product submitted on 10-01-2026) dated 19-04-2023, 19-07-2023, 19-10-2023 have exactly the same values of RT, area & height, and the date acquired has been changed in chromatograms. 2. Squiggly red line appearing under different chromatograms of stability of drug product which submitted initially that the chromatograms are made up in Microsoft word. 3. Header of HPLC software (lab solution, shimadzu, empower etc) is also missing.	
175	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Zeta Pharmaceuticals** 494-A Sundar Industrial Estate Lahore **(000818)**

	Application Form Dy. No / Tracking ID & date of submission	(VXQ-DMN-7V1N, 2025-01-13)
	Detail of Fee Submitted	30000.0, 2023-11-15,
	The proposed proprietary name / brand name	**Gabipro 300mg Capsule**
	Label Claim	Each Capsule Contains 300 mg Pregabalin
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1*30-As per SRO
	Shelf Life (Unit)	2 YearAmbient
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CTX Life Science 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	Available
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted the chromatograms at 0, 3 and 6 month time point having exactly the same values for standard runs for RT, height and area as submitted for 150mg capsule.	
	Decision	
	Rejected he Board discussed the evaluator remarks and decided to reject the application as the firm has submitted the chromatograms at 0, 3 and 6 month time point having exactly the same values for standard runs for RT, height and area as submitted for 150mg capsule.	
176	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Zeta Pharmaceuticals** 494-A Sundar Industrial Estate Lahore **(000818)**
	Application Form Dy. No / Tracking ID & date of submission	(LHZ-1P2-PP8A, 2025-01-13)
	Detail of Fee Submitted	30000.0, 2023-11-15,
	The proposed proprietary name / brand name	**Deslozet 10mg Tablet**
	Label Claim	10mg Tablet of desloratadine
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10-As per SRO
	Shelf Life (Unit)	2 YearAmbient
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Tagoor Laboratories PVT LTD INDIA
	Detail of stability batches of drug product	

	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Available
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

Evaluation Remarks

Text cursor is visible in submitted chromatograms of standard and sample run submitted in the initial dossier confirming the file was created using Microsoft word.
Squiggly red line appearing under different chromatograms of stability of drug product submitted on 10-01-2025 indicating that the chromatograms are made up in Microsoft word.
In chromatograms acquired on 17-04-2023 (submitted on 10-01-2025), table move pointer can be seen which is used for copying a tablet in Microsoft word document.
Header of HPLC software (lab solution, shimadzu, empower etc) is also missing.

Decision

Rejected

The Board discussed the evaluator remarks and decided to reject the application on following grounds:-

1. Text cursor is visible in submitted chromatograms of standard and sample run submitted in the initial dossier confirming the file was created using Microsoft word.

2. Squiggly red line appearing under different chromatograms of stability of drug product submitted on 10-01-2025 indicating that the chromatograms are made up in Microsoft word.

3. In chromatograms acquired on 17-04-2023 (submitted on 10-01-2025), table move pointer can be seen which is used for copying a tablet in Microsoft word document.

4. Header of HPLC software (lab solution, shimadzu, empower etc) is also missing.

177	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, 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.
	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.	
	The case was deferred in 360th meeting for submission of stability data of commercial batches. The firm has submitted a declaration from the manufacturer that the commercial batch size of the applied product is 3000 vials and the validation batch size is also 3000 vials.	
	Decision	
	Approved as per import policy for inspection of manufacturer abroad.	
178	Case Category	Routine (Farooq Aslam)

	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(5ZD-GWE-AYU1, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	**BRAINZON INJECTION IM**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	EL-CEF INJECTION IM BY LINEAR PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T05, T06 (Batch size: 5000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 1g Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. 5ZD-GWE-AYU1 and ID No. BRW-QRV-BSN9 for Ceftriaxone for Injection 1g IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T05 and T06 (batch size 5000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
179	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(BRW-QRV-BSN9, 2024-06-24)

	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	**BRAINZON INJECTION IV**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 1000mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Antrix Injection by Fynk Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T05, T06 (Batch size: 5,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 1g Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. 5ZD-GWE-AYU1 and ID No. BRW-QRV-BSN9 for Ceftriaxone for Injection 1g IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T05 and T06 (batch size 5000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
180	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(PRB-H1T-9MAA, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	**BRAINZON INJECTION IV**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 250mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Antrix Injection by Fynk Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T01, T02 (Batch size: 10,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 250mg Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. 2LL-M7T-DMS4 and ID No. PRB-H1T-9MAA for Ceftriaxone for Injection 1g IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T03 and T04 (batch size 5000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
181	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(HQY-J3Z-5LRY, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-22,
	The proposed proprietary name / brand name	**Brainzone 1gm Injection IV**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 1000mg
	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)	Antrix Injection by Fynk Pharma

	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	Batches: T05, T06 (Batch size: 5,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 1g Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. SDH-373-MZNE and ID No. HQY-J3Z-5LRY for Ceftriaxone for Injection 1g IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T05 and T06 (batch size 5000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
182	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(SDH-373-MZNE, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-22,
	The proposed proprietary name / brand name	**Brainzone 1gm Injection IM**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 1000mg
	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)	EL-CEF INJECTION IM by Linear Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd.,

	Detail of stability batches of drug product	Batches: T05, T06 (Batch size: 5000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 1g Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. SDH-373-MZNE and ID No. HQY-J3Z-5LRY for Ceftriaxone for Injection 1g IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T05 and T06 (batch size 5000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
183	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(YX6-JJ9-EXAJ, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-22,
	The proposed proprietary name / brand name	**Brainzone 500mg Injection IV**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Antrix Injection by Fynk Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T03, T04 (Batch size: 5,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.

	Documents for the procurement of API with approval from DRAP (in case of Import)	.Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 500mg Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. 1X7-PWG-9DHX and ID No. YX6-JJ9-EXAJ for Ceftriaxone for Injection 500mg IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T03 and T04 (batch size 5,000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
184	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(1X7-PWG-9DHX, 2024-06-25)
	Detail of Fee Submitted	75000.0, 2024-06-22,
	The proposed proprietary name / brand name	**Brainzone 500mg Injection IM**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	EL-CEF INJECTION IM by Linear Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	Batches: T03, T04 (Batch size: 5,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 500mg Injection by M/s Sami Pharmaceuticals.

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. 1X7-PWG-9DHX and ID No. YX6-JJ9-EXAJ for Ceftriaxone for Injection 500mg IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T03 and T04 (batch size 5,000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
185	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(T1V-4P9-A3TV, 2024-06-25)
	Detail of Fee Submitted	75000.0, 2024-06-22,
	The proposed proprietary name / brand name	**Brainzone 250mg Injection IV**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Antrix Injection by Fynk Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T01, T02 (Batch size: 10,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	.Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 250mg Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. GYA-R2M-6Z95 and ID No. T1V-4P9-A3TV for Ceftriaxone for Injection 250mg IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T01 and T02 for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
186	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(2LL-M7T-DMS4, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	**BRAINZON INJECTION IM**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	EL-CEF INJECTION IM BY LINEAR PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T01, T02 (Batch size: 10,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 250mg Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.

	Evaluation Remarks	
	The firm has submitted application ID No. 2LL-M7T-DMS4 and ID No. PRB-H1T-9MAA for Ceftriaxone for Injection 1g IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T03 and T04 (batch size 5000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
187	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(NHB-W5N-M1WR, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	**BRAINZON INJECTION IV**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) .....500mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	Antrix Injection by Fynk Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T03, T04 (Batch size: 10,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 500mg Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. BE3-1X7-946A and ID No. NHB-W5N-M1WR for Ceftriaxone for Injection 1g IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	

	The firm has submitted stability data of 02 batches i.e. T01 and T02 (batch size 10,000 vials each) for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
188	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(BE3-1X7-946A, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-21,
	The proposed proprietary name / brand name	**BRAINZON INJECTION IM**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25c
	For generic drugs (me-too Status)	EL-CEF INJECTION IM BY LINEAR PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase II, Industrial Area, Hattar.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Batches: T03, T04 (Batch size: 10,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 500mg Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. BE3-1X7-946A and ID No. NHB-W5N-M1WR for Ceftriaxone for Injection 250mg IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T01 and T02 (batch size 10,000 vials each) for both applications.	

	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	
	Decision	
	Approved	
189	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(GYA-R2M-6Z95, 2024-06-24)
	Detail of Fee Submitted	75000.0, 2024-06-22,
	The proposed proprietary name / brand name	**Brainzone 250mg Injection IM**
	Label Claim	Each Vial Contains: Ceftriaxone as Sodium (USP) 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 25°c
	For generic drugs (me-too Status)	EL-CEF INJECTION IM by Linear Pharma
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Weather Folds Pharmaceuticals-Plot No. 69/2, Phase-II, Industrial Estate, Hattar, KPK-
	Name & address of API manufacturer	Sinopharm Weiqida Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	Batches: T01, T02 (Batch size: 10,000 vials) 06 months real time and 06 months accelerated stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 06-04-2023 is submitted (weather folds)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Oxidil 250mg Injection by M/s Sami Pharmaceuticals.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	36 months real time and 06 months accelerated stability data is submitted according to zone IV-A for 03 batches.
	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	Dry Powder Injection (Cephalosporin) is approved.
	Evaluation Remarks	
	The firm has submitted application ID No. GYA-R2M-6Z95 and ID No. T1V-4P9-A3TV for Ceftriaxone for Injection 250mg IM and IV respectively. Diluent for reconstitution for IV injection is WFI and for IM injection, it is Lidocaine.	
	The firm has submitted stability data of 02 batches i.e. T01 and T02 for both applications.	
	The firm has performed compatibility/in use stability studies with each diluent i.e WFI and Lidocaine separately for both of the batches at 0, 3 and 6 month time points and submitted the test results at initial, after 8 hours and 24 hours (storage conditions: 2-8oC).	
	Same USP monograph is applicable to IM and IV Ceftriaxone for Injection.	

	Decision	
	Approved	
190	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(G27-GDQ-XS7S, 2026-04-20)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**Ontozy Tablet 100mg**
	Label Claim	Each Film Coated Tablet contains Cenobamate.....100mg. Finished Product Specification: Innovators Specification.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1 x 10's)-De-Controlled,14's (2 x 7's)-De-Controlled,20's (2 x 10's)-De-Controlled,21's (3 x 7's)-De-Controlled,28's (4 x 7's)-De-Controlled,30's (3 x 10's)-De-Controlled,7's (1 x 7's)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Coprex tablet 100mg manufactured by Nabiqasim Industries (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Cenobamate: Anticonvulsants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jinan Gaohua Pharmaceuticals Co.,Ltd No.8 Panwang road, Mingshui Economic Development Zone, Zhanqiu City, Shandong Province, China
	Detail of stability batches of drug product	Stability data conducted on 3 batches(238 DS01, 238 DS02, 238 DS03) (6 Month Accelerated 40C + 2C and 75% RH + 5% and 6 Month Long Term 30C + 2C and 75% RH + 5%) Batch size: 4500 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 22-05-2025 for 6kg material is submitted. Unattested invoice No. H007-2503017 dated 13-05-2025 is submitted along with airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been conducted against Xcopri Tablet 100 manufactured by Endo Ventures Ltd, Dublin, Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long Term:36 Months 30 ± 2°C , Humidity: 65 ± 5%, Accelerated_6 Months40 ± 2°C , Humidity: 75 ± 5%. Batches. 210218, 210224 ,210228
	The status in reference regulatory authorities	USFDA Approved detailed provided in Module 1 Section 1.5.9
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-08-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Under export facilitation vide General Request TID G5M-SJ6-P41X	

	The firm has submitted Risk Management plan and copy of email to pv@dra.gov.pk confirming the nomination of PV officer.	
	Decision	
	Approved	
191	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(WDJ-A83-EYS4, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**Ontozy Tablet 12.5mg**
	Label Claim	Each tablet contains Cenobamate.....12.5mg. Finished Product Specification: Innovators Specification.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1 x 10's)-De-Controlled,14's (2 x 7's)-De-Controlled,20's (2 x 10's)-De-Controlled,21's (3 x 7's)-De-Controlled,28's (4 x 7's)-De-Controlled,30's (3 x 10's)-De-Controlled,7's (1 x 7's)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Coprex tablet 12.5mg manufactured by Nabiqasim Industries (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Cenobamate: Anticonvulsants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jinan Gaohua Pharmaceuticals Co.,Ltd No.8 Panwang road, Mingshui Economic Development Zone, Zhanqiu City, Shandong Province, China
	Detail of stability batches of drug product	Stability data conducted on 3 batches(235 DS01, 235 DS02, 235 DS03) (6 Month Accelerated 40C + 2C and 75% RH + 5% and 6 Month Long Term 30C + 2C and 75% RH + 5%)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 22-05-2025 for 6kg material is submitted. Unattested invoice No. H007-2503017 dated 13-05-2025 is submitted along with airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been conducted against Xcopri Tablet 12.5 manufactured by Endo Ventures Ltd, Dublin, Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long Term:36 Months, Accelerated_6 Months. Batches. 210218, 210224 ,210228
	The status in reference regulatory authorities	USFDA Approved 9
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-08-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Under export facilitation vide General Request TID G5M-SJ6-P41X	
	The firm has submitted Risk Management plan and copy of email to pv@dra.gov.pk confirming the nomination of PV officer.	

	Decision	
	Approved	
192	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(NVM-HPS-PWA3, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**Ontozy Tablet 25mg**
	Label Claim	Each Film Coated Tablet contains Cenobamate.....25mg. Finished Product Specification: Innovators Specification.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1 x 10's)-De-Controlled,14's (2x 7's)-De-Controlled,20's (2 x 10's)-De-Controlled,21's (3 x 7's)-De-Controlled,28's (4 x 7's)-De-Controlled,30's (3 x 10's)-De-Controlled,7's (1 x 7's)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Coprex Tablet 25mg manufactured by Nabiqasim Industries (Pvt). Ltd
	Pharmacotherapeutic Group of (API)	Cenobamate: Anticonvulsants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jinan Gaohua Pharmaceuticals Co.,Ltd No.8 Panwang road, Mingshui Economic Development Zone, Zhanqiu City, Shandong Province, China
	Detail of stability batches of drug product	Stability data conducted on 3 batches(236 DS01, 236 DS02, 236 DS03) (6 Month Accelerated 40C + 2C and 75% RH + 5% and 6 Month Long Term 30C + 2C and 75% RH + 5%)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 22-05-2025 for 6kg material is submitted. Unattested invoice No. H007-2503017 dated 13-05-2025 is submitted along with airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been conducted against Xcopri Tablet 25 manufactured by Endo Ventures Ltd, Dublin, Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long Term:36 Months 30 ± 2°C , Humidity: 65 ± 5%, Accelerated_6 Months 40 ± 2°C , Humidity: 75 ± 5%. Batches. 210218, 210224 ,210228
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-08-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Under export facilitation vide General Request TID G5M-SJ6-P41X	
	The firm has submitted Risk Management plan and copy of email to pv@dra.gov.pk confirming the nomination of PV officer.	
	Decision	

	Approved	
193	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(9TS-REG-GWNW, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**Ontozy Tablet 50mg**
	Label Claim	Each Film Coated Tablet contains Cenobamate.....50mg. Finished Product Specification: Innovators Specification.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1 x 10's)-De-Controlled,14's (2x 7's)-De-Controlled,20's (2 x 10's)-De-Controlled,21's (3x 7's)-De-Controlled,28's (4 x 7's)-De-Controlled,30's (3 x 10's)-De-Controlled,7's (1 x 7's)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Coprex tablet 50mg manufactured by Nabiqasim Industries (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Cenobamate: Anticonvulsants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jinan Gaohua Pharmaceuticals Co.,Ltd No.8 Panwang road, Mingshui Economic Development Zone, Zhanqiu City, Shandong Province, China
	Detail of stability batches of drug product	Stability data conducted on 3 batches(237 DS01, 237 DS02, 237 DS03) (6 Month Accelerated 40C + 2C and 75% RH + 5% and 6 Month Long Term 30C + 2C and 75% RH + 5%)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 22-05-2025 for 6kg material is submitted. Unattested invoice No. H007-2503017 dated 13-05-2025 is submitted along with airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been conducted against Xcopri Tablet 50 manufactured by Endo Ventures Ltd, Dublin, Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long Term:36 Months30 ± 2°C , Humidity: 65 ± 5%, Accelerated_6 Months40 ± 2°C , Humidity: 75 ± 5%. Batches. 210218, 210224 ,210228
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-08-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Under export facilitation vide General Request TID G5M-SJ6-P41X	
	The firm has submitted Risk Management plan and copy of email to pv@dra.gov.pk confirming the nomination of PV officer.	
	Decision	

	Approved	
194	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(6DX-DS7-RG42, 2026-04-20)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**Ontozy Tablet 200mg**
	Label Claim	Each Film Coated Tablet contains Cenobamate.....200mg. Finished Product Specification: Innovators Specification.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's (1 x 10's)-De-Controlled,14's (2 x 7's)-De-Controlled,20's (2 x 10's)-De-Controlled,21's (3 x 7's)-De-Controlled,28's (4 x 7's)-De-Controlled,30's (3 x 10's)-De-Controlled,7's (1 x 7's)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Coprex tablet 200mg manufactured by Nabiqasim Industries (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Cenobamate: Anticonvulsants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jinan Gaohua Pharmaceuticals Co.,Ltd No.8 Panwang road, Mingshui Economic Development Zone, Zhanqiu City, Shandong Province, China
	Detail of stability batches of drug product	Stability data conducted on 3 batches(240 DS01, 240 DS02, 240 DS03) (6 Month Accelerated 40C + 2C and 75% RH + 5% and 6 Month Long Term 30C + 2C and 75% RH + 5%)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 22-05-2025 for 6kg material is submitted. Unattested invoice No. H007-2503017 dated 13-05-2025 is submitted along with airway bill.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been conducted against Xcopri Tablet 200 manufactured by Endo Ventures Ltd, Dublin, Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long Term:36 Months 30 ± 2°C , Humidity: 65 ± 5%, Accelerated_6 Months40 ± 2°C , Humidity: 75 ± 5%. Batches. 210218, 210224 ,210228
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-08-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Under export facilitation vide General Request TID G5M-SJ6-P41X	
	The firm has submitted Risk Management plan and copy of email to pv@dra.gov.pk confirming the nomination of PV officer.	
	Decision	

	Approved	
195	Case Category	Routine (Farooq Aslam)
	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	(XP4-44B-295U, 2024-08-05)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**LESNOP 5mg TABLET**
	Label Claim	Each Uncoated Tablet contains: Lisinopril as Dihydrate (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 Year20-25C
	For generic drugs (me-too Status)	Lis-BP 5mg Tablets by Akson Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The product has already been approved in 343rd meeting on form 5F vide application No. Dy.No 27480 dated 23-11-2023. The firm shall submit:	
	Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufactruer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products	
	Applicable fee for changing the status of already approved data.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
196	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Weather Folds Pharmaceuticals** Plot no. 69/2, Phase II, Industrial Area, Hattar, Pakistan. **(000644)**
	Application Form Dy. No / Tracking ID & date of submission	(5G6-N32-S8XB, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Lisnop 5mg Tablet**

	Label Claim	Each Uncoated Tablet contains: Lisinopril as Dihydrate (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 YearStore below 25°c
	For generic drugs (me-too Status)	Lis-BP 5mg Tablets by Akson Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	
	Evaluation Remarks	
	The product has already been approved in 343rd meeting on form 5F vide application No. Dy.No 27480 dated 23-11-2023. The firm shall submit Applicable fee for changing the status of already approved data.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
197	Case Category	Routine (Farooq Aslam)
	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	(61A-S95-6J6M, 2024-11-23)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Preaed 75mg Capsule**
	Label Claim	Each Capsule contains: Pregabalin.....75mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Gablin capsule 75mg by CCL Ltd (050257)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-
	Name & address of API manufacturer	AXIS PHARMA CHEM., PLOT NO. CI/3916 NR CRYSTAL CHOWKDI SOUTH 8 ROAD GIDC ANKLESHWAR - 393002 BAHARUCH GUJARAT INDIA.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP	

	(in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Pregabalin Milpharm 75mg capsules by Milpharm Limited Ares Block, Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom approved by EMA/MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted similar chromatograms of 5 standard runs at 0 month time point by changing the name of sample set and acq. Method set (strength of pregabalin) in all the 04 strengths for one batch. The same pattern is repeated for 3rd month time point testing. (Different standards runs for dissolution and assay at one time point).	
	In dissolution testing at 0 month time point for standard run, all the parameters are same except acq. Method set name (strength of pregabalin) for all the 04 strengths and sample set name in 03 strengths.	
	Some of the values of Area were observed to be exactly the same in different runs of standard	
	Moreover, the HPLC system is not 21 CFR compliant.	
	Decision	
	Rejected The matter was placed before the Registration Board. The Board observed that the firm had submitted identical chromatograms of five standard runs at the 0-month time point by merely changing the sample set and acquisition method set names across all four strengths of pregabalin. The same pattern was repeated at the 3-month time point. Furthermore, in dissolution testing at the 0-month time point, the parameters remained identical except for changes in the acquisition method set name and sample set names. In view of these discrepancies, which raise serious concerns regarding the authenticity and integrity of the submitted data, the Board decided to reject the case.	
198	Case Category	Routine (Farooq Aslam)
	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	(T5W-G1D-88ZS, 2024-11-23)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Preaed 50mg Capsule**
	Label Claim	Each Capsule contains: Pregabalin.....50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Gablin capsule 50mg by CCL Ltd (078854)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-
	Name & address of API manufacturer	AXIS PHARMA CHEM., PLOT NO. CI/3916 NR CRYSTAL CHOWKDI SOUTH 8 ROAD

		GIDC ANKLESHWAR - 393002 BAHARUCH GUJARAT INDIA.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Pregabalin Milpharm 50mg capsules by Milpharm Limited Ares Block, Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom approved by EMA/MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has submitted similar chromatograms of 5 standard runs at 0 month time point by changing the name of sample set and acq. Method set (strength of pregabalin) in all the 04 strengths for one batch. The same pattern is repeated for 3rd month time point testing. (Different standards runs for dissolution and assay at one time point).	
	In dissolution testing at 0 month time point for standard run, all the parameters are same except acq. Method set name (strength of pregabalin) for all the 04 strengths and sample set name in 03 strengths.	
	Some of the values of Area were observed to be exactly the same in different runs of standard	
	Moreover, the HPLC system is not 21 CFR compliant.	
	Decision	
	Rejected The matter was placed before the Registration Board. The Board observed that the firm had submitted identical chromatograms of five standard runs at the 0-month time point by merely changing the sample set and acquisition method set names across all four strengths of pregabalin. The same pattern was repeated at the 3-month time point. Furthermore, in dissolution testing at the 0-month time point, the parameters remained identical except for changes in the acquisition method set name and sample set names. In view of these discrepancies, which raise serious concerns regarding the authenticity and integrity of the submitted data, the Board decided to reject the case.	
199	Case Category	Routine (Farooq Aslam)
	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	(AVR-T7N-B2YL, 2024-11-23)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Preaed 25mg Capsule**
	Label Claim	Each Capsule contains: Pregabalin.....25mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Gablin capsule 25mg by CCL Ltd (078853)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-
	Name & address of API manufacturer	AXIS PHARMA CHEM., PLOT NO. CI/3916 NR CRYSTAL CHOWKDI SOUTH 8 ROAD GIDC ANKLESHWAR - 393002 BAHARUCH GUJARAT INDIA.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Pregabalin Milpharm 25mg capsules by Milpharm Limited Ares Block, Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom approved by EMA/MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

Evaluation Remarks

The firm has submitted similar chromatograms of 5 standard runs at 0 month time point by changing the name of sample set and acq. Method set (strength of pregabalin) in all the 04 strengths for one batch. The same pattern is repeated for 3rd month time point testing. (Different standards runs for dissolution and assay at one time point).
In dissolution testing at 0 month time point for standard run, all the parameters are same except acq. Method set name (strength of pregabalin) for all the 04 strengths and sample set name in 03 strengths.
Some of the values of Area were observed to be exactly the same in different runs of standard
Moreover, the HPLC system is not 21 CFR compliant.

Decision

Rejected

The matter was placed before the Registration Board. The Board observed that the firm had submitted identical chromatograms of five standard runs at the 0-month time point by merely changing the sample set and acquisition method set names across all four strengths of pregabalin. The same pattern was repeated at the 3-month time point. Furthermore, in dissolution testing at the 0-month time point, the parameters remained identical except for changes in the acquisition method set name and sample set names.

In view of these discrepancies, which raise serious concerns regarding the authenticity and integrity of the submitted data, the Board decided to reject the case.

200	Case Category	Routine (Farooq Aslam)
	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	(WWD-LEW-777M, 2024-11-23)
	Detail of Fee Submitted	93000.0, 2024-10-31,
	The proposed proprietary name / brand name	**Preaed 100mg Capsule**
	Label Claim	Each Capsule contains: Pregabalin.....100mg

	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Gablin capsule 100mg by CCL Ltd (078855)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A-159, S.I.T.E. Super Highway, Karachi-Pakistan-
	Name & address of API manufacturer	AXIS PHARMA CHEM., PLOT NO. CI/3916 NR CRYSTAL CHOWKDI SOUTH 8 ROAD GIDC ANKLESHWAR - 393002 BAHARUCH GUJARAT INDIA.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Pregabalin Milpharm 100mg capsules by Milpharm Limited Ares Block, Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom approved by EMA/MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	

Evaluation Remarks

The firm has submitted similar chromatograms of 5 standard runs at 0 month time point by changing the name of sample set and acq. Method set (strength of pregabalin) in all the 04 strengths for one batch. The same pattern is repeated for 3rd month time point testing. (Different standards runs for dissolution and assay at one time point).
In dissolution testing at 0 month time point for standard run, all the parameters are same except acq. Method set name (strength of pregabalin) for all the 04 strengths and sample set name in 03 strengths.
Some of the values of Area were observed to be exactly the same in different runs of standard
Moreover, the HPLC system is not 21 CFR compliant.

Decision

Rejected

The matter was placed before the Registration Board. The Board observed that the firm had submitted identical chromatograms of five standard runs at the 0-month time point by merely changing the sample set and acquisition method set names across all four strengths of pregabalin. The same pattern was repeated at the 3-month time point. Furthermore, in dissolution testing at the 0-month time point, the parameters remained identical except for changes in the acquisition method set name and sample set names.

In view of these discrepancies, which raise serious concerns regarding the authenticity and integrity of the submitted data, the Board decided to reject the case.

201	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)**
	Application Form Dy. No / Tracking ID & date of submission	(LVJ-N1T-BMGZ, 2024-12-02)

	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**SOPRAL 5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Bisoprolol Fumarate 5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and protect from light
	For generic drugs (me-too Status)	Concor 5mg Tablet
	Pharmacotherapeutic Group of (API)	Antihypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sichuan Qingmu Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	03 batches : 1500 tablets 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Unattested invoice dated 11-10-2023 (0.1kg), Packing list, FeDex receipt. Form 6 dated 15-09-2023 for .1kg material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the comparator's product i.e Concor by N/s MardinDow.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to 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 28-02-2024.
	Evidence of approval of manufacturing facility	Tablet general Section is approved
	Evaluation Remarks	
	GD No. LPAF-4579-21102023 Date: 21-10-2023 is submitted.	
	Decision	
	Approved	
202	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**QADIR PHARMACEUTICALS** FATEH GHAR SAHUWALA ROAD SIALKOT **(000944)**
	Application Form Dy. No / Tracking ID & date of submission	(E94-EEG-181X, 2024-12-02)
	Detail of Fee Submitted	37000.0, 2024-11-08,
	The proposed proprietary name / brand name	**SOPRAL 10mg Tablet**
	Label Claim	Each film-coated Tablets Contains: Bisoprolol Fumarate 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2x7's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C and protect from light
	For generic drugs (me-too Status)	Concor 10mg Tablet
	Pharmacotherapeutic Group of (API)	Anti hypertensive
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sichuan Qingmu Pharmaceutical Co., Ltd.

	Detail of stability batches of drug product	03 batches : 1500 tablets 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Unattested invoice dated 11-10-2023 (0.1kg), Packing list, FeDex receipt.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been submitted against the comparator's product i.e Concor by N/s MardinDow.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 48 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Approved in EMA, HPRA, EMC, FDA regulatory authorities.
	GMP status of the firm	....
	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Unattested invoice dated 11-10-2023 (0.1kg), Packing list, FeDex receipt. (GD No. LPAF-4579-21102023 Date: 21-10-2023). Form 6 dated 15-09-2023 for 0.1kg material. GMP certificate issued on the basis of inspection conducted on 28-02-2024.	
	Decision	
	Approved	
203	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Next Pharmaceutical Products (Pvt.) Ltd** Plot # 44 A & B, Sunder Industrial Estate Raiwind Road Lahore **(000847)**
	Application Form Dy. No / Tracking ID & date of submission	(9RZ-B9B-2VPL, 2024-07-31)
	Detail of Fee Submitted	30000.0, 2024-07-23,
	The proposed proprietary name / brand name	**Mirabegron 25mg Tablets**
	Label Claim	Each film coated extended release tablet contains: Mirabegron.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	selective agonist for human beta 3-adrenoceptor/Urogynecology
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Huadong Medicine Group Zhejiang Huayi Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	03 batches : Batch size 1000 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 11-04-2023 for 1kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product Mibega 25mg tablet by

		M/s GetzPharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 29-05-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved
	Evaluation Remarks	
	Initially, the firm had included the results dissolution testing at 12 month time point, upon clarification the firm has submitted complete dissolution testing at all the timepoints (2, 4, 12hrs).	
	Decision	
	Approved	
204	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Next Pharmaceutical Products (Pvt.) Ltd** Plot # 44 A & B, Sunder Industrial Estate Raiwind Road Lahore **(000847)**
	Application Form Dy. No / Tracking ID & date of submission	(QM7-ESS-UPXB, 2024-11-12)
	Detail of Fee Submitted	30000.0, 7000.0 2024-07-23, 2024-10-22
	The proposed proprietary name / brand name	**Mirabegron 50mg Tablets**
	Label Claim	Each film coated extended release tablet contains: Mirabegron.....50mg
	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 and Protect from light and moisture.
	For generic drugs (me-too Status)	available
	Pharmacotherapeutic Group of (API)	selective agonist for human beta 3-adrenoceptor/Urogynecology
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Hangzhou Huadong Medicine Group Zhejiang Huayi Pharmaceutical Co., Ltd.,
	Detail of stability batches of drug product	03 batches : Batch size 1000 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 11-04-2023 for 1kg material is submitted,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the comparator's product Mibega 50mg tablet by M/s GetzPharma
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 29-05-2024.
	Evidence of approval of manufacturing facility	Tablet General section is approved
	Evaluation Remarks	

	Initially, the firm had included the results dissolution testing at 12hr time point, upon clarification the firm has submitted complete dissolution testing at all the timepoints (2, 4, 12hrs).	
	Decision	
	Approved	
205	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(PWH-ZS1-4X7P, 2025-01-23)
	Detail of Fee Submitted	75000.0, 2024-11-16,
	The proposed proprietary name / brand name	**Varin 1mg tablet**
	Label Claim	Each film coated tablet contains: Varenicline as tartrate.....1mg
	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)	Varipuf tablet by Genix
	Pharmacotherapeutic Group of (API)	it is a nicotinic receptor partial agonist indicated for use as an aid to smoking cessation treatment
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom pharmaceutical Co., Ltd, China.
	Detail of stability batches of drug product	03 batches : 1000 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 12-08-2024 is submitted. (Horizon Healthcare, Lahore) The firm has not submitted loan letter from M/s Horizon Healthcare. However, R&I receiving of loan intimation letter dated 04-09-2024 for 15 grams of material is submitted.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Chantix tablet 1mg by M/s Pfizer Labs INc., USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Registered drug by US FDA as CHANTIX (Varenicline as Tartrate 1mg Tablets), for ORAL Use.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 07-04-2025.
	Evidence of approval of manufacturing facility	Tablet General section is approved as per submitted GMP certificate.
	Evaluation Remarks	
	Clearance certificate dated 12-08-2024 is submitted. (Horizon Healthcare, Lahore)The firm has not submitted loan letter from M/s Horizon Healthcare. However, R&I receiving of loan intimation letter dated 04-09-2024 for 15 grams of material is submitted.	
	Decision	

	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
206	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(2JL-YQP-EQN8, 2025-01-23)
	Detail of Fee Submitted	75000.0, 2024-11-16,
	The proposed proprietary name / brand name	**Varin 0.5mg Tablet**
	Label Claim	Each film coated tablet contains: 0.85 mg of Varenicline tartrate equivalent to 0.5 mg of Varenicline free base. (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 below 30°C in Cool & Dry Place.
	For generic drugs (me-too Status)	Varipuf tablet by Genix
	Pharmacotherapeutic Group of (API)	it is a nicotinic receptor partial agonist indicated for use as an aid to smoking cessation treatment
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom pharmaceutical Co., Ltd,
	Detail of stability batches of drug product	03 batches : 1000 tablets
	Documents for the procurement of API with approval from DRAP (in case of Import)	Clearance certificate dated 12-08-2024 is submitted. (Horizon Healthcare, Lahore) The firm has not submitted loan letter from M/s Horizon Healthcare. However, R&I receiving of loan intimation letter dated 04-09-2024 for 15 grams of material is submitted from M/s Hamaz Pharmaceuticals,
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e. Chantix tablet 1mg by M/s Pfizer Labs INc., USA.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	Registered drug by US FDA as CHANTIX (Varenicline as Tartrate 0.5mg Tablets), for ORAL Use.
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 13-04-2021.
	Evidence of approval of manufacturing facility	Tablet General section is approved as per submitted GMP certificate.
	Evaluation Remarks	

	Clearance certificate dated 12-08-2024 is submitted. (Horizon Healthcare, Lahore)The firm has not submitted loan letter from M/s Horizon Healthcare. However, R&I receiving of loan intimation letter dated 04-09-2024 for 15 grams of material is submitted from M/s Hamaz Pharmaceuticals,	
	Decision	
	Deferred The board decided to call the representatives of the firms' M/s Horizon Pharmaceuticals Lahore and M/s Hamaz pharmaceuticals to clarify their position on following points; 1. Same R&D officer (Mr. M. Bilal) has processed the chromatograms in both firms. 2. Same R&D Manager (Ms. Naheed Yousaf) has signed documents of both firms. 3. Same UV-Vis Spectrophotometer (S. No. A11635581124ML) is used in analysis by both firms. 4. Same data logger sheets are submitted in cases of both firms.	
207	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Wimits Pharmaceuticals Pvt. Ltd** 129-Sunder Industrial Estate, Lahore **(000789)**
	Application Form Dy. No / Tracking ID & date of submission	(TL4-2QZ-UR9G, 2024-11-30)
	Detail of Fee Submitted	75000.0, 2024-10-16,
	The proposed proprietary name / brand name	**Peradol-T 500/2mg Tablet**
	Label Claim	Each tablet contains: Paracetamol .....500mg Thiocolchicoside.....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)	Thiopara by Kaizen
	Pharmacotherapeutic Group of (API)	NSAID/skeletal muscle relaxant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CarryFor Pharmaceutical (Pvt) Ltd, Add: Plot No.:- E-81, North Western Industrial Zone, Port Qasim, Karachi, Pakistan,Sarv BioLabs Pvt. Limited. Add: Plot No.2, Trilokpur Road(Behind IITT College of Engg.) Kala Amb-173 030Himachal Pradesh, India
	Detail of stability batches of drug product	06 months real time and 06 months accelerated stability data of 03 batches according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Thiocolchicoside: Clearance certificate dated 04-09-2023 for 2kg material. Paracetamol: Locally procured from M/s Carryfor Tax invoice Number 454 dated 21-05-2022.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference prodct i.e. Descontran 500/2mg by M/s Azevedos.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Paracetamol: 06 months accelerated and 24 mnths real time stability data accrdng to zone IV-A for 03 batches. Thiocolchicoside: 06 months accelerated and 06 months real time stability data according to zone IV-A for 03 bathces.
	The status in reference regulatory authorities	CIMA Spain approved.

	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 03-04-2023.
	Evidence of approval of manufacturing facility	Tablet general section is approveed.
	Evaluation Remarks	
	Decision	
	Approved	
208	Case Category	Priority As Per 257-M of RB (Farooq Aslam)
	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	(XQ8-2AQ-PT97, 2025-10-02)
	Detail of Fee Submitted	75000.0, 2025-04-24,
	The proposed proprietary name / brand name	**Maceta 10mg Tablets**
	Label Claim	Each film coated tablet contains: Macitentan.....10mg
	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-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Macitentan: It belongs to the pharmacotherapeutic group of endothelin receptor antagonists (ERAs), specifically a dual ERA, used for the treatment of pulmonary arterial hypertension (PAH).
	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	The applicant has manufactured 03 stability batches comprising of 1200 tablets. 06 months real time and 06 month accelerated stability data is submitted according to zone IV-A is submitted.
	Documents for the procurement of API with approval from DRAP (in case of Import)	...
	Pharmaceutical Equivalence and Comparative Dissolution Profile	The applicant has established pharmaceutical equivalency and performed CDP studies against the reference product i.e. Opsumit tablet by Actelion Pharmaceuticals Ltd., Switzerland.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 24 months of real time stability data of 03 batches according to the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	OPSUMIT® (Macitentan) tablets, for oral use Initial U.S. Approval: 2013 Actelion Pharmaceuticals US, Inc. 5000 Shoreline Court, Ste. 200 South San Francisco, CA 94080, USA ACT20181023
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 11-01-202.

	Evidence of approval of manufacturing facility	Tablet General Section is approved
	Evaluation Remarks	
	Query: Since you have adopted DS manufacturer's method of analysis and the manufacturer has used intermediate, starting material, impurity A and B for system suitability testing. Therefore, for confirming the validity of assay test for DS, system suitability is required to be performed by spiking the dilution with impurity A and B,	
	Reply: We have not procured and used impurity A and B in AMV system suitability as per manufacturer method. DRAP gave relaxation for impurities testing, But for future, if essential, we will procure for commercial batches as per manufacturer after getting approval.	
	The case was deferred in 357th meeting for:	
	1. For further deliberation regarding the active polymorphic form produced by the drug substance ma and the form used for manufacturing of innovator's product.	
	Evaluated by PEC: Drug substance exists in two polymorphic forms I and II. The innovator's literatu describes the polymorphism but the specific form used in the product has not been disclosed. The ap submitted a declaration from DS manufacturer that Form-II has been produced and the same is used development.	
	As per google patent (https://patents.google.com/patent/WO2014198178A1/en), The present invento found that Form I is hydrophobic, has poor solubility in water, and has a slow dissolution rate of tabl these properties may limit the concentration and rate of active ingredients in the bloodstream of the p oral administration, affecting the efficacy. Therefore, there is a need in the art to develop new crystall of macitentan. Summary of the invention.	
	The new crystalline form has at least one of the following advantageous properties compared to know crystalline forms: higher crystallinity, greater solubility, faster dissolution rate, better particle morpho prone to polymorphic transformation, thermals Good mechanical stability, low hygroscopicity, better compressibility and apparent density for suitable formulation applications, good storage stability, low solvents, etc.	
	Remarks: As per USFDA's document "Guidance for Industry: ANDAs: Pharmaceutical Solid Polym polymorphic forms of drug substance differ in internal solid state structure but not in chemical struct ANDA applicant is required to demonstrate that, among ither things, the drug product exhibits suffici stability and is bioequivalent to RLD. While the polymorphic form can affect drug product stability a bioequivalence, these performance characteristics are also dependent on formulation, the manufactur and other physiological properties of both drug substance and formulation excipients. Moreover, acc the same document, using a drug substance polymorphic form that is different from that of RLD may preclude an ANDA applicant from formulating a generic drug product that exhibits bioequivalence a and the drug substance in the generic drug product need not have the polymorphic form as the drug s the RLD.	
	2. For submission system suitability testing by spiking the dilution with impurity A and B as done by substance manufacturer. (Reply: submitted along with COAs of impurity standards and chromatogra	
	Moreover, Moreover, the firm has Risk management plan, R&I receiving of nomination of pharmacovigilance officer dated15-04-2026 and RMP of innovator's product.	
	Decision	
	Approved	
209	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, 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
	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.	
	The case was deferred in 360t meeting for submission of stability data of commercial batches:	
	The firm has submitted the stability data of exhibit batches of 20,000 previously. The firm has stated that the applied product was registered initially in China with commercial batch size of 20,000 and 03 batches were placed for long term stability study according to zone IV-A.	
	The firm has further stated that the commercial batch size was changed from 20,000 to 90,000 and 03 batches were placed for long term stability studies.	
	The firm has submitted 03 months real time stability data for 02 batches and 06 months stability data of 01 batch (Batch size: 90,000).	
	Decision	
	Approved AS per import policy for inspection of manufacturer abroad.	
210	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(YR8-5ES-5BHQ, 2025-01-23)

	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Mclig 15 mg Tablets**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin (as Besylate).....15 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's, 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Miro 15 mg Tablets (By Nabi Qasim)
	Pharmacotherapeutic Group of (API)	Diabetic peripheral neuropathic pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	03 batches : 1000 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)	Form 6 dated 10-02-2023 for 325grams of material is submitted along with unattested invoice No. k017-2301019 dated 19-10-2023.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Tarlige tablet by Daichi, PMDA Japan approved.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	https://www.pmda.go.jp/files/000267880.pdf (Tarlige 15 mg Tablets)
	GMP status of the firm	...
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
211	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(QRY-W12-VU6M, 2025-01-23)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Mclig 2.5 mg Tablets**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin (as Besylate)..... 2.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's' 30's, 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Miro 2.5 mg Tablets
	Pharmacotherapeutic Group of (API)	Diabetic peripheral neuropathic pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	03 batches : 1000 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)	Form 6 dated 10-02-2023 for 325grams of material is submitted along with unattested invoice No. k017-2301019 dated 19-10-2023.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Tarlige tablet by Daichi, PMDA Japan approved.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	(Tarlige 2.5 mg Tablets by Diiachi Sankyo, Japan) https://www.pmda.go.jp/files/000267880.pdf
	GMP status of the firm	Last inspection report dated 29-04-2025 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
212	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(J1R-A58-8DRT, 2025-01-23)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Mclig 5 mg Tablets**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin (as Besylate).....5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's, 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Miro 5 mg Tablets (By Nabi Qasim)
	Pharmacotherapeutic Group of (API)	Diabetic peripheral neuropathic pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	03 batches : 1000 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)	Form 6 dated 10-02-2023 for 325grams of material is submitted along with unattested invoice No. k017-2301019 dated 19-10-2023.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Tarlige tablet by Daichi, PMDA Japan approved.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	https://www.pmda.go.jp/files/000267880.pdf (Tarlige 5 mg Tablets)
	GMP status of the firm	Last inspection report dated 29-04-2025 is submitted.

	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
213	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(PYZ-QMR-QU8P, 2025-01-23)
	Detail of Fee Submitted	37000.0, 2024-10-29,
	The proposed proprietary name / brand name	**Mclig 10 mg Tablets**
	Label Claim	Each Film Coated Tablet Contains: Mirogabalin (as Besylate)..... 10 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 20's, 30's, 10-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30C
	For generic drugs (me-too Status)	Miro 10 mg Tablets (By Nabi Qasim)
	Pharmacotherapeutic Group of (API)	Diabetic peripheral neuropathic pain
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Kehui Pharmaceutical Co., Ltd.
	Detail of stability batches of drug product	03 batches : 1000 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)	Form 6 dated 10-02-2023 for 325grams of material is submitted along with unattested invoice No. k017-2301019 dated 19-10-2023.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP studies have been performed against the reference product i.e Tarlige tablet by Daichi, PMDA Japan approved.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-A.
	The status in reference regulatory authorities	https://www.pmda.go.jp/files/000267880.pdf (Tarlige 10 mg Tablets)0
	GMP status of the firm	Last inspection report dated 29-04-2025 is submitted.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Decision	
	Approved	
214	Case Category	Routine (Farooq Aslam)
	Name, address of Applicant.	**Macter International Limited** F-216,S.I.T.E.,Karachi-Pakistan **(000141)**
	Application Form Dy. No / Tracking ID & date of submission	(T61-214-91MP, 2025-01-30)
	Detail of Fee Submitted	93000.0, 2024-10-09,
	The proposed proprietary name / brand name	**Roxanix 70mg Tablets**

	Label Claim	Each Film Coated Tablet contains: Roxadustat.....70mg (Product Complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's, 12's, 14's, 20-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree centigrade.
	For generic drugs (me-too Status)	Approved by Getz, CCL, Kaizen and Horizon.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. WnsFeild Pharmaceuticls-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	UK MHRA Approved.
	Detail of previous approval	
	Evaluation Remarks	
	The firm has referred the minutes of 360th meeting, the applied strength vide application ID (R4H-JZM-RUAY, 2024-10-21) was approved. The firm shall submitted Declaration for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products and applicable fee for changing the status of application to data approved.	
	Decision	
	Approved Subject to submission of: 1. Declaration from the applicant for adopting same source of drug substance, drug product formulation, specifications and container closure as adopted by the manufacturer and In case of any post registration variation by contract manufacturer, the applicant will adopt the same and immediately will apply for change (if any) as per post registration variation guidelines for pharmaceuticals products. 2. Applicable fee for changing the status of data approved already.	
215	Case Category	New License (Farooq Aslam)
	Name, address of Applicant.	**Orbis Pharmaceuticals** Plot # K-138 , SITE Super Highway Phase 2 , Karachi **(000979)**
	Application Form Dy. No / Tracking ID & date of submission	(ANU-EGE-TMHV, 2026-01-02)
	Detail of Fee Submitted	37000.0, 1700.0 2025-02-17, 2025-09-11
	The proposed proprietary name / brand name	**Desra**
	Label Claim	Each ml contains: Desloratadine 0.5mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	60ml,120ml,90ml-As per SRO
	Shelf Life (Unit)	2 Year(s)Store in cool & dry place below 30°C
	For generic drugs (me-too Status)	Neo-antial 0.5mg/mL syrup by M/s Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antihistamines
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Morepen Laboratories Limited
	Detail of stability batches of drug product	Batches: T001, T002, T003 (Batch size 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)	AD attested invoice dated 09-02-2022 is submitted (Semos Pharmaceuticals (Pvt) Ltd.)
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies have been performed against Neo-Antial 0.5mg/mL Syrup by M/s Sami Pharmaceuticals.
	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 the conditions of zone IV-A is submitted.
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	New license was granted w.e.f. 27-10-2023.
	Evidence of approval of manufacturing facility	Liquid syrup/suspension/solution (General) is approved. New License
	Evaluation Remarks	
	New License.	
	Decision	
	Approved	
216	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**AGP Limited** B-23-C, S.I.T.E., Karachi **(000348)**
	Application Form Dy. No / Tracking ID & date of submission	(1YR-ZM9-B8BN, 2026-04-13)
	Detail of Fee Submitted	38700, 2026-03-25,
	The proposed proprietary name / brand name	**Ontozy Tablet 150mg**
	Label Claim	Each Film Coated Tablet contains Cenobamate.....150mg. Finished Product Specification: Innovators Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10’s (1 x 10’s)-De-Controlled,14’s (2 x 7’s)-De-Controlled,20’s (2 x 10’s)-De-Controlled,21’s (3 x 7’s)-De-Controlled,28’s (4 x 7’s)-De-Controlled,30’s (3 x 10’s)-De-Controlled,7’s (1 x 7’s)-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 ºC in a dry place away from direct heat or sunlight.
	For generic drugs (me-too Status)	Locally available with the brand name Coprex tablet 150mg manufactured by Nabiqasim Industries (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Cenobamate: Anticonvulsants
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Jinan Gaohua Pharmaceuticals Co.,Ltd No.8 Panwang road, Mingshui Economic Development Zone, Zhanqiu City, Shandong Province, China
	Detail of stability batches of drug product	Stability data conducted on 3 batches(239 DS01, 239 DS02, 239 DS03) (6 Month Accelerated 40C + 2C and 75% RH + 5% and 6 Month Long Term 30C + 2C and 75% RH + 5%)
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6 dated 22-05-2025 for 6kg material is submitted. Unattested invoice No. H007-2503017 dated 13-05-2025 is submitted along with airway bill.

	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE and CDP have been conducted against Xcopri Tablet 150 manufactured by Endo Ventures Ltd, Dublin, Ireland
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Long Term:36 Months 30 ± 2°C , Humidity: 65 ± 5%, Accelerated_6 Months 40 ± 2°C , Humidity: 75 ± 5%. Batches. 210218, 210224 ,210228
	The status in reference regulatory authorities	USFDA Approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 04-08-2025.
	Evidence of approval of manufacturing facility	Tablet General Section is approved.
	Evaluation Remarks	
	Under export facilitation vide General Request TID G5M-SJ6-P41X	
	The firm has submitted Risk Management plan and copy of email to pv@dra.gov.pk confirming the nomination of PV officer.	
	Decision	
	Approved	
217	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(GL4-UDN-E8GD, 2025-04-04)
	Detail of Fee Submitted	93000.0, 2024-12-11,
	The proposed proprietary name / brand name	**Respeze Nebuliser Solution**
	Label Claim	Each 2ml Respule contains: Ipratropium Bromide..... 500mcg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	6's and 1's-De-Controlled
	Shelf Life (Unit)	3 Year(s)Store below 30 degree celsius
	For generic drugs (me-too Status)	Ventpro Nebulizer solution by M/s Surge
	Pharmacotherapeutic Group of (API)	anticholinergic agents/bronchodilator
	Name, address of Manufacturing site:	surge laboratories (Pvt) Ltd-10TH KM FAISAL ABAD ROAD,BIKHI DISTRICT,SHEIKHOPURA-
	Name & address of API manufacturer	Aarti industries LTD
	Detail of stability batches of drug product	03 batches : 25,000 respules 06 months accelerated and 36 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice issued on 20-02-2020 for 600g material s submitted (Surge).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies against the comparator's product i.e. Easehale inhalation solutiion 500mcg/2mL by M/s Hudson.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	MHRA APPROVED
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-09-2024 (Surge)

	Evidence of approval of manufacturing facility	Liquid injectable (including blow fill seal area) General Section is approved (Surge)
	Evaluation Remarks	
	Export facilitation.	
	Decision	
	Approved	
218	Case Category	Export Facilitation (Farooq Aslam)
	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(1SN-PDY-5Z4G, 2025-04-09)
	Detail of Fee Submitted	93000.0, 2025-01-30,
	The proposed proprietary name / brand name	**Respeze Nebuliser Solution 250mcg/ml**
	Label Claim	Each ml contains: Ipratropium Bromide BP....250mcg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's, 5's and 6's res-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Ventpro Nebulizer solution by M/s Surge
	Pharmacotherapeutic Group of (API)	anticholinergic agents/bronchodilator
	Name, address of Manufacturing site:	Surge Laboratories (Pvt.) Ltd.-10th Km, Faisalabad road, Bikhi, District Sheikhupura - Pakistan-
	Name & address of API manufacturer	Aarti Industries Limited
	Detail of stability batches of drug product	03 batches : 2000 respules 06 months accelerated and 06 months real time stability data according to zone IV-A.
	Documents for the procurement of API with approval from DRAP (in case of Import)	AD attested invoice issued on 20-02-2020 for 600g material s submitted (Surge).
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE studies against the comparator's product i.e. Ipneb inhalation solutiion 250mcg/mL (filled volume: 20mL) by M/s Atco.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	06 months accelerated and 36 months real time stability data of 03 batches according to zone IV-B.
	The status in reference regulatory authorities	MHRA Approved (Ipratropium Bromide 250micrograms/ml by Accord Healthcare Limited, UK)
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 27-09-2024 (Surge)
	Evidence of approval of manufacturing facility	Liquid injectable (including blow fill seal area) General Section is approved (Surge)
	Evaluation Remarks	
	PE studies against the comparator's product i.e. Ipneb inhalation solutiion 250mcg/mL (filled volume: 20mL) by M/s Atco.	
	The firm has stated that the concentration of both of the product is same i.e. 0.025%.	
	Both products are nebulizer solution and pharmaceutically equivalent.	
	Decision	

	Approved	
219	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(DL4-9BG-3V3E, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD BREEZE ORAL LIQUID**
	Label Claim	Each ml contains: Tylosin Tartrate.....100 mg Doxycycline Hydrochloride.....200mg Colistin Sulphate.....480,000 IU Bromhexine HCl.....5 mg (As per innovator's specifications)
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	NAWA DOX ORAL LIQUID (074097)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
220	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(4LG-QQ6-Z4UB, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD CINA ORAL LIQUID**
	Label Claim	Each ml contains: Trimethoprim.....25 mg Sulphamethazine.....50 mg Sulphamethoxypyridazine.....75 mg Enrofloxacin.....75 mg (As per innovator's specifications).
	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 Yearat Room Temperature

	For generic drugs (me-too Status)	Rold-Cina 225 Oral liquid (109050) M/S Haarolds Pharmaceticals Bhimber AJK
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Deferred 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 combination of antibiotics.	
221	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(S8A-HS6-ST5L, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD BURSA ORAL LIQUID**
	Label Claim	Each 1ml contains: - Trimethoprim.....80 mg Sulphadizaine.....400 mg. (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Diatrim Oral Liquid. registration NO 122008
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
222	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**

	Application Form Dy. No / Tracking ID & date of submission	(SEB-XB8-31AH, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD FENICOL 23 % ORAL LIQUID**
	Label Claim	Each 100 ml contains: - Florfenicol.....23 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ml 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Fen 23% Liquid (121909)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
223	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(TY8-YGA-86EA, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD FENICOL 100 ORAL LIQUID**
	Label Claim	Each ml contains: Florfenicol.....100 mg (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ml 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Florobak Oral Liquid registration NO 063839
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
224	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(486-B95-YH8R, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD FENICOL 2500 ORAL LIQUID**
	Label Claim	Each ml contains: - Florfenicol.....250 mg (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ml 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Fen 25% Liquid Registration no 121910
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
225	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(JUW-SPU-Z1SR, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD FLOX 20% ORAL LIQUID**
	Label Claim	EACH 100ML CONTAINS:- NORFLOXACIN .....20GM. (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 Yearat Room Temperature
	For generic drugs (me-too Status)	Floxin 20% Liquid Registration No (046512)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices

		(GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
226	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(H4E-E8D-T8BY, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**GUA FORD AE 24OO ORAL LIQUID**
	Label Claim	Each ml contains: Enrofloxacin.....100mg Aminophylline.....100mg Guaiphenesin.....40mg (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 Yearat Room Temperature
	For generic drugs (me-too Status)	Carlos Flox AG Oral Liquid Registration No. 109058
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
227	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(9DH-RZ1-EEZT, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**GUA FORD AE 24% ORAL LIQUID**
	Label Claim	Each 100ml contains: Enrofloxacin.....10g Aminophylline.....4g Guaiphenesin.....10g (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 Yearat Room Temperature
	For generic drugs (me-too Status)	Carlos Flox AG Oral Liquid Registration No. 109058
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The same formulation is applied with the name of product "GUA FORD AE 2400 ORAL LIQUID", So the clarification is required with the composition similarity.	
	Decision	
	Approved	
228	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(T1Q-BLL-TU5V, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**N FORD 10% ORAL LIQUID**
	Label Claim	Each 100 ml contains:- Enrofloxacin ..... 10 gm. (As per innovator’s specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Roxcin 10 Liquid Registration NO 122009
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
229	Case Category	Routine (Hafiz Muhammad Jawad Ali)

	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(JBV-LNP-RU6G, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**N FORD 20% ORAL LIQUID**
	Label Claim	Each 100 ml contains:- Enrofloxacin ..... 20 gm. (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Roxcin 20 Liquid Registration NO 122010
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
230	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(DYT-4Y7-V38J, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**N FORD 25% ORAL LIQUID**
	Label Claim	Each 100 ml contains:- Enrofloxacin ..... 25 gm. (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Roxcin 20 Liquid Registration NO 122011
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
231	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(GMM-LP2-N8HG, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD TIN 10% ORAL LIQUID**
	Label Claim	Each 100 ml contains: - Enrofloxacin.....10 g Colistin Suphate.....50 MIU (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	ENROLD C-15 ORAL LIQUID Registration NO 109056
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
232	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(4YY-4X3-NXZM, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD TIN 20%ORAL LIQUID**
	Label Claim	Each 100 ml contains:- Enrofloxacin.....20 g Colistin Sulphate.....50 MIU
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	ENROLD C-25 ORAL LIQUID Registration NO 109055

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
233	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(Z4V-X28-ATX8, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD SELL E LIQUID**
	Label Claim	EACH 100ML CONTAINS: - SILYMARIN.....2500 MG VITAMIN E.....1500 MG (As per innovators Specifications)
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	LIVERSOL LIQUID Registration no: 069659
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
234	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(X96-TTQ-7QRX, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD RILL ORAL LIQUID**

	Label Claim	Each 1000 ml contains: Toltrazuril.....25g Vitamin K3.....3g (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Tolmars Liquid Registration NO 075746
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
235	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(13D-R9R-PJQS, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD LIV ORAL liquid**
	Label Claim	Each ml contains (As Per Innovator Spec.) L-Carnitine ..... 50mg Betaine ..... 20mg Inositol ..... 7mg Choline Chloride ..... 100mg Sorbitol ..... 200mg Magnesium Sulphate 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ml 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Aug Liv Oral Liquid (121992)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
236	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(ZPA-BDX-5E1H, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**GUMBO FORD ORAL POWDER**
	Label Claim	Each 100gm contains: Ammonium Chloride.....70 gm Methionine.....10 gm Sorbitol.....5 gm Vitamin A.....150,000 IU Vitamin C.....10 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Gumbor water soluble Powder (120878)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
237	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(XGV-YV3-4VYN, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**PRO-CRD ORAL POWDER**
	Label Claim	Each 100 gm contains: Doxycycline HCl.....40 mg Tylosin Tartrate.....20 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Butoxy Water Soluble Powder (097981)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
238	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(VSL-JGT-P1EN, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**SPEC-MYCIN ORAL POWDER**
	Label Claim	Each 150gm Powder Contains:- Lincomycin as HCl ...33.3 g Spectinomycin as HCl .....66.7 g (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	LINCO-S 100 W/S POWDER (062169)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
239	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(284-UPX-XWJR, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**LINCO-CIN 1.1% ORAL POWDER**
	Label Claim	Each gram contains, Lincomycin as HCl.....11 mg (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Linco 11 (122002)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
240	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(3UW-ZYZ-6RUJ, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**DANO FORD 20% ORAL POWDER**
	Label Claim	Each gm contains:- Danofloxacin ..... 100mg. (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	DANOFLOX 10% POWDER. (049653)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
241	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(8UU-3H6-8T95, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-06,

	The proposed proprietary name / brand name	**STRO OX N ORAL POWDER**
	Label Claim	Each gram powder contains: Neomycin sulphate.....60mg Oxytetracycline HCl.....200mg Streptomycin Sulphate.....20mg (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	14. Neostrox Powder (092184)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
242	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(5JH-SEW-657Z, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**SPIRA LIN ORAL POWDER**
	Label Claim	Each gm contains:- Spiramycin Adipate.....75mg Lincomycin HCl.....25mg (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	SPECTO ORAL POWDER (080134)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
243	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(AR9-BN5-YE3H, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**PEFLOX FORD ORAL LIQUID**
	Label Claim	Each ml contains: Pefloxacin Methane Sulfonate Eq. to Pefloxacin.....100 mg (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Pef-Rold Oral Liquid Registration NO 109062
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
244	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(EW5-BWP-54BS, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**TYLAN FORD ORAL POWDER**
	Label Claim	Each 1000gm Powder Contains:- Tylosin As Phosphate.....100gm (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	TYSIN MIX 10 POWDER (062177)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring

		compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
245	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(EQW-Y3L-NN59, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**C-TIN FORD ORAL POWDER**
	Label Claim	EACH KG CONTAINS:- COLISTIN SULPHATE ..... 4GM. BROMHEXINE HCL..... 5GM. NEOMYCIN SULPHATE..... 70GM. CHLORTETRACYCLINE HCL..... 80GM (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	NEOCOLICIN PLUS POWDER. (044949)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
246	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(DV3-NLP-BJ14, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**HEXA FLUSH ORAL POWDER**
	Label Claim	EACH 100G CONTAINS: - METHENAMINE .....95G VITAMIN B2 .....920MG

		VITAMIN K3 .....2G (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Met Mars Water Soluble Powder (074076)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
247	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(YE3-L1V-MN37, 2026-02-08)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**DIARO FORD ORAL POWDER**
	Label Claim	Each 12gm contains: Neomycin Sulphate.....400 mg Sreptomycin Sulphate.....400 mg Sulphaguanidine.....4000 mg Pectin.....400 mg Bismuth Subnitrate.....2000 mg Vitamin A Acetate.....80,000 IU Kaolin.....4000 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10GM, 12GM, 100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Archoban Forte Powder (121901)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

248	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(WRG-734-VU1G, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**MANTO-FORD 100 ORAL POWDER**
	Label Claim	Each 100 gms contains: Amantadine HCl.....1gm (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	ROLDINE 1% W/S POWDER (109105)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The formulation contains Amantadine: 1g/100g of Oral powder. So the case may be taken as per the decision related to Amantadine.	
	Decision	
	Deferred For submission of target species and clinical indications of the subject product.	
249	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(JAN-247-9R5T, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**LINCO-CIN 40% ORAL POWDER**
	Label Claim	EACH GM CONTAINS:- LINCOMYCIN (AS LINCOMYCIN HYDROCHLORIDE).....400MG (As Per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Lincosol 40% Oral Powder (081301)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
250	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(JH5-LB4-EQUE, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**RESPOXY ORAL LIQUID**
	Label Claim	Each ml contains: Doxycycline Hcl =200 mg Tylosin Tartrate =100 mg Colistin Sulphate =500,000 IU Bromhexine Hcl =10 mg
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Tycox Oral Liquid Registration No: 078259
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
251	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(M13-62Q-GL1J, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD LIN TIN ORAL POWDER**
	Label Claim	Each gm contains:- Lincomycin HCl..... 100mg. Colistin as Sulphate..... 8,000,000 IU. (As Per Innovators Specification)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	VETY LINCOCO POWDER (046665)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
252	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(MNB-DNW-VJYY, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**LINCO-CIN 4.4% ORAL POWDER**
	Label Claim	Each gram contains, Lincomycin as HCl.....44 mg (USP specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Linco 44 (122003)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
253	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(LDV-47E-L458, 2026-02-07)

	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD ADEK ORAL LIQUID**
	Label Claim	EACH LITER CONTAINS:- VITAMIN A.....25000000 IU. VITAMIN D3.....250000 IU. VITAMIN E.....15000MG. VITAMIN K3.....2500MG. (As per innovator's specifications
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	ADEK GOLD ORAL SOLUTION (063813)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
254	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(PPE-L4L-ULXN, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**COX FORD ORAL POWDER**
	Label Claim	Each gm contains:- Sulphachlorpyridazine.....33.33% Vitamin K3 .....3mg (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	CLORICOX WATER SOLUBLE POWDER (075702)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
255	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(NGN-G83-AUA7, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD ANTHY 50% ORAL POWDER**
	Label Claim	Each kg contains:- Levamisole HCl..... 500gm. (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	ANTHIY POWDER. (044964)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
256	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(BQS-7MQ-YBL8, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**BALLO FLUSH ORAL POWDER**
	Label Claim	EACH 1000GM CONTAINS:- FRUSEMIDE ..... 20GM. EXTRACT BELLADONNA .... 2GM. (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	FRUSENAL POWDER. (043153)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices

		(GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The product contains Belladona extract, so may take in consideration for veterinary committee.	
	Decision	
	Approved	
257	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(D1P-1Z2-DGQW, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**PRO-CRD 40/20 ORAL POWDER**
	Label Claim	Each Gram Conatins: Doxycycline HCl.....400 mg Tylosin as Tartrate.....200 mg Colistin Sulphate.....0.5 MIU Bromhexine HCl.....10 mg (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	CRD Arch 40 Oral Powder. (121993)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
258	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(D4J-PQG-U4B6, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**CETA FORD C ORAL POWDER**
	Label Claim	EACH 100GM CONTAINS:- PARACETAMOL.....2GM VITAMIN C (ASCORBIC ACID).....20GM CALCIUM CARBONATE.....4.5GM MAGNESIUM SULPHATE.....3.5GM

		POTASSIUM CHLORIDE.....4GM (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	SPIN-C POWDER (078239)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
259	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(GY8-BL7-HZHA, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**SPIRO FORD B ORAL POWDER**
	Label Claim	Each 100 gram contains, Lincomycin as HCl.....5 gm Spectinomycin HCl.....7.5 gm Spiramycin Adipate.....2.5 gm Bromhexine HCl.....0.5 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Spiro Spec Powder (122006)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
260	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi

		(001018)
	Application Form Dy. No / Tracking ID & date of submission	(J6B-64Q-65WJ, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**OXY FORD 95% ORAL POWDER**
	Label Claim	Each gram contains: Oxytetracycline HCl.....950 mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Nawa-Oxy 950 powder (120730)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
261	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(USD-DYM-2W9U, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**THREP FORD ORAL LIQUID**
	Label Claim	Each Litr contains: Enrofloxacin.....100 g N-Acetyl L-Cystine.....186 g Propylene Glycol.....100 g Benzyl Alcohol.....20 mg (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	PENPROL SOLUTION (063718)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved	
262	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(PX5-2GH-5PTD, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**MANTO-FORD 10 ORAL POWDER**
	Label Claim	Each 100 g contains: Amantadine HCl.....10% (As Per Innovator's Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	ROLDINE 10% W/S POWDER (109104)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applied formulation contains single ingredient Amantadine 10% in 100 gm, 250 gm, 500 gm, 1 kg. The case may be taken as per consideration of decision of EWG for amantadine. "The Registration Board in 358th decided that the firms having already registered amantadine-containing formulations shall be granted a timeline of six (06) months to align their products in accordance with international practices for use only in non-food producing animals and with pack sizes up to 100 gm/ml through the Post Registration Variation (PRV). In case of non-compliance within the stipulated timeline, the registration of such products shall processed for cancellation."	
	Decision	
	Deferred For submission of target species and clinical indications of the subject product.	
263	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(PYG-H1D-9V9T, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**THIAM FORD 25% ORAL LIQUID**
	Label Claim	Each ml contains: Thiamphenicol.....250 mg (As per innovator's specifications).
	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 Yearat Room Temperature
	For generic drugs (me-too Status)	Thiam Rold 25% Oral Liquid (109059)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
264	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(QB5-JQU-A8VV, 2026-02-08)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FON FORD 98% POWDER**
	Label Claim	Each gm contains: Trichlorfon.....980 mg (as per innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 12gm,100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Stone Fon 98 Powder (121904)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
265	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(QBU-7ZG-8U55, 2026-02-14)

	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD STREP-DOX ORAL POWDER**
	Label Claim	Each gram contains, Doxycycline HCl.....200 mg Tylosin as tartrate.....100 mg Dihydrostreptomycin.....20 mg Bromhexine HCl.....5 mg (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Strep dox-20 Powder (122004)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
266	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(S27-GMW-2B7U, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**MANTO FORD 98% ORAL POWDER**
	Label Claim	Each 100 g contains: Amantadine HCl.....98 gm (As Per Innovator’s Specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	ROLDINE 98 W/S POWDER (109103)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applied formulation contains Amantadine 98% (as a single ingredient) with pack size of 100gm, 250gm, 500gm, 1kg. The case may be taken as per consideration of the EWG. and as decided below: - "The Registration Board in its 358th meeting decided on the recommendations of EWG that the firms having already registered amantadine-containing formulations shall be granted a timeline of	

	six (06) months to align their products in accordance with international practices for use only in non-food producing animals and with pack sizes up to 100 gm/ml through the Post Registration Variation (PRV). In case of non-compliance within the stipulated timeline, the registration of such products shall processed for cancellation."	
	Decision	
	Deferred for submission of target species and clinical indications of the subject product.	
267	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(SJE-7MQ-X25E, 2026-02-16)
	Detail of Fee Submitted	38700, 2026-02-09,
	The proposed proprietary name / brand name	**AMPRO C VIT ORAL POWDER**
	Label Claim	EACH GM CONTAINS:- AMPROLIUM HCL .....200MG. COLISTIN SULPHATE .....500,000 I.U. VITAMIN K..... 50MG. VITAMIN A .....5,000 I.U. (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	AMPRCOL WATER SOLUBLE POWDER. (034529)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
268	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(YNR-LT3-UJAP, 2026-02-08)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**GESTO FORD ORAL POWDER**
	Label Claim	Each 1000 gm contains: Propionic Acid Calcium.....250 gm Propionic acid Sodium.....400 gm Acetanilide.....150

		gm Magnesium Oxide.....125 gm Iron II sulphate.....400 mg Zinc Sulphate.....100 mg Magnesium Sulphate.....200 mg Copper Sulphate.....450 mg Cobalt Sulphate.....400 mg Sodium Molybdate.....100 mg Sodium Chloride.....20 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 12gm,100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Gasiton Powder (121902)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
269	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(S8B-444-X7JY, 2026-02-07)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD FENICOL 20 % ORAL LIQUID**
	Label Claim	Each 100 ml contains: - Florfenicol.....20 gm (as per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML, 150 ml 250 ML, 500 ML, 1000 ML-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Arch Fen 20% Liquid registration NO 121908
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	

	Approved	
270	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(TB9-ZGJ-VRU5, 2026-02-08)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**BANA GRANULES POWDER**
	Label Claim	EACH GM CONTAINS:- ALBENDAZOLE....200MG (As per Innovators specs.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 12gm,100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	ALPRO 20% GRANULES (026465)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm clarifies the dosage form, as Oral Powder	
	Decision	
	Approved	
271	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(68A-TY9-HBBX, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	**Met-Vetz Oral Powder**
	Label Claim	Each 100gm Contains: Methenamine .....90gm Vitamin B1.....700mg Vitamin C.....100mg Sorbitol.....5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1 kg, 5kg, 10kg , 20kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	Uronax-SC Oral Powder
	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	
272	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(HJP-4MU-BL49, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-04-01,
	The proposed proprietary name / brand name	**JF-Vit C Powder**
	Label Claim	Each gram contains: Ascorbic Acid ..... 1000 mg (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,10kg-De-Controlled,15gm-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,20gm-De-Controlled,25 kg-De-Controlled,250g-De-Controlled,25gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearStore in cool & dry place.
	For generic drugs (me-too Status)	Ascor-C Powder
	Pharmacotherapeutic Group of (API)	
	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	
273	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(A9B-5EM-W5VX, 2026-04-01)
	Detail of Fee Submitted	38700, 2026-04-01,
	The proposed proprietary name / brand name	**JF-Broment Oral Liquid**
	Label Claim	Each ml Contains Bromhexine HCl.....20mg Menthol.....40mg As per Innovators Specification
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,25ltr-De-Controlled,30ml-De-Controlled,500ml-De-Controlled,50ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 YearStore in cool & dry place.
	For generic drugs (me-too Status)	Le-Bro
	Pharmacotherapeutic Group of (API)	
	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	
274	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(DNV-GAE-VZDM, 2026-04-02)
	Detail of Fee Submitted	38700, 2026-04-01,
	The proposed proprietary name / brand name	**JF-Ampro Powder**
	Label Claim	Each 1000gm contains: Amprolium HCI.... 600gm (USP Specification)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,10kg-De-Controlled,15gm-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,20gm-De-Controlled,25 kg-De-Controlled,250g-De-Controlled,25gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearStore in cool & dry place.
	For generic drugs (me-too Status)	Ampko-Vet 60 Oral Powder
	Pharmacotherapeutic Group of (API)	
	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	

275	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(2R1-YDW-H8ES, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-04-01,
	The proposed proprietary name / brand name	**JF-OxyFlor Powder**
	Label Claim	Each kg contains: Oxytetracycline... 150gm Florfenicol... 150gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm -De-Controlled,10gm-De-Controlled,10kg-De-Controlled,15gm-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,20gm-De-Controlled,25 kg-De-Controlled,250g-De-Controlled,25gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearStore in cool & dry place.
	For generic drugs (me-too Status)	Flowim Oral Powder
	Pharmacotherapeutic Group of (API)	
	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	
276	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(DPN-MEH-SRSN, 2026-04-04)
	Detail of Fee Submitted	38700, 2026-04-01,
	The proposed proprietary name / brand name	**JF-TYLO-G Injection**
	Label Claim	Each ml contains: Gentamycin Sulphate ... 50mg Tylosin Tartrate ...100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore in a dark place at below 25°C
	For generic drugs (me-too Status)	G-Tylo Injection
	Pharmacotherapeutic Group of (API)	
	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	
277	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(XTU-AGM-59E1, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-04-01,
	The proposed proprietary name / brand name	**JF-Mega-C Powder**
	Label Claim	Each 100gm contains: Paracetamol.....2 gm Vitamin C (Ascorbic acid)....20gm Calcium Carbonate ....4.5gm Potassium Chloride.....4gm Magnesium Sulphate.....3.5gm (Innovator Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm -De-Controlled,10kg -De-Controlled,15gm-De-Controlled,1kg-De-Controlled,2.5kg-De-Controlled,20gm-De-Controlled,25 kg-De-Controlled,250g-De-Controlled,25gm-De-Controlled,500gm-De-Controlled,50gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 YearStore in cool & dry place.
	For generic drugs (me-too Status)	Paralite-C Powder
	Pharmacotherapeutic Group of (API)	
	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	
278	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(RHP-GMS-MUA9, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-03-12,

	The proposed proprietary name / brand name	**Trizole Bolus**
	Label Claim	Each Bolus contains:- Triclabendazole.....250mg (Innovator’s Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20’s, 50’s, 100’s-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 25°C.
	For generic drugs (me-too Status)	Triclan-S Bolus Reg. # 043283
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	"Our firm maintains a 'Highly Satisfied' GMP compliance status, as officially recognized by the Drug Regulatory Authority of Pakistan (DRAP)."
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
279	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(ARN-DQT-86RY, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-03-12,
	The proposed proprietary name / brand name	**Trifen SC Drench**
	Label Claim	Each ml contains:- Triclabendazole.....50 mg Fenbendazole .....25 mg Selenium (as sodium selenite) ...0.5 mg Cobalt (as cobalt sulphate) ....1.67 mg (Innovator’s Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 25°C.
	For generic drugs (me-too Status)	Tribenzol Plus Reg. # 046526
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	"Our firm maintains a 'Highly Satisfied' GMP compliance status, as officially recognized by the Drug Regulatory Authority of Pakistan (DRAP)."
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
280	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(ENH-LSS-JBYS, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-03-12,
	The proposed proprietary name / brand name	**Trizole Plus Bolus**

	Label Claim	Each Bolus contains:- Triclabendazole .....900 mg Levamisole HCl.....90mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5's, 10's, 20's, 50's-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 25°C.
	For generic drugs (me-too Status)	Tribazole Plus Bolus Reg. # 074039
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	"Our firm maintains a 'Highly Satisfied' GMP compliance status, as officially recognized by the Drug Regulatory Authority of Pakistan (DRAP)."
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
281	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(JTX-WUB-UVNP, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-03-12,
	The proposed proprietary name / brand name	**Fenzostar 10% Drench**
	Label Claim	Each ml contains: Fenbendazole BP..... 100mg (B.P Vet Specifications)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	1000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 25°C.
	For generic drugs (me-too Status)	Fenzole-10% Drench Reg. # 062113
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	"Our firm maintains a 'Highly Satisfied' GMP compliance status, as officially recognized by the Drug Regulatory Authority of Pakistan (DRAP)."
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
282	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(Y6H-QEM-MG92, 2026-04-04)
	Detail of Fee Submitted	38700, 2026-04-01,
	The proposed proprietary name / brand name	**JF-Floro 30% Injection**
	Label Claim	Each ml contains: Florfenicol.....300mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore in a dark place at below 25°C
	For generic drugs (me-too Status)	Neflox Injection
	Pharmacotherapeutic Group of (API)	
	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	
283	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(S97-PZ8-Y1Z1, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	**Tylovetz 100% Oral Powder**
	Label Claim	Each gm contains: Tylosin as Tartrate.....1000mg (as per Innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm, 250gm, 500gm, 1 kg, 5kg, 10kg, 20kg, 25kg-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	Tylosin Pure Water Soluble Powder
	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	
284	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(P8T-PUN-9T5Z, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-03-12,
	The proposed proprietary name / brand name	**Levozan Super Drench**
	Label Claim	Each ml contains:- Levamisole HCI.....30mg Oxyclozanide.....60mg Cobalt Sulphate.....3.34mg Sodium

		Selenite.....1.00mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml, 500 ml, 1000 ml-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 25°C.
	For generic drugs (me-too Status)	Helmex Gold Drench Reg. # 057005
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	"Our firm maintains a 'Highly Satisfied' GMP compliance status, as officially recognized by the Drug Regulatory Authority of Pakistan (DRAP)."
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
285	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(81J-GVQ-4MZ9, 2026-04-07)
	Detail of Fee Submitted	38700, 2026-04-06,
	The proposed proprietary name / brand name	**Libro-SS Powder**
	Label Claim	Each Kg Contents
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled,1kg-De-Controlled,20 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore in cool and dry place keep away from direct sunlight
	For generic drugs (me-too Status)	Spiraline-B Powder reg.# 079716 M/s Attabak Pharma Islamabad
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The label claim is missing in the submitted application, firm is requested to re- submit the label claim and all particulars of the application, with applicable fee.	
	Decision	
	Approved	
286	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(MV1-ZLU-MHVS, 2026-04-07)
	Detail of Fee Submitted	38700, 2026-04-06,
	The proposed proprietary name / brand name	**Duraf-AK Powder**

	Label Claim	Each KG Contents
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm-De-Controlled,1000 gm-De-Controlled,20 gm-De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Yearstore in cool and dry place keep away from direct sunlight
	For generic drugs (me-too Status)	F. FLUSH POWDER. REG# 053930 M/S ATTABAK PHARMA, ISLAMABAD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The label claim is missing in the submitted application, firm is requested to re- submit the label claim and all particulars of the application, with applicable fee.	
	Decision	
	Approved	
287	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(7YU-38X-9BL7, 2026-04-17)
	Detail of Fee Submitted	38700, 2026-04-17,
	The proposed proprietary name / brand name	**TAYALO 85% GRANULATED POWDER**
	Label Claim	Each gm Contains: Acetyl Isovaleryl Tylosin Tartrate..... 850mg (As per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Tylovalo Forte Granules Reg NO. 130415
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
288	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(UQX-JYJ-NEX4, 2026-04-07)
	Detail of Fee Submitted	38700, 2026-04-06,
	The proposed proprietary name / brand name	**NTC-28 Liquid**
	Label Claim	Each 100 ml Contains
	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 Yearstore in cool and dry place keep away from direct sunlight
	For generic drugs (me-too Status)	NORCOTYL ORAL SOLUTION, REG# 071021 M/S BIOGEN PAHRMA, RAWAT
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The label claim is missing in the submitted application, firm is requested to re- submit the label claim and all particulars of the application, with applicable fee.	
	Decision	
	Approved	
289	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(VJX-6UQ-EBSY, 2026-04-10)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**Sultradox Powder**
	Label Claim	Each 100 gram contains: Doxycycline HCl.....40gm Tylosin Tartrate .....20gm Colistin Sulphate .....50MIU Bromhexine HCl.....1gm (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 YearStore below 25°C in a cool and dry place. Protect form light
	For generic drugs (me-too Status)	Product Name:: Dox-40 Water Soluble Powder Registration No: 074096 Company Name: Nawal Pharmaceuticals Company Address: Plot No 11-A, Punjab Small Industrial Estate, Taxila, Rawalpindi
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	Decision	
	Approved	
290	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	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	(QM4-ZT4-RU3Q, 2026-04-29)
	Detail of Fee Submitted	38700, 2026-04-21,
	The proposed proprietary name / brand name	**Clovet Oral Suspension**
	Label Claim	Each ml contains: Closantel - 110mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,20gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 YearAT ROOM TEMPERATURE
	For generic drugs (me-too Status)	Clocent Oral Suspension of Decent Pharma (Reg#097877)
	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	
291	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(G5B-AQ8-ERH9, 2026-02-08)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FON FORD 100% POWDER**
	Label Claim	Each gm contains: Trichlorfon.....1000 mg (as per innovator’s specification)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 12gm,100 GM, 250 GM, 500 GM, 1 KG-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Harry phon 100 W/S Powder (109122)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
292	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(Z84-4HD-AWRR, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**FORD C LYTE ORAL POWDER**
	Label Claim	Each 1000g Contains:- Vitamin-C.....200g Asprin.....67g Potassium Chloride.....3g Sodium Citrate.....7g (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	CLORICOX WATER SOLUBLE POWDER (075702)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
293	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**GHAZALI BROTHERS** 1ST FLOOR AZZAINAB COURT CAMPBELL STREET

		(629)
	Application Form Dy. No / Tracking ID & date of submission	(NGE-ZZ4-721H, 2026-02-17)
	Detail of Fee Submitted	313500, 2026-02-16,
	The proposed proprietary name / brand name	**PENIFORT (4 MEGA)**
	Label Claim	Each vial contains: Penicillin G Procaine 3000000IU Benzylpenicillin Sodium 1000000IU
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	10 VIALS/BOX-De-Controlled
	Shelf Life (Unit)	36 MonthSTORE BELOW 30C. PROTECT FROM LIGHT
	For generic drugs (me-too Status)	PENISEL-40 DRY POWDER INJECTION REG NO. 080956
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	HEBEI LIHUA PHARMACEUTICAL CO., LTD-NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, CHINA-China
	Name, address of Marketing Authorization Holder:	HEBEI LIHUA PHARMACEUTICAL CO., LTD, NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, 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	
	FSC issued by relevant Body i.e., Agriculture and Rural affair Bureau of respective province of China. Manufacturer follows innovator specification.	
	Decision	
	Approved Approved, as per current import policy. The importer shall submit original legalized CoPP/ GMP & FSC and letter of Authorization before issuance of the registration certificate.	
294	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**GHAZALI BROTHERS** 1ST FLOOR AZZAINAB COURT CAMPBELL STREET **(629)**
	Application Form Dy. No / Tracking ID & date of submission	(468-9SD-YQMQ, 2026-03-14)
	Detail of Fee Submitted	313500, 2026-01-16,
	The proposed proprietary name / brand name	**GENSOL 10% INJECTION 100ML**
	Label Claim	Each ML contains: Gentamicin (as gentamicin sulfate).....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 VIAL (100ML) / BOX-De-Controlled
	Shelf Life (Unit)	3 YearSTORE BELOW 30C. PROTECT FROM LIGHT
	For generic drugs (me-too Status)	G ONE 10% LIQUID INJECTION
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	HEBEI LIHUA PHARMACEUTICAL CO., LTD-NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, CHINA-China
	Name, address of Marketing Authorization Holder:	HEBEI LIHUA PHARMACEUTICAL CO., LTD, NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, 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 Approved, as per current import policy. The importer shall submit original legalized CoPP/ GMP, FSC and letter of Authorization before issuance of the registration certificate.	
295	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(V2Q-XUZ-L1WX, 2026-02-08)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**MINRO FORD ORAL POWDER**
	Label Claim	Each Kg contains: - Vitamin A.....0.8gm Vitamin D3.....0.16gm Vitamin E.....0.38gm Vitamin B1..... 1 gm 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 Dibasic Calcium Phosphate.....150gm Sodium Chloride.....120gm Vitamin B6.....4gm (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm, 12gm,100 GM, 250 GM, 500 GM, 1 KG, 25 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Min Rold Water Soluble Powder (109284)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The

		Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
296	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**westmont pharmaceutical industry** mini industrial estate, G.T road Gujar Khan, Rawalpindi. **(000631)**
	Application Form Dy. No / Tracking ID & date of submission	(575-NAR-6BZV, 2026-04-16)
	Detail of Fee Submitted	38700, 2026-04-15,
	The proposed proprietary name / brand name	**NEMO-70 Oral Powder**
	Label Claim	Each 100g contains Neomycin sulphate 70g
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	100g, 250g, 500g, 1000g-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30˚C. Store in a dry place. Protect from heat and light. Keep all medicine out of reach of children.
	For generic drugs (me-too Status)	NEMOCIN-70
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Compliant with cGMP
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
297	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**Oxford Health Care** Plot No.12 & 13 Street No SS1, RCCI Industrial Estate Rawat Rawalpindi **(001018)**
	Application Form Dy. No / Tracking ID & date of submission	(7RL-ZVB-ZRR4, 2026-02-14)
	Detail of Fee Submitted	38700, 2026-02-06,
	The proposed proprietary name / brand name	**OLIO-BATE ORAL POWDER**
	Label Claim	Each gm Contains:- Amporlium HCl ..... 200mg. Ethopabate..... 20mg. (As Per Innovators Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 gm, 250 gm, 500 gm, 1 kg-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	CLORICOX WATER SOLUBLE POWDER (075702)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring

		compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
298	Case Category	New License (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(GNV-1MR-L2AX, 2026-04-03)
	Detail of Fee Submitted	38700, 2026-03-12,
	The proposed proprietary name / brand name	**Levasen Drench**
	Label Claim	Each 100 ml contains:- Closantel .....5% Levamisole HCl..... 1.5% (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml, 500 ml, 1000 ml-De-Controlled
	Shelf Life (Unit)	2 YearSTORE BELOW 25°C.
	For generic drugs (me-too Status)	Zentol Plus Suspension Reg. # 062132
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	"Our firm maintains a 'Highly Satisfied' GMP compliance status, as officially recognized by the Drug Regulatory Authority of Pakistan (DRAP)."
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
299	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**NeoTech Pharmaceuticals Pvt Ltd** 28-km Gujranwala to Lahore chak hinda kamoke ,Gujranwala **(000929)**
	Application Form Dy. No / Tracking ID & date of submission	(1AM-MPZ-WAWB, 2026-04-04)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**Hepamarine Oral Suspension**
	Label Claim	Each 100ml contains: Silymarin .....2100mg Vitamin E 1500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter-De-Controlled,10 Liter-De-Controlled,2.5 Liter-De-Controlled,25 Liter-De-Controlled,5 Liter-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Yearcool and dry places
	For generic drugs (me-too Status)	Liver Guard Oral Suspension ... Alina Combine Pharmaceuticals ....Each 100ml

		contains.....Silymarin .....2100mg and Vitamin E.....1500 mg.... Reg...058871
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The certificate is valid for three years from the date of inspection. Responsibility to maintain quality of Good Manufacturing Standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drugs act, 1976 and th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
300	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**NeoTech Pharmaceuticals Pvt Ltd** 28-km Gujranwala to Lahore chak hinda kamoke ,Gujranwala **(000929)**
	Application Form Dy. No / Tracking ID & date of submission	(QL1-QVT-VUAY, 2026-04-04)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**Virginamix Super Powder**
	Label Claim	Each 100 gm contains: Vitamin D3.....2gm Vitamin E.....9gm Choline Chloride....100gm L-Lysine.....25gm DL-Methionine....50gm Virginiamycin.....12gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,10kg-De-Controlled,2.5kg-De-Controlled,25kg-De-Controlled,500gm-De-Controlled,5kg-De-Controlled
	Shelf Life (Unit)	2 Yearcool and dry places
	For generic drugs (me-too Status)	Supercine TM Powder.... Leads Pharmaceuticals Reg.019946 ..... Each 1000gm Contains:..... Vitamin D3.....2gm and Vitamin E.....9gm and Choline Chloride....100gm....and Lysine....
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The certificate is valid for three years from the date of inspection. Responsibility to maintain quality of Good Manufacturing Standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drugs act, 1976 and th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
301	Case Category	Routine (Hafiz Muhammad Jawad Ali)
	Name, address of Applicant.	**GHAZALI BROTHERS** 1ST FLOOR AZZAINAB COURT CAMPBELL STREET

		(629)
	Application Form Dy. No / Tracking ID & date of submission	(VE5-YN8-98QM, 2026-04-14)
	Detail of Fee Submitted	313500, 2026-04-14,
	The proposed proprietary name / brand name	**STREPTOVET 5GM**
	Label Claim	Each vial contains: Streptomycin (as Streptomycin Sulfate).....5G Penicillin G Procaine.....1500000IU Benzylpenicillin Sodium.....500000IU
	Reference to Finished product specifications	Manufacturers Specification
	Proposed Pack Size	10 VIALS/BOX-De-Controlled
	Shelf Life (Unit)	3 YearSTORE BELOW 30C. PROTECT FROM LIGHT
	For generic drugs (me-too Status)	STREPTOCIN 5GM INJECTION
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	HEBEI LIHUA PHARMACEUTICAL CO., LTD-NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, CHINA-China
	Name, address of Marketing Authorization Holder:	HEBEI LIHUA PHARMACEUTICAL CO., LTD, NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, 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 Approved, as per current import policy. The importer shall submit original legalized CoPP, GMP, FSC and letter of Authorization before issuance of the registration certificate.	
302	Case Category	Routine (Haleema Sharif)
	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	(ZUJ-G4P-ZS3B, 2024-09-02)
	Detail of Fee Submitted	30000.0, 2024-07-30,
	The proposed proprietary name / brand name	**Taxidol-P Tablets**
	Label Claim	Each film coated tablet contains: Paracetamol.....650mg Tramadol HCl.....75mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)As per zone-IVA
	For generic drugs (me-too Status)	Tonoflex-P Forte Tablet
	Pharmacotherapeutic Group of (API)	Analgesic
	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 (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	Approved in Spain
	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	

303	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(X6Z-J8R-D1YJ, 2025-12-12)
	Detail of Fee Submitted	38700, 2025-10-03,
	The proposed proprietary name / brand name	**Vee-Cat 100mg/2ml Injection**
	Label Claim	Each ml contains: Ketamine as HCl .....50mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2ml x 5's , 2ml x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Attached Module I P1.5.8
	Pharmacotherapeutic Group of (API)	General anesthetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Supriya Lifescience Ltd.
	Detail of stability batches of drug product	Attached M III 3.2 P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached M III 3.2 P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached Module III 3.2. P.2.2.1 (B)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached Module III P 3.2. S.7
	The status in reference regulatory authorities	Attached Module I P 1.5.9
	GMP status of the firm	Attached Module I P 1.3.4
	Evidence of approval of manufacturing facility	Attached Module I P 1.3.4
	Evaluation Remarks	

Query	Response of firm
Please share link of any reference product having EDTA in it.	Compatibility studies with EDTA demonstrated satisfactory results, confirming its suitability for incorporation into the formulation. EDTA has therefore been included as a chelating agent and preservative enhancer, contributing to the control of

		trace metal ions and supporting the overall stability and microbiological quality of the finished product.

Decision

Deferred

Registration Board decided to defer the case for the following:

1. Evidence of any reference product having EDTA in it.

2. List of approved API's of Drug Substance Manufacturer by the relevant Regulatory Authority of country of Origin.

304	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(U3S-L5E-HZLA, 2025-12-12)
	Detail of Fee Submitted	38700, 2025-10-03,
	The proposed proprietary name / brand name	**Vee-Cat 500mg/10ml Injection**
	Label Claim	Each ml contains: Ketamine as HCl 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10ml x 1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Attached Module I P1.5.8
	Pharmacotherapeutic Group of (API)	General anesthetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Supriya lifescience limited
	Detail of stability batches of drug product	Attached M III 3.2 P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached M III 3.2 P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached Module III 3.2. P.2.2.1 (B)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached Module III P 3.2. S.7
	The status in reference regulatory authorities	Attached Module I P 1.5.9
	GMP status of the firm	Attached Module I P 1.3.4
	Evidence of approval of manufacturing facility	Attached Module I P 1.3.5

Evaluation Remarks

Query	Response of firm
Please share link of any reference product having EDTA in it.	Compatibility studies with EDTA demonstrated satisfactory results, confirming its suitability for incorporation into the formulation. EDTA has therefore been included as a chelating agent and preservative enhancer, contributing to the control of trace metal ions and supporting the overall stability and microbiological quality of the finished product.

Decision

Deferred

Registration Board decided to defer the case for the following:

	1. Evidence of any reference product having EDTA in it. 2. List of approved API's of Drug Substance Manufacturer by the relevant Regulatory Authority of country of Origin.	
305	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	(R3W-9QN-AWJR, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Metson 50mcg Nasal Spray**
	Label Claim	Each Spray Contains: Mometasone Furoate Monohydrate eq.to Mometasone furoate .....50mcg (Product complies BP 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)	Hivate Nasal Spray by Saffron Pharma
	Pharmacotherapeutic Group of (API)	Nasal corticosteroids
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Form 6
	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
	GMP status of the firm	--
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) Section is approved of manufacturer as letter submitted in dossier
	Evaluation Remarks	
	Application was evaluated and few deficiencies were conveyed to the firm to which firm has informed that The data of said product has been approved in DRB 359th Meeting. You're requested to please consider our product in cross referred category.	
	Decision	
	Approved Subject to submission of Declaration that Applicant will adopt same source of drug substance, drug product formulation, specifications and container closure system.	
306	Case Category	Routine (Haleema Sharif)
	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	(QEP-GJV-EQS1, 2024-09-30)

	Detail of Fee Submitted	93000.0, 2024-09-21,
	The proposed proprietary name / brand name	**METSON 50mcg Nasal Drops**
	Label Claim	Each Spray Contains: Mometasone Furoate Monohydrate eq.to Mometasone furoate .....50mcg (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)Stability 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)	Hivate Nasal Spray Each actuation contains:- MOMETASONE FUROATE BP ……..50ug Saffron Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	M/S Winbrains Research Laboratories, -Plot no. 69/1, Block B, Phase I & II, Industrial Estate, Hattar, KPK -
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	-
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per conditions of zone Iva
	The status in reference regulatory authorities	Approved in USFDA, MHRA
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-10-2022 (Winbrains
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) is approved.
	Evaluation Remarks	
	Application was evaluated and few deficiencies were conveyed to the firm to which firm has informed that The data of said product has been approved in DRB 359th Meeting. You're requested to please consider our product in cross referred category.	
	Decision	
	Approved Subject to submission of Declaration that Applicant will adopt same source of drug substance, drug product formulation, specifications and container closure system.	
307	Case Category	Routine (Haleema Sharif)
	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	(HB6-A7M-Q69P, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**METSON 50mcg Nasal Drops**
	Label Claim	Each Spray Contains: Mometasone Furoate Monohydrate eq.to Mometasone furoate .....50mcg (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)	Hivate Nasal Spray by Saffron Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Corticosteroid
	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	-
	Documents for the procurement of API with approval from DRAP (in case of Import)	-
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-
	The status in reference regulatory authorities	MHRA approved
	GMP status of the firm	GMP certificate issued on the basis of inspection conducted on 12-10-2022 (Winbrains)
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) is approved.
	Evaluation Remarks	
	Application was evaluated and few deficiencies were conveyed to the firm to which firm has informed that The data of said product has been approved in DRB 359th Meeting. You're requested to please consider our product in cross referred category	
	Decision	
	Approved Subject to submission of Declaration that Applicant will adopt same source of drug substance, drug product formulation, specifications and container closure system.	
308	Case Category	Routine (Haleema Sharif)
	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	(GZ6-WJX-JJXX, 2024-06-27)
	Detail of Fee Submitted	75000.0, 2024-06-24,
	The proposed proprietary name / brand name	**Flutas 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 Year(s)Store below 25°c
	For generic drugs (me-too Status)	Flexosone Nasal Spray Each actuation contains:- Fluticasone Propionate BP ……..50ug Reg No. 040863 Schazoo Laboratories
	Pharmacotherapeutic Group of (API)	Corticosteroid
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, hattar, KPK-
	Name & address of API manufacturer	

	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 USFDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	Eye/Ear/Nasal Drop (General) Section is approved.
	Evaluation Remarks	
	Application was evaluated and few deficiencies were conveyed to the firm to which firm has informed that The data of said product has been approved in DRB 359th Meeting (Flutas 50mcg NASAL DROPS of M/s. Welcome Pakistan Trading Pharma contract manufactured by M/s. Winbrains Research Laboratories). You're requested to please consider our product in cross referred category.	
	Decision	
	Approved Subject to submission of Declaration that Applicant will adopt same source of drug substance, drug product formulation, specifications and container closure system.	
309	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	(9T5-ZV8-HJ4H, 2024-06-03)
	Detail of Fee Submitted	75000.0, 2024-05-29,
	The proposed proprietary name / brand name	**Acotide 100mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Acotiamide HCl Hydrate.....100mg
	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)	Dyspenal Tablet 100mg of M/s Kaizen Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Gastroprokinetic agent
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-129-Sunder Industrial Estate, Raiwind Road, Lahore-
	Name & address of API manufacturer	Metrochem API Private Limited, Add: Plot No. 34B, 40B & 60B, J.N. Pharma City, Thanam Village, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, 531021 India.
	Detail of stability batches of drug product	--
	Documents for the procurement of API with approval from DRAP (in case of Import)	---
	Pharmaceutical Equivalence and Comparative Dissolution Profile	---

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	--
	The status in reference regulatory authorities	Acofide Tablets 100 mg of M/s Zeria Pharmaceutical Co., Ltd (PMDA Approved)
	GMP status of the firm	GMP certificate issued to the firm based on Inspection conducted on 03.04.2023 (M/s. Wimits)
	Evidence of approval of manufacturing facility	GMP certificate issued to the firm based on Inspection conducted on 03.04.2023 (M/s. Wimits0 indicate Tablet General section of the firm.
	Evaluation Remarks	
	Firm has informed following: Please note that we had applied for the subject product under toll manufacturing. At the time of submission of the application, the manufacturer's product approval was not available. However, the manufacturer's product has now been approved in 358th RB meeting. You are therefore kindly requested to take up our application in cross reference accordingly. But firm has not submitted undertaking that they will use the same source and fee for change of title of firm from M/s. Siam to M/s. Cell Health.	
	Decision	
	Approved Subject to submission of Declaration that Applicant will adopt same source of drug substance, drug product formulation, specifications and container closure system & Fee for change of title of firm from M/s. Siam to M/s. Cell Health.	
310	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Alliance Pharmaceuticals (pvt) Ltd** 112-A Hayatabad Industrial Estate **(000594)**
	Application Form Dy. No / Tracking ID & date of submission	(DPX-RD4-AWPG, 2024-08-22)
	Detail of Fee Submitted	30000.0, 2023-11-21,
	The proposed proprietary name / brand name	**Terbac 250 mg**
	Label Claim	Each tablet Contains Terbinafine as HCl..... 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 TABLETS-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30 C
	For generic drugs (me-too Status)	Lamisil 250 mg
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	TAGOOR LABORATORY PVT. 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)	Loan letter from M/s. Medicraft
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted but not with supporting documents
	The status in reference regulatory authorities	FDA
	GMP status of the firm	Not submitted

	Evidence of approval of manufacturing facility	section approval letter for tablet general section attached inside dossier.
	Evaluation Remarks	
	The firm has not submitted/provided the following documents and clarifications: 1. API Stability Data: Stability data for the API has not been submitted as per the conditions of Zone IVa, along with the relevant supporting documents. 2. Reference Product Excipients: A link or supporting evidence to verify that the excipients used in the reference product are similar to those in the applied product has not been provided. Alternatively, drug–excipient compatibility studies are also not submitted. 3.Verification of Chromatogram: One chromatogram was shared with the firm for verification against the submitted audit trail report. However, the firm has not provided the requested verification and has instead submitted a guideline on stability studies, which does not address the query raised.	
	Decision	
	Rejected Registration Board decided to reject the application for the following: 1. Stability data for the API has not been submitted as per the conditions of Zone IVa, along with the relevant supporting documents. 2. A link or supporting evidence to verify that the excipients used in the reference product are similar to those in the applied product has not been provided. Alternatively, drug–excipient compatibility studies are also not submitted. 3. Chromatogram submitted with stability studies have not been verified against the submitted audit trail report.	
311	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha **(000874)**
	Application Form Dy. No / Tracking ID & date of submission	(9D5-YP3-Q9ZA, 2024-05-24)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	**airrio 40/240 tablet**
	Label Claim	40/240mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1x 8's-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	Arceva by Sami
	Pharmacotherapeutic Group of (API)	Antimalarial agent
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Calyx Chemicals and Pharmaceuticals Limited
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached inside dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	FDA APPORVED
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 15.11.2022

	Evidence of approval of manufacturing facility	CLB letter indicating tablet general section is uploaded by firm

Evaluation Remarks

Query	Response of firm
Upload stability studies of drug substance Artemether as per conditions of Zone IVa	Firm has submitted only real time data at zone IVa accelerated data is still required.
Reference of any guideline that dissolution test is not needed for applied product.	International pharmacopeia omits dissolution test for artemether & lumifantrine, also FDA dissolution data base not include artenmether & lumifantrine in dissolution data. **Firm is performing Disintegration test.
COA of imported lots of API.	Firm has submitted COA of other lots along with clearance certificate. **In dossier DRAP attested invoice was already attached

Decision

Deferred

Registration Board decided to defer the case for the following:

1. Submission of stability studies of drug substance Artemether at accelerated condition.

2. Clarification regarding drug substance/ API lot used in stability studies of applied formulation along with COA of imported API as firm has submitted had documents for two consignments of API, which are inconsistent with one another.

312	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Winlet Pharmaceuticals (Pvt) Ltd.** 30-Km, Lahore Sargodha Raod, Sargodha **(000874)**
	Application Form Dy. No / Tracking ID & date of submission	(44D-UP7-AWGD, 2024-05-24)
	Detail of Fee Submitted	30000.0, 2024-04-02,
	The proposed proprietary name / brand name	**Airrio 80/480 tablet**
	Label Claim	80/480 mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1 x 6,s-As per SRO
	Shelf Life (Unit)	2 Year(s)Below 30 °C
	For generic drugs (me-too Status)	Arceva by Sami
	Pharmacotherapeutic Group of (API)	Anti-Malarial
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Calyx Chemicals and Pharmaceuticals Limited
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	-
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted only real time
	The status in reference regulatory authorities	FDA APPORVED
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 25.11.2022

	Evidence of approval of manufacturing facility	CLB letter indicating tablet general section is submitted by firm

Evaluation Remarks

Query	Response of firm
Upload stability studies of drug substance Artemether as per conditions of Zone IVa	Firm has submitted only real time data at zone IVa accelerated data is still required.
Reference of any guideline that dissolution test is not needed for applied product.	International pharmacopeia omits dissolution test for artemether & lumifantrine, also FDA dissolution data base not include artenmether & lumifantrine in dissolution data. **Firm is performing Disintegration test.
COA of imported lots of API.	Firm has submitted COA of other lots along with clearance certificate. **In dossier DRAP attested invoice was already attached

Decision

Deferred

Registration Board decided to defer the case for the following:

1. Submission of stability studies of drug substance Artemether at accelerated condition.

2. Clarification regarding drug substance lot used in stability studies of applied formulation along with COA of imported lot of API as firm has submitted two import documents inconsistent with one another.

313	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Alliance Pharmaceuticals (pvt) Ltd** 112-A Hayatabad Industrial Estate **(000594)**
	Application Form Dy. No / Tracking ID & date of submission	(NUW-1T7-2Y1S, 2024-10-09)
	Detail of Fee Submitted	37000.0, 2024-09-20,
	The proposed proprietary name / brand name	**Terbac 125mg tab**
	Label Claim	Each Tablet Contains: Terbinafine as HCl.....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10s-As per SRO
	Shelf Life (Unit)	2 Year(s)30 C
	For generic drugs (me-too Status)	Lamisil
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	
	Detail of stability batches of drug product	Submitted for three batches
	Documents for the procurement of API with approval from DRAP (in case of Import)	Loan letter from M/s. Medicraft
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted but not with supporting documents
	The status in reference regulatory authorities	Terbinol Tablets USFDA. MHRA approved
	GMP status of the firm	Not submitted

	Evidence of approval of manufacturing facility	section approval letter for tablet general section attached inside dossier.
	Evaluation Remarks	
	The firm has not submitted/provided the following documents and clarifications: 1. API Stability Data: Stability data for the API has not been submitted as per the conditions of Zone IVa, along with the relevant supporting documents. 2. Reference Product Excipients: A link or supporting evidence to verify that the excipients used in the reference product are similar to those in the applied product has not been provided. Alternatively, drug–excipient compatibility studies are also not submitted. 3.Verification of Chromatogram: One chromatogram was shared with the firm for verification against the submitted audit trail report. However, the firm has not provided the requested verification and has instead submitted a guideline on stability studies, which does not address the query raised.	
	Decision	
	Rejected Registration Board decided to reject the application for the following: 1. Stability data for the API has not been submitted as per the conditions of Zone IVa, along with the relevant supporting documents. 2. A link or supporting evidence to verify that the excipients used in the reference product are similar to those in the applied product has not been provided. Alternatively, drug–excipient compatibility studies are also not submitted. 3. Chromatogram submitted with stability studies have not been verified against the submitted audit trail report.	
314	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**VENUS PHARMA** 23-KM MULTAN ROAD, LAHORE **(000300)**
	Application Form Dy. No / Tracking ID & date of submission	(YXS-7UJ-5HNV, 2026-04-02)
	Detail of Fee Submitted	38700, 2025-10-03,
	The proposed proprietary name / brand name	**Vee-Cat 250mg/5ml Injection**
	Label Claim	Each ml contains: Ketamine as HCl 50mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	5ml x 5's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Attached Module I P1.5.8
	Pharmacotherapeutic Group of (API)	General anesthetic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Supriya lifescience limited
	Detail of stability batches of drug product	Attached M III 3.2 P.8
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached M III 3.2 P.8
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached Module III 3.2. P.2.2.1 (B)
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached Module III P 3.2. S.7
	The status in reference regulatory authorities	Attached Module I P 1.5.9
	GMP status of the firm	Attached Module I P 1.3.4
	Evidence of approval of manufacturing facility	Attached Module I P 1.3.5

	Evaluation Remarks	
	The firm has submitted only Module 1 of Form 5F, referring to Letter No. 14-1/2022-PEC dated 06 August 2025, wherein the Authority approved revised submission procedures for liquid injectable products having the same strength per unit but varying fill volumes. The firm has stated that a complete Form 5F (CTD) dossier for the same formulation and composition has already been submitted under Tracking ID X6Z-J8R-D1YJ.	
	Decision	
	Deferred Registration Board decided to defer the case for the following: 1. Evidence of any reference product having EDTA in it. 2. List of approved API's of Drug Substance Manufacturer by the relevant Regulatory Authority of country of Origin. 3. Evidence of approval of reference product and Me Too product in applied Strength i.e. 250mg/5ml.	
315	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Global Pharmaceuticals Pvt Ltd** Plot Number 204-205 Industrial Triangle Kahuta Road **(000417)**
	Application Form Dy. No / Tracking ID & date of submission	(D15-M4Z-ME2D, 2024-08-26)
	Detail of Fee Submitted	75000.0, 2024-08-19,
	The proposed proprietary name / brand name	**TRAMICOX 56mg/44mg TABLETS**
	Label Claim	Each Film-coated Tablet Contains: Celecoxib .....56mg Tramadol HCl.....44mg (INNOVATOR SPECS)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C.
	For generic drugs (me-too Status)	NOT APPLICABLE
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	NAME; AARTI DRUGS LIMITED Address: . Plot No. W 71 (B) and 72 (B) M.I.D.C., Tarapur, Tal. - Palghar, Dist.: Thane - 401 506, Maharashtra. INDIA.,Name: M/s. Aurobindo Pharma Limited Address: Plot No: 02, Maitrivihar, Ameerpet, Hyderbad -500038, Tenagana, INDIA
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has submitted ADC attested invoice for one API and clearance certificate for the other
	Pharmaceutical Equivalence and Comparative Dissolution Profile	--
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	US-FDA

	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted o n 2.05.2024
	Evidence of approval of manufacturing facility	GMP certificate issued to the firm based on inspection conducted o n 2.05.2024 indicate tablet general section of the firm
	Evaluation Remarks	
	For Board consideration, the following points are noted: The applied product is manufactured using Celecoxib sourced from M/s. Aarti Drugs Limited and Tramadol Hydrochloride sourced from M/s. Aurobindo Pharma Limited. The innovator product, SEGLENTIS® (Celecoxib and Tramadol Hydrochloride tablets), contains a co-crystal of celecoxib and tramadol hydrochloride with a molecular weight of 681.2, in a 1:1 molecular ratio. The proposed product, however, does not contain the celecoxib–tramadol hydrochloride co-crystal, raising a concern regarding its equivalence to the innovator product. As per the available US FDA database, SEGLENTIS® is listed as discontinued. Further, as per the available Spanish regulatory database, its marketing authorization has reportedly been revoked. The manufacturer was requested to submit valid GMP certificates for both drug-substance manufacturers other than export purpose. However, the applicant submitted only the Drug Mmanufcaturing License for celecoxib. Furthermore, Celecoxib is not included in the list of approved products submitted/available for M/s. Aarti Drugs Limited, which raises an additional concern regarding the regulatory status and manufacturing authorization of the proposed source of celecoxib.	
	Decision	
	Rejected Registration Board decided to reject applied formulation for following reasons:' • The innovator product, SEGLENTIS® (Celecoxib and Tramadol Hydrochloride tablets), contains a co-crystal of celecoxib and tramadol hydrochloride with a molecular weight of 681.2, in a 1:1 molecular ratio. The proposed product, however, does not contain the celecoxib–tramadol hydrochloride co-crystal, raising a concern regarding its equivalence to the innovator product. • As per the available US FDA database, SEGLENTIS® is listed as discontinued. Further, as per the available Spanish regulatory database, its marketing authorization has reportedly been revoked. • The manufacturer was requested to submit valid GMP certificates for both drug-substance manufacturers other than export purpose. However, the applicant submitted only the Drug Manufacturing License for celecoxib. Furthermore, Celecoxib is not included in the list of approved products submitted/available for M/s. Aarti Drugs Limited, which raises an additional concern regarding the regulatory status and manufacturing authorization of the proposed source of celecoxib.	
316	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Scotmann Pharmaceuticals** Plot #5D , Industrial Area, I-10/3 Islamabad **(000498)**
	Application Form Dy. No / Tracking ID & date of submission	(JX1-U9N-92MT, 2024-06-05)
	Detail of Fee Submitted	75000.0, 2024-01-16,
	The proposed proprietary name / brand name	**Naifa Tablet 25mg**
	Label Claim	Each film coated tablet contains: Dexketoprofen trometamol eq. to Dexketoprofen..... 25mg (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
	Shelf Life (Unit)	2 Year(s)Below 25 °C

	For generic drugs (me-too Status)	Dexito 25mg Tablet, Manufactured by: S.J & G. Fazul Ellahie (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Analgesic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Source of Drug Substance: Hunan Jiudian Hongyang Pharmaceutical Co., Ltd. Address: Tongguan Circular Economy Industrial base, Wangcheng Economic and Technological Development Zone, Hunan, China
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	Firm has attached DRAP attested invoice.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted but not with supporting documents
	The status in reference regulatory authorities	Keral Tablets 25mg, Registered in Medicines and Healthcare Regulatory Agency (MHRA)
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 22.02.2024
	Evidence of approval of manufacturing facility	GMP certificate issued to the firm based on inspection conducted on 22.02.2024 indicate tablet general section of the firm.

Evaluation Remarks

Query	Response
In section 3.2.s.7 i.e. protocol of stability studies conditions is temperature 25oC, 60%RH how stability summary sheets are according to zone Iva conditions, clarify. upload audit trail report. Supporting documents of stability studies like raw data sheets, chromatograms from drug substance manufacturer so to verify that stability studies of drug substance are as per zone IVA conditions.	This was a typographic mistake. Revised Stability Protocol is attached. We have requested the supporting documents of stability studies like chromatograms, raw data sheets but the supplier is not responded till today. Once we have received the requested data from supplier, we will provide you. kindly include this product for the up-coming agenda of the meeting of DRB.
Drug excipient compatibility studies OR evidence that excipients of applied product are similar to innovator product as submitted studies are forced degradation studies not drug excipient compatibility studies.	The firm has submitted drug–excipient compatibility studies only for magnesium stearate; however, compatibility studies for the other excipients used in the formulation have not been submitted.

Decision

Deferred

Registration Board decided to defer the case for the following:

1. Supporting documents of stability studies like chromatograms, raw data sheets, audit trail etc by drug substance manufacturer.

2. Drug–excipient compatibility studies for all other excipients used in the applied formulation.

317	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd.** Kalalwala Stop, 20 Km Lahore-Jaranwala Road, District Sheikhupura **(000019)**

Application Form Dy. No / Tracking ID & date of submission	(9W5-T7U-LVJL, 2024-07-24)
Detail of Fee Submitted	30000.0, 2021-10-26,
The proposed proprietary name / brand name	**Eyecol Eye Drops**
Label Claim	Each ml Contains Polyethylene Glycol 400 USP.....4 mg Propylene Glycol BP .....3 mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1X15 ml -As per SRO
Shelf Life (Unit)	2 Year(s)1. Store in a cool and dry Place 2. Protect from heat light and moisture
For generic drugs (me-too Status)	Systane (Novartis)
Pharmacotherapeutic Group of (API)	Eye wash
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	DOW CHEMICAL PACIFIC (SINGAPORE)PTE LTD,LOTTE CHEMICAL CORPORATION
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 Local purchase invoice for one API/drug substance and DHL documents for other API.
Pharmaceutical Equivalence and Comparative Dissolution Profile	PE; submitted
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Provided as per conditions of zone IVa
The status in reference regulatory authorities	Systane Lubricant Eye Drops (Alcon Laboratories USA)
GMP status of the firm	Not submitted
Evidence of approval of manufacturing facility	Section approval letter dated 26th February 2016 indicated eye/nasal drop section.

Evaluation Remarks

The firm has submitted an ISO certification instead of a GMP certificate. ISO certification alone does not establish compliance with applicable pharmaceutical GMP requirements. The submitted documentation does not clearly establish that the material is of pharmaceutical grade. The relevant pharmaceutical grade/specification is not clearly mentioned in the documents submitted by the drug substance manufacturer. Clearance certificate has not been submitted by the firm for the material under consideration instead procurement invoice and DHL documents are submitted The manufacturer has not provided evidence of testing for residual solvents as it is not mentioned in COA. Audit trail records have not been provided/are not available for review, as firm has used UV and titration method, limiting verification of the integrity and traceability of the relevant data and data

Decision

Deferred

Registration Board decided to defer the case for the following:

- Valid GMP certificate of both drug substance manufacturer, as ISO certification alone does not establish compliance with applicable pharmaceutical GMP requirements.
- The submitted documentation does not clearly establish that the material is of pharmaceutical grade. The relevant pharmaceutical grade/specification is not clearly mentioned in the documents submitted by the drug substance manufacturer.

- Clearance certificate OR DRAP attested invoice has not been submitted by the firm for the material under consideration instead procurement invoice and DHL documents are submitted
- The manufacturer has not provided evidence of testing for residual solvents as it is not mentioned in COA of drug substances.

318	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**AUSPEC PHARMACEUTICALS PVT LTD** 21, Km, Raiwind Road, Lahore. **(000964)**
	Application Form Dy. No / Tracking ID & date of submission	(7XQ-ZRP-2MS1, 2024-09-15)
	Detail of Fee Submitted	75000.0, 2024-02-06,
	The proposed proprietary name / brand name	**Combat 500mcg/ml Injection**
	Label Claim	Each 1ml ampoule Contains: Mecobalamin....500mcg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml x 10's/As per SR-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	Cyno-12 Injection 500mcg/ml by Aulton Pharmaceutical, Hattar
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	AULTON PHARMACEUTICAL-84/1, Block A, Phase 5, Industrial Estate, Hattar-Pakistan-
	Name & address of API manufacturer	M/s UNICHEM PHARMACEUTICALS LIMITED. by Plot No 310, Industrial triangle, Kahuta road, Islamabad-Pakistan.
	Detail of stability batches of drug product	-
	Documents for the procurement of API with approval from DRAP (in case of Import)	-
	Pharmaceutical Equivalence and Comparative Dissolution Profile	-
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	-
	The status in reference regulatory authorities	METHYCOBAL Solution for injection by Eisai Co. Ltd, 4-6-10 Koishikawa, Bunkyo-ku, Tokyo, Japan.
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	-

Evaluation Remarks

Query	Response
Audit Trial report of 21CFR Compliant system.	At the time of CTD dossier preparation and submission, the computerized system used for generation, processing, and management of analytical data was not 21 CFR Part 11compliant. This fact was clearly declared and documented in the submitted CTD dossier. Therefore, an Audit Trail Report generated from a 21 CFR Part 11 compliant system cannot be provided for the submitted data.
Link to verify Excipients of reference Product.	The Excipient used by the reference product manufacturer is same as that of Innovator Product. SmPc Link of Innovator Product is attached which contain List of Excipients. ** however link is not submitted.

Valid GMP Certificate of Drug Substance Manufacturer.	The company has been sold. New Management has taken over and yet to apply for new GMP.
Test for residual solvents is not performed by Drug Substance manufacturer as per COA, Why?	Test for residual solvents is not performed by Drug Substance manufacturer as per COA, Because Residual Solvents Test is not mentioned in JP Monograph.
DRAP attested invoice or Clearance Certificate.	The Active Pharmaceutical Ingredient (API) is sourced from Unichem Laboratories Ltd., which is a local manufacturer and supplier. The material was procured domestically and was not imported by our company. Therefore, no import-related documents such as a DRAP-attested invoice, import clearance certificate, customs clearance documents, are available. Supporting procurement documents from the local manufacturer/supplier

Decision

Deferred

Registration Board decided to defer the case for the following:

1. To devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.

2. Valid GMP certificates of drug substance manufacturer along with letter for change in title/ management of drug substance manufacturer.

3. Link of RRA / reference product to verify excipients of reference product.

4. Justification for not performing test for residual solvents in the light relevant ICH guideline.

5. Documents confirming import of API/drug substance like DRAP attested Invoice OR clearance certificate.

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Case Category	Routine (Haleema Sharif)
Name, address of Applicant.	**UNISON CHEMICAL WORKS** POST OFFICE ARAIAN 15-km RAIWIND ROAD LAHORE **(000174)**
Application Form Dy. No / Tracking ID & date of submission	(8DY-8ET-JARJ, 2024-07-18)
Detail of Fee Submitted	30000.0, 2024-05-24,
The proposed proprietary name / brand name	**Fai-Cam 20mg Injection**
Label Claim	Each ml contains: Piroxicam... 20mg
Reference to Finished product specifications	Manufacturer Specification
Proposed Pack Size	1 x 5's-As per SRO
Shelf Life (Unit)	24 Year(s)Below 30°C
For generic drugs (me-too Status)	Pcam (Reg No 018048)
Pharmacotherapeutic Group of (API)	NSAID
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Alcon Biosciences Pvt. Limited
Detail of stability batches of drug product	Submitted for three batches
Documents for the procurement of API with approval from DRAP (in case of Import)	-

	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	France
	GMP status of the firm	-
	Evidence of approval of manufacturing facility	Evidence of Liquid Injectable ampoule and vial (general) is submitted by the firm
	Evaluation Remarks	
	Application is still incomplete for the following: The firm initially submitted the Certificate of Analysis (COA) of Piroxicam (USP) Working Standard, Batch No. PCM/WS/18/06, valid up to October 2019. In response to the query, the firm subsequently submitted a COA of a different working standard having a retest date of December 2019. However, the potency of the working standard used in the analytical calculations does not correspond to the potency reported in either of the submitted COAs.	
	Decision	
	Deferred Registration Board decided to defer the case for the following: Clarification regarding working standard' s lot used in testing of applied formulation along with COA of it as firm initially submitted the Certificate of Analysis (COA) of Piroxicam (USP) Working Standard, Batch No. PCM/WS/18/06, valid up to October 2019. In response to the query, the firm subsequently submitted a COA of a different working standard having a retest date of December 2019. However, the potency of the working standard used in the analytical calculations does not correspond to the potency reported in either of the submitted COAs.	
320	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(WRS-L3U-UG4V, 2024-07-23)
	Detail of Fee Submitted	30000.0, 2024-03-18,
	The proposed proprietary name / brand name	**Prical 5mcg Injection**
	Label Claim	Each ml contains:Paricalcitol .....5mcg(USP Spec)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Paristol
	Pharmacotherapeutic Group of (API)	vitamin D analogs
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	CARBOGENAMCISB.V.,Nieuweweg2a,VEENEN Netherlands
	Detail of stability batches of drug product	Submitted
	Documents for the procurement of API with approval from DRAP (in case of Import)	clearance certificate 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 USFDA. Zemplar (Paricalcitol injection) 5 mcg/mL
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 01.06.2023
	Evidence of approval of manufacturing facility	CLB letter indicating Ampoule Section SVP is submitted by the firm
	Evaluation Remarks	
	Decision	
	Approved	
321	Case Category	Routine (Haleema Sharif)
	Name, address of Applicant.	**Onyx Pharmaceuticals** 30-A small Industrial Estate mansehra **(000440)**
	Application Form Dy. No / Tracking ID & date of submission	(BW5-WPH-9G45, 2024-07-18)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**ONBAMIN**
	Label Claim	Each ml contains: Mecobalamin 500mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 25°C
	For generic drugs (me-too Status)	Flench Injection 500mcg/ml injection by TABROS PHARMA (PVT). LTD
	Pharmacotherapeutic Group of (API)	Vitamin B12
	Name, address of Manufacturing site:	Seraph Pharmaceutical-Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad-
	Name & address of API manufacturer	Mahima Life Sciences Pvt. Ltd., BST road, Ganaur, Distt. Sonepat (Haryana) INDIA
	Detail of stability batches of drug product	--
	Documents for the procurement of API with approval from DRAP (in case of Import)	--
	Pharmaceutical Equivalence and Comparative Dissolution Profile	--
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	--
	The status in reference regulatory authorities	Comezengen injection 500mcg by PMDA Japan
	GMP status of the firm	--
	Evidence of approval of manufacturing facility	CLB letter indicating Liquid injectable ampoule general is submitted by the firm
	Evaluation Remarks	
	Firm has informed that EVOCOBAL500mcg/ml Injection of M/s. Evoluation Pharmaceuticals contact manufactured by M/s. Seraph Pharma has already been approved in 351st RB meeting as per copy of minutes attached by firm.	
	Decision	
	Approved Subject to submission of Declaration that Applicant will adopt same source of drug substance, drug product formulation, specifications and container closure system.	
322	Case Category	Routine (Haleema Sharif)

	Name, address of Applicant.	**Nabiqasim Industries (Pvt) Ltd.,** Plot No. 17/24 & Plot No. 52/24, Korangi Industrial Area, Karachi. **(000105)**
	Application Form Dy. No / Tracking ID & date of submission	(E9X-TV5-57TY, 2025-03-06)
	Detail of Fee Submitted	37000.0, 2024-12-19,
	The proposed proprietary name / brand name	**Apremil Tablet 30mg**
	Label Claim	Each film-coated tablet contains: Apremilast.....30mg (Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20'-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Immunosuppressant
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Zhejiang Huayi Pharmaceutical Co., Ltd.
	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	Submitted
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted
	The status in reference regulatory authorities	Approved in USFDA (Otezla Tablet 30mg by Amgen Inc., USA) & MHRA Approved (Otezla 30 mg film-coated tablets by Amgen Limited, UK)
	GMP status of the firm	GMP certificate issued to the firm based on inspection conducted on 22.05.2023
	Evidence of approval of manufacturing facility	CLB letter indicating Tablet General section is submitted by the firm.
	Evaluation Remarks	
	Decision	
	Approved Registration Board decided to approve the application however registration letter of instant product will be processed after approval of starter pack by the Board.	
323	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(1SG-UX5-YN4T, 2026-01-05)
	Detail of Fee Submitted	97200, 2025-11-05,
	The proposed proprietary name / brand name	**Neoprox EZ**
	Label Claim	Neoprox EZ 375/20mg Tablet Each modified release tablet contains: Naproxen....375mg (enteric coated core) Esomeprazole magnesium

		trihydrate eq. esomeprazole...20mg (Immediate release layer) (As per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30°C
	For generic drugs (me-too Status)	Name of Product: Glomov, Company: Global Pharmaceuticals Pakistan, Composition: 375/20mg Tablet, Reg. No.: 109339
	Pharmacotherapeutic Group of (API)	Naproxen: NSAIDs, Esomeprazole: PPI
	Name, address of Manufacturing site:	M/s Global Pharmaceuticals Pakistan. -Plot No. 8, St. No. S-8, RCCI Industrial Estate Rawat.-
	The status in reference regulatory authorities	Vimovo tablets (USFDA)
	Detail of previous approval	Glomov 375/20mg Tablet (DRB 289)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID RJR-8PM-W3BR dated 05 December 2025.	
	Decision	
	Approved Approved	
324	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Martin Dow Marker Limited** 7, Jail Road Quetta. **(000028)**
	Application Form Dy. No / Tracking ID & date of submission	(RJB-B5R-G292, 2026-01-08)
	Detail of Fee Submitted	97200, 2025-11-05,
	The proposed proprietary name / brand name	**Neoprox EZ**
	Label Claim	Neoprox EZ 500/20mg Tablet Each modified release tablet contains: Naproxen....500mg (enteric coated core) Esomeprazole magnesium trihydrate eq. esomeprazole...20mg (Immediate release layer) (As per innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30
	For generic drugs (me-too Status)	Name of Product: Glomov Company: Global Pharmaceuticals Pakistan Composition: 500/20mg Tablet Reg. No.: 109338
	Pharmacotherapeutic Group of (API)	Naproxen: NSAIDs, Esomeprazole: PPI
	Name, address of Manufacturing site:	M/s Global Pharmaceuticals Pakistan.-Plot No. 8, St. No. S-8, RCCI Industrial Estate Rawat.-
	The status in reference regulatory authorities	Vimovo tablets (USFDA)
	Detail of previous approval	Glomov 500/20mg Tablet (DRB 289)

	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID GSY-G1B-6ESL dated 05 December 2025.	
	Decision	
	Approved Approved	
325	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar **(000995)**
	Application Form Dy. No / Tracking ID & date of submission	(ZJ6-99G-7SBZ, 2026-06-16)
	Detail of Fee Submitted	93000.0, 2025-04-22,
	The proposed proprietary name / brand name	**PROSTAM-D**
	Label Claim	Each hardgelatin capsule contains: Dutasteride (assoftgelatin capsule) ..... 0.5 mg Tamsulosinhydrochloride (as modified release pellets) .....0.4 mg As per Innovaor Spec
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25
	For generic drugs (me-too Status)	Yes
	Pharmacotherapeutic Group of (API)	Alpha-adreno receptor antagonists
	Name, address of Manufacturing site:	BiogenLife Sciences-8-km, Chakbeli Road, Rawat, Rawalpindi -
	The status in reference regulatory authorities	Medicines and Healthcare products Regulatory Agency (MHRA) Mil pharm Limited
	Detail of previous approval	DUTARIDE-T CAPSULE,335th meeting of Registration Board,
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

326	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nexus Pharma (Pvt) Ltd** Plot No. 4/19-4/36, Sector 21 Korangi Industrial Area, Karachi - Pakistan **(000421)**
	Application Form Dy. No / Tracking ID & date of submission	(Z5Z-7BE-LZ13, 2026-06-03)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**CIBAPAT**
	Label Claim	Each ml Contains: Olopatadine as Hydrochloride.....2mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 degree centigrade
	For generic drugs (me-too Status)	OCUDINE By Barrette Hodgson
	Pharmacotherapeutic Group of (API)	histamine H1 antagonist and mast cell stabilizer
	Name, address of Manufacturing site:	Winthrox Laboratories (Pvt) Ltd.-Plot No. K-219/A, Phase -II S.I.T.E., Super Highway, Karachi-
	The status in reference regulatory authorities	MHRA-Approved
	Detail of previous approval	Olopton 2mg Eye Drops, 339 DRB
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
327	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar Khan, District Rawalpindi **(000718)**
	Application Form Dy. No / Tracking ID & date of submission	(X52-U6V-T7YJ, 2026-06-24)
	Detail of Fee Submitted	97200, 2026-04-03,
	The proposed proprietary name / brand name	**E-NAP tablet**
	Label Claim	Each modified release tablets contains: Naproxen... ..... 500mg (enteric coated core) Esomeprazole as magnesium trihydrate ..... 20mg (immediate release coat) (As per *Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	28-As per SRO

	Shelf Life (Unit)	24 Month15c-30c
	For generic drugs (me-too Status)	Glomov 20/500 mg tablet by global
	Pharmacotherapeutic Group of (API)	NSAID and proton pump inhibitor
	Name, address of Manufacturing site:	Medizan Laboratories (PVT) ltd-Plot 313 industiral triangle kahuta road islamabad-
	The status in reference regulatory authorities	Vimovo delayed release tablet 20/500mg Tablets
	Detail of previous approval	Esik 500mg/20mg MR Tablets approved in PRV meeting via tracking id MD5-JST-R8LA
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID MD5-JST-R8LA dated 24 October 2025.	
	Decision	
	Approved Approved	
328	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Invictus Pharmaceuticals** Plot No. 21, 26 Street No. NS.2, National Industrial Zone Rawat, Islamabad **(000892)**
	Application Form Dy. No / Tracking ID & date of submission	(WPM-721-3G2H, 2026-06-10)
	Detail of Fee Submitted	97200, 2025-10-29,
	The proposed proprietary name / brand name	**Desohit 2.5mg/5ml Syrup**
	Label Claim	Each 5ml of syrup contains; Desloratadine 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO -As per SRO
	Shelf Life (Unit)	24 Month25°C
	For generic drugs (me-too Status)	Neo-Antial Syrup by Sami Pharma
	Pharmacotherapeutic Group of (API)	Tagoor Laboratories Private Limited Address: Plot No.: 75, H.No.: 1 – 98/3, 1st and 2nd floor, Jubilee Enclave, Hitech City, Hyderabad, Telangana,
	Name, address of Manufacturing site:	SERAPH PHARMACEUTICAL-Plot # 210, Industrial Triangle, Kahuta road, Islamabad, Pakistan-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	DESENT 2.5mg/5ml Syrup in 336th DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the	

	same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
329	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Allmed (Pvt.) Ltd** Plot # 590 & 591 Sunder Industrial Estate **(000645)**
	Application Form Dy. No / Tracking ID & date of submission	(NT7-SU8-HLUV, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Seldinamed**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Advagen Pharma limited, 666 Plainsboro Road Suite 605, Plain boro, NJ, 08536, USA
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already approved tab of eapplicaiton. Later on, the applicant informed that their cross referred product has been approved and attached registration letter alongwith fee. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
330	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Allmed (Pvt.) Ltd** Plot # 590 & 591 Sunder Industrial Estate **(000645)**
	Application Form Dy. No / Tracking ID & date of submission	(6RL-L47-9BBB, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Seldinamed**

	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Advagen Pharma limited, 666 Plainsboro Road Suite 605, Plain boro, NJ, 08536, USA
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already approved tab of eapplicaiton. Later on, the applicant informed that their cross referred product has been approved and attached registration letter alongwith fee. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
331	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Allmed (Pvt.) Ltd** Plot # 590 & 591 Sunder Industrial Estate **(000645)**
	Application Form Dy. No / Tracking ID & date of submission	(UD9-SB7-LSPE, 2025-02-13)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Seldinamed**
	Label Claim	Each Film Coated Tablet contains: Sildenafil citrate Equivalent to Sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x5's, 1 x 10's, 2 x-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Advagen Pharma limited, 666 Plainsboro Road Suite 605, Plain boro, NJ, 08536, USA
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already approved tab of eapplicaiton. Later on, the applicant informed that their cross referred product has been approved and attached registration letter alongwith fee. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is	

	being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
332	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Allmed (Pvt.) Ltd** Plot # 590 & 591 Sunder Industrial Estate **(000645)**
	Application Form Dy. No / Tracking ID & date of submission	(2GW-J8T-36ZS, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Tadalamed**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....2.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already approved tab of eapplicaiton. Later on, the applicant informed that their cross referred product has been approved and attached registration letter alongwith fee. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
333	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Allmed (Pvt.) Ltd** Plot # 590 & 591 Sunder Industrial Estate **(000645)**
	Application Form Dy. No / Tracking ID & date of submission	(SZ6-ZEE-A5BQ, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Tadalamed**

	Label Claim	Each Film coated Tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already approved tab of eapplicaiton. Later on, the applicant informed that their cross referred product has been approved and attached registration letter alongwith fee. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
334	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Allmed (Pvt.) Ltd** Plot # 590 & 591 Sunder Industrial Estate **(000645)**
	Application Form Dy. No / Tracking ID & date of submission	(UVE-6SS-VGXS, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Tadalamed**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already approved tab of eapplicaiton. Later on, the applicant informed that their cross referred product has been approved and attached registration letter alongwith fee. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same	

	source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
335	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Allmed (Pvt.) Ltd** Plot # 590 & 591 Sunder Industrial Estate **(000645)**
	Application Form Dy. No / Tracking ID & date of submission	(HXY-7DX-86N7, 2025-02-11)
	Detail of Fee Submitted	93000.0, 2024-12-23,
	The proposed proprietary name / brand name	**Tadalamed**
	Label Claim	Each Film coated Tablet contains: Tadalafil.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x4's, 1x5's, 1x10's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30C
	For generic drugs (me-too Status)	New Product
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Ajanta Pharma USA Inc., Bridgewater, NJ 08807
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected NO in the data already approved tab of eapplicaiton. Later on, the applicant informed that their cross referred product has been approved and attached registration letter alongwith fee. Accordingly, In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
336	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(GYD-A55-4WEP, 2026-06-11)
	Detail of Fee Submitted	75000.0, 22500 2024-01-04, 2025-09-18
	The proposed proprietary name / brand name	**Nefcon 1mg/ml Eye Drops**
	Label Claim	Each mL Contains: Nepafenac .....1mg (0.1%) (Product complies Innovator's Specs)

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Neplo Opthalmic Solution Alza Pharmaceuticals 081620
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Nefcon Eye Drops, DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
337	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nexus Pharma (Pvt) Ltd** Plot No. 4/19-4/36, Sector 21 Korangi Industrial Area, Karachi - Pakistan **(000421)**
	Application Form Dy. No / Tracking ID & date of submission	(RVP-E6Q-LBU4, 2026-06-22)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**LOTIMEN-T**
	Label Claim	Each ml of Ophthalmic Suspension Contains: Loteprednol Etabonate.....5mg Tobramycin.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Year15 DEGREE TO 25 DEGREE CENTIGRADE
	For generic drugs (me-too Status)	LOTETOB OPTHALMIC SUSPENSION BY HELIX PHARMA
	Pharmacotherapeutic Group of (API)	ophthalmic corticosteroids with anti-infectives
	Name, address of Manufacturing site:	WINTHROX LABORATORIES (PVT) LTD.-PLOT NO. K-219/A, PHASE-II, SITE, SUPER HIGHWAY, KARACHI-
	The status in reference regulatory authorities	USFDA APPROVED
	Detail of previous approval	LOTINON, DRB 333 MEETING
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
338	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(PTJ-6SA-EQT9, 2026-06-09)
	Detail of Fee Submitted	97200, 2026-01-22,
	The proposed proprietary name / brand name	**Esonep 500mg / 20mg Tablet**
	Label Claim	Each modified release tablet contains: - Naproxen (Enteric coated core)....500mg Esomeprazole as magnesium trihydrate (Immediate release coat) .....20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-As per SRO,4 x 7's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	Glomov 500/20 mg Tablet, Global Pharmaceuticals (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Gastroprotective NSAID
	Name, address of Manufacturing site:	DeMont Research Laboratories Pvt. Ltd.-20-km, Lahore Sharikpur Road, Sheikhupura -
	The status in reference regulatory authorities	VIMOVO 500/20mg Modified release tablets, MHRA
	Detail of previous approval	Nap-E Tablet, Meeting # 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
339	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nexus Pharma (Pvt) Ltd** Plot No. 4/19-4/36, Sector 21 Korangi Industrial Area, Karachi - Pakistan **(000421)**
	Application Form Dy. No / Tracking ID & date of submission	(HDL-XZJ-DEPS, 2026-06-18)
	Detail of Fee Submitted	97200, 2026-02-04,

	The proposed proprietary name / brand name	**TOBRAMEN**
	Label Claim	Each ml Contains: Tobramycin.....3mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Year2 DEGREE TO 25 DEGREE CENTIGRADE
	For generic drugs (me-too Status)	TOBREX OPHTHALMIC SOLUTION BY NOVARTIS
	Pharmacotherapeutic Group of (API)	AMINOGLYCOSIDE ANTIBIOTIC
	Name, address of Manufacturing site:	WINTHROX LABORATORIES (PVT) LTD.-PLOT NO. K-219/A, PHASE-II, SITE, SUPER HIGHWAY, KARACHI-
	The status in reference regulatory authorities	USFDA APPROVED
	Detail of previous approval	TYCIN, 333 DRB MEETING
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
340	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(V3A-TJD-Q8LZ, 2026-04-15)
	Detail of Fee Submitted	97200, 2026-02-24,
	The proposed proprietary name / brand name	**COXTO 120MG TABLET**
	Label Claim	Each Film Coated Tablet Contains: Etoricoxib.....120mg (Product complies Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25c
	For generic drugs (me-too Status)	ETOXIB 120MG TABLET
	Pharmacotherapeutic Group of (API)	NSAID Selective inhibitor of cyclooxygenase-2 (COX-2)
	Name, address of Manufacturing site:	Welmark Pharmaceuticals-Plot No. 122, Phase-V, Block-B, Industrial Estate, Hattar, KPK-
	The status in reference regulatory authorities	UK MHRA Approved
	Detail of previous approval	OTORN TABLET, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
341	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(VE2-HY7-9P8S, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	**Tolvip Tablets 15mg**
	Label Claim	Each uncoated tablet contains: Tolvaptan.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2x10's-As per SRO,3x10's-As per SRO,4x10's-As per SRO,5x10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Tolvaptal Tablets by Kaizen Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Diuretics, Vasopressin Antagonists
	Name, address of Manufacturing site:	M/s Genome Pharmaceuticals (Pvt.) Ltd-16/1, Phase-IV, Industrial Estate, Hattar, Haripur.-Pakistan
	The status in reference regulatory authorities	Jynarque Tablet by US-FDA
	Detail of previous approval	Meeting No. 323, Reg No. 120328
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
342	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(RXJ-UUU-A3VN, 2026-05-11)

	Detail of Fee Submitted	97200, 2026-02-16,
	The proposed proprietary name / brand name	**Tolvip Tablets 30mg**
	Label Claim	Each uncoated tablet contains: Tolvaptan.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2x10's-As per SRO,3x10's-As per SRO,4x10's-As per SRO,5x10's-As per SRO
	Shelf Life (Unit)	24 Month(s)Store below 30°C
	For generic drugs (me-too Status)	Tolvaptal Tablets by Kaizen Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Diuretics, Vasopressin Antagonists
	Name, address of Manufacturing site:	M/s Genome Pharmaceuticals (Pvt.) Ltd.-16/1, Phase-IV, Industrial Estate, Hattar, Haripur.-Pakistan
	The status in reference regulatory authorities	Jynarque Tablet by US-FDA
	Detail of previous approval	Meeting No. 323, Reg No. 120329
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
343	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(GE1-XHP-VUHE, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-01-21,
	The proposed proprietary name / brand name	**Citipenem Injection 1g IV**
	Label Claim	Each vial contains: Meropenem trihydrate eq. to Meropenem.....1g (Blended with sodium carbonate) (As per USP specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore in cool and dry place below 30°C.
	For generic drugs (me-too Status)	Merrem Injection by Global Pharmaceutical
	Pharmacotherapeutic Group of (API)	Carbapenenm Antibiotic
	Name, address of Manufacturing site:	M/s Global Pharmaceuticals (Pvt.) Limited-Plot No.204-205, Industrial Triangle, Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Merrem Injection 1g Pfizer New York,USA, USFDA Approved.
	Detail of previous approval	Merrem Injection of Global Pharmaceutical
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
344	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Pasteur & Fleming Pharma** Plot # 70A , Phase -3, Road No-04, Industrial Estate Hattar, K.P.K. Pakistan **(000945)**
	Application Form Dy. No / Tracking ID & date of submission	(DXH-WR6-64JH, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-01-22,
	The proposed proprietary name / brand name	**Eprax 500mg / 20mg Tablet**
	Label Claim	Each modified release tablet contains: - Naproxen (Enteric coated core)....500mg Esomeprazole as magnesium trihydrate (Immediate release coat) .....20mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2 x 7's-As per SRO,4 x 7's-As per SRO
	Shelf Life (Unit)	2 Yearstore below 30 degree centigrade
	For generic drugs (me-too Status)	Glomov 500/20 mg Tablet, Global Pharmaceuticals (Pvt.) Ltd
	Pharmacotherapeutic Group of (API)	Gastroprotective NSAID
	Name, address of Manufacturing site:	DeMont Research Laboratories Pvt. Ltd.-20-km, Lahore Sharikpur Road, Sheikhupura -
	The status in reference regulatory authorities	VIMOVO 500/20mg Modified release tablets, MHRA
	Detail of previous approval	Nap-E Tablet, Meeting # 345
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
345	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**

	Application Form Dy. No / Tracking ID & date of submission	(BE4-48W-87NB, 2026-05-11)
	Detail of Fee Submitted	97200, 2026-03-03,
	The proposed proprietary name / brand name	**Medron 5mg Tablet**
	Label Claim	Each Film Coated Tablet Contains: Midodrine Hydrochloride.....5mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°c
	For generic drugs (me-too Status)	Midotab Tablet by Wnsfeild PHarmaceuticals
	Pharmacotherapeutic Group of (API)	Alpha-Adrenergic Agonists
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Medron Tablet, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
346	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nexus Pharma (Pvt) Ltd** Plot No. 4/19-4/36, Sector 21 Korangi Industrial Area, Karachi - Pakistan **(000421)**
	Application Form Dy. No / Tracking ID & date of submission	(8BT-9U4-1H9Z, 2026-06-04)
	Detail of Fee Submitted	97200, 2026-02-04,
	The proposed proprietary name / brand name	**CIBAMOX**
	Label Claim	Each ml Contains: Moxifloxacin as HCl.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-As per SRO
	Shelf Life (Unit)	2 Year2 DEGREE TO 25 DEGREE CENTIGRADE
	For generic drugs (me-too Status)	VIGAMOX EYE DROPS BY NOVARTIS PHARMA
	Pharmacotherapeutic Group of (API)	fluoroquinolone antibiotic
	Name, address of Manufacturing site:	WINTHROX LABORATORIES (PVT) LTD.-PLOT NO. K-219/A, PHASE-II, SITE, SUPER HIGHWAY, KARACHI-
	The status in reference regulatory authorities	MHRA APPROVED
	Detail of previous approval	MOXON 5mg, DRB 339 MEETING

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
347	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)**
	Application Form Dy. No / Tracking ID & date of submission	(2JQ-7PS-RLLG, 2026-05-19)
	Detail of Fee Submitted	97200, 2025-10-28,
	The proposed proprietary name / brand name	**TOMAC Injection 40mg**
	Label Claim	Each vial contains: Pantoprazole sodium, USP equivalent to Pantoprazole ..... 40mg (BP Specifications)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Zopent 40mg Injection Hilton Pharma Karachi
	Pharmacotherapeutic Group of (API)	PPI
	Name, address of Manufacturing site:	Swera Pharmaceuticals -Plot No. 27, Street No. S-4 National Industrial Zone, Rawat, Islamabad, Pakistan.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	344 Meetings of Registration Board held on 31th Dec,2024 to 2nd Jan 2025.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
348	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medisynth Pharmaceuticals** Khasra No. 1028/1029, Mouza Jellyari Gujri, Tehsil Gujar

		Khan, District Rawalpindi **(000718)**
	Application Form Dy. No / Tracking ID & date of submission	(3SZ-B51-HHER, 2026-06-24)
	Detail of Fee Submitted	97200, 2026-04-03,
	The proposed proprietary name / brand name	**Irfomed**
	Label Claim	Each Ampoule contains: Iron as Ferric Carboxymaltose 500mg/10ml (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	24 Month15c-30C
	For generic drugs (me-too Status)	Ferinject injection by RG pharma
	Pharmacotherapeutic Group of (API)	Anti-anemic
	Name, address of Manufacturing site:	Carer Pharmaceuticals-Plot 27 Main rawat industrial road rawat-
	The status in reference regulatory authorities	Injectafer Injection USFDA approved
	Detail of previous approval	Carbifer injection registration NO:123815 registration meeting 333
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
349	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(UUZ-LZY-U38P, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**DARIXT 50MG TABLETS**
	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	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-

	The status in reference regulatory authorities	QUVIVIQ (DARIDOREXANT as HCl) tablets, for oral use Tablets: 25 & 50 mg Initial U.S. Approval: January 10, 2022 Distributed by: Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087 Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/a
	Detail of previous approval	354th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
350	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(DHG-7G9-BNWJ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**DARIXT 25MG TABLETS**
	Label Claim	Each film-coated tablet contains: DARIDOREXANT as HCL eq. to DARIDOREXANT.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	QUVIVIQ (DARIDOREXANT as HCL) tablets, for oral use Tablets: 25 & 50 mg Initial U.S. Approval: January 10, 2022 Distributed by: Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087 Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/a
	Detail of previous approval	354th meeting

	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
351	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(GNV-W5B-R1SE, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-16,
	The proposed proprietary name / brand name	**Suzemay 50MG TABLETS**
	Label Claim	Each film-coated tablet contains: Suzetrigine 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Selective $Na_v1.8$ voltage-gated sodium channel blocker
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	JOURNAVX (Suzetrigine) tablets, for oral use Tablets: 50 mg Initial U.S. Approval: 2025 Manufactured for: Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210 JOURNAVX, VERTEX and associated logos are registered trademarks of Vertex Pharmaceuticals Incorporated. Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/l https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatf
	Detail of previous approval	354th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
352	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(LBY-NEG-LB6Y, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-16,
	The proposed proprietary name / brand name	**UBROMAY -100TABLETS**
	Label Claim	Each tablet contains: Ubrogepant Trihydrate eq. to Ubrogepant 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Anti-migraine preparations
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	UBRELVY (Ubrogepant) tablets, for oral use Tablets: 50mg & 100mg Initial U.S. Approval: 2019 Distributed by: Distributed by: Allergan USA, Inc. Madison, NJ 07940 UBRELVY™ is a trademark of Allergan Pharmaceuticals International Limited. Allergan® and its design are trademarks of Allergan, Inc. Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/l https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.
	Detail of previous approval	354th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
353	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**

	Application Form Dy. No / Tracking ID & date of submission	(37W-HGQ-Z4PB, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-16,
	The proposed proprietary name / brand name	**Vadamay 150MG TABLETS**
	Label Claim	Each film-coated tablet contains: Vadadustat 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Vadadustat is an oral hypoxia-inducible factor prolyl-hydroxylase inhibitor used to treat symptomatic anemia associated with chronic kidney disease in adults on chronic maintenance dialysis.
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	VAFSEO® (Vadadustat) tablets, for oral use Tablets: 150 mg Initial U.S. Approval: 2024 Manufactured for: Akebia Therapeutics®, Inc., Cambridge, MA 02142 VAFSEO® is a registered trademark of Akebia Therapeutics, Inc. Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/la https://www.accessdata.fda.
	Detail of previous approval	354th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
354	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(PJY-MMJ-8XMQ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-16,
	The proposed proprietary name / brand name	**Vadamay 300MG TABLETS**

	Label Claim	Each film-coated tablet contains: Vadadustat 300mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Vadadustat is an oral hypoxia-inducible factor prolyl-hydroxylase inhibitor used to treat symptomatic anemia associated with chronic kidney disease in adults on chronic maintenance dialysis.
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	VAFSEO® (Vadadustat) tablets, for oral use Tablets: 150 mg Initial U.S. Approval: 2024 Manufactured for: Akebia Therapeutics®, Inc., Cambridge, MA 02142 VAFSEO® is a registered trademark of Akebia Therapeutics, Inc. Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.gov/drugsatfda_docs/la https://www.accessdata.fda.
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
355	Case Category	Contract Manufacturing (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	(NZW-TLV-5LA8, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Sildora Tablet 25mg**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil citrate eq to sildenafil ... 25mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO,10's-As per SRO,12's-As per SRO,2's-As per SRO,24's-As per SRO,4's-As per SRO,8's-As per SRO
	Shelf Life (Unit)	2 Year15° to 30°C

	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. -28-km Ferozepur Road, Lahore – Pakistan.-
	The status in reference regulatory authorities	Viagra tablet 25mg Distributed by Pfizer labs USFDA approved
	Detail of previous approval	Panagra, 345th Meeting of Registration Board
	Evaluation Remarks	
	The applicant has informed that they have obtained the product registration for the same molecule for self-manufacturing, as per the attached registration letter. Therefore, they are no longer interested in contract manufacturing.	
	Decision	
	Rejected The Registration Board decided to Reject the instant application as withdrawn by the applicant.	
356	Case Category	Contract Manufacturing (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	(U7E-XWH-3R97, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Sildora Tablet 50mg**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil citrate eq to sildenafil.....50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO,10’s-As per SRO,12’s-As per SRO,2's-As per SRO,24’s-As per SRO,4’s-As per SRO,8’s-As per SRO
	Shelf Life (Unit)	2 Year15° to 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. -28-km Ferozepur Road, Lahore – Pakistan.-
	The status in reference regulatory authorities	Viagra tablet 50mg Distributed by Pfizer labs USFDA approved
	Detail of previous approval	Panagra, 345th Meeting of Registration Board
	Evaluation Remarks	
	The applicant has informed that they have obtained the product registration for the same molecule for self-manufacturing, as per the attached registration letter. Therefore, they are no longer interested in contract manufacturing.	
	Decision	
	Rejected The Registration Board decided to Reject the instant application as withdrawn by the applicant.	
357	Case Category	Contract Manufacturing (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	(WQT-NVA-QXTX, 2025-04-25)
	Detail of Fee Submitted	93000.0, 2025-03-20,
	The proposed proprietary name / brand name	**Sildora Tablet 100mg**
	Label Claim	Each Film Coated Tablet Contains: Sildenafil citrate eq to sildenafil.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO,10’s-As per SRO,12’s-As per SRO,2's-As per SRO,24’s-As per SRO,4’s-As per SRO,8’s-As per SRO
	Shelf Life (Unit)	2 Year15° to 30°C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. NovaMed Pharmaceuticals (Pvt.) Ltd. -28-km Ferozepur Road, Lahore – Pakistan.-
	The status in reference regulatory authorities	Viagra tablet 100mg Distributed by Pfizer labs USFDA approved
	Detail of previous approval	Panagra, 345th Meeting of Registration Board
	Evaluation Remarks	
	The applicant has informed that they have obtained the product registration for the same molecule for self-manufacturing, as per the attached registration letter. Therefore, they are no longer interested in contract manufacturing.	
	Decision	
	Rejected The Registration Board decided to Reject the instant application as withdrawn by the applicant.	
358	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(NGV-XWZ-SDJ3, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-16,
	The proposed proprietary name / brand name	**UBROMAY -50TABLETS**
	Label Claim	Each tablet contains: Ubrogepant Trihydrate eq. to Ubrogepant 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Anti-migraine preparations
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	UBRELVY (Ubrogepant) tablets, for oral use Tablets: 50mg & 100mg Initial U.S. Approval: 2019 Distributed by: Distributed by: Allergan USA, Inc. Madison, NJ 07940 UBRELVY™ is a trademark of Allergan Pharmaceuticals International Limited. Allergan® and its design

		are trademarks of Allergan, Inc. Study Reference: https://www.accessdata.fda.gov/drugsatfda_docs/l https://www.accessdata.fda.gov/drugsatfda_docs/n https://www.accessdata.fda.
	Detail of previous approval	354th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
359	Case Category	Contract Manufacturing (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	(1Q5-1DY-3LVJ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-06-15,
	The proposed proprietary name / brand name	**Suzet 50mg Tablets**
	Label Claim	Each film coated tablet contains: Suzetrigine.....50mg As per Innovator's specs
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,14's-De-Controlled,20's-De-Controlled,28's-De-Controlled,30's-De-Controlled,5's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Suzet 50mg Tablets by Medizan Laboratories (Pvt) Ltd (Reg No. 135535)
	Pharmacotherapeutic Group of (API)	Suzetrigine is a selective $Na_v1.8$ voltage-gated sodium channel blocker
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD. -Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	JOURNAVX (Suzetrigine) tablets, for oral use Tablets: 50 mg, Initial U.S. Approval: 2025 Manufactured for Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210
	Detail of previous approval	Suzet 50mg Tablets, 354th DRB
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of	

	already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
360	Case Category	Contract Manufacturing (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	(HVM-U47-HNED, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-18,
	The proposed proprietary name / brand name	**Darix 25mg Tablets**
	Label Claim	Each film coated tablet contains: Daridorexant HCL eq. to Daridorexant.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,21's-De-Controlled,28's-De-Controlled,30's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD. -Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant), Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087
	Detail of previous approval	Darix 25mg Tablet, 354th DRB
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
361	Case Category	Contract Manufacturing (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	(W5Q-SD2-HW78, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-18,
	The proposed proprietary name / brand name	**Darix 50mg Tablets**
	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	10's-De-Controlled,100's-De-Controlled,14's-De-Controlled,20's-De-Controlled,21's-De-Controlled,28's-De-Controlled,30's-De-Controlled,50's-De-Controlled,7's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 ºC
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD. -Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant), Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087
	Detail of previous approval	Darix 50mg Tablet, 354th DRB
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
362	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**McOlson Research Laboratories Pvt. Ltd** Plot No. 02, M-2 Pharmazone, 26th Km Lahore Sharikpur Road Sheikhupura Pakistan **(000664)**
	Application Form Dy. No / Tracking ID & date of submission	(295-Z4R-P36R, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-02-18,
	The proposed proprietary name / brand name	**Versik 1% Lotion**
	Label Claim	Each gram contains Terbinafine as HCl 10 mg (1%)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	20 ml-De-Controlled

	Shelf Life (Unit)	24 MonthBelow 30C
	For generic drugs (me-too Status)	Terbisil Lotion by Saffron Pharmaceuticals (Reg#90109)
	Pharmacotherapeutic Group of (API)	Anti-fungal
	Name, address of Manufacturing site:	Bio-Labs (Pvt) Ltd.-Plot No.145, Industrial Triangle Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Lamisil lotion 1% Netherland Approved and Ireland, Sweden Approved,
	Detail of previous approval	Funasole 1% Lotion, M-335
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
363	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Highnoon Laboratories Ltd** 17.5 KM, Multan Road, **(000155)**
	Application Form Dy. No / Tracking ID & date of submission	(A8N-WXM-JE5Z, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-26,
	The proposed proprietary name / brand name	**Omevex 40mg Injection**
	Label Claim	Each vial contains; Omeprazole (as sodium) Lyophilized powder.....40mg BP specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	M/s Getz Pharma Risek Injection 40mg
	Pharmacotherapeutic Group of (API)	proton pump inhibitors (PPI), ATC Code: A02BC01
	Name, address of Manufacturing site:	BIO-LABS PVT LTD-BIO-LABS PVT LTD Plot # 1475, Industrial Triangle Kahuta road-Islamabad, Pakistan-
	The status in reference regulatory authorities	Omeprazole Powder for solution for infusion 40mg MHRA
	Detail of previous approval	Omepranext 40mg injection IV Approved in 324th DRB.
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and	

	fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
364	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(X62-DQG-9SQ9, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-26,
	The proposed proprietary name / brand name	**LINZO 100MG TABLETS**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 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)	Lingolix 100mg Tablets BY M/s Medizan Laboratories (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Selective GnRH receptor antagonist
	Name, address of Manufacturing site:	M/s Medizan Laboratories (Pvt) Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad -
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Lingolix 100mg Tablets, 351 DRB-M
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
365	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(6DR-Z79-EULG, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-26,

	The proposed proprietary name / brand name	**LINZO 200MG TABLETS**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 200mg
	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)	Lingolix 200mg Tablets BY M/s Medizan Laboratories (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Selective GnRH receptor antagonist
	Name, address of Manufacturing site:	M/s Medizan Laboratories (Pvt) Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Lingolix 200mg Tablets, 351 DRB-M
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
366	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(VHW-29Z-VN55, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**Akzith 250mg Tablet**
	Label Claim	Each film coated tablet contains; Azithromycin dihydrate (eq. to Azithromycin).....250mg (USP Specs.)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*6's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Orzit 250mg Tablets (by M/s Martin Dow Ltd)
	Pharmacotherapeutic Group of (API)	Antibacterial - Macrolides
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Zithromax 250mg Tablets (by Haupt Pharma Latina S.r.l. S.S 156 Km 47,600 04100 Borgo San Michele Latina Italy.Marketed by: M/s Pfizer Inc, USFDA Approved)

	Detail of previous approval	Azysol 250mg Tablets, DRB 352
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
367	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Genesis Pharmaceuticals Pvt. Ltd.** 25-Sundar Industrial Estate, Raiwind Road Lahore **(000793)**
	Application Form Dy. No / Tracking ID & date of submission	(7X1-D84-GEST, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**Gen-D 5ml Injection**
	Label Claim	Each ml contains: Cholecalceferol (Vitamin D3).....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1ml x 1's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	New D-Injection (NP News Pharma)
	Pharmacotherapeutic Group of (API)	Vitamin D Analog
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-208-C Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	VITAMIN D3 CHOLECALCIFEROL (VITAMIN INJECTION AMPOULES(PROVIDENT HOUSE 44 HARPUR STREET BEDFORD MK40 2QT)
	Detail of previous approval	D3 Vibe Injection 5mg/ml (Meeting No. 351st Case No. 161)
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

368	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(BRH-XG5-L4GD, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**Akzith 500mg Tablet**
	Label Claim	Each film coated tablet contains; Azithromycin dihydrate (equivalent to Azithromycin).....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1*10's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Orzit 500mg Tablets (by M/s Martin Dow Ltd)
	Pharmacotherapeutic Group of (API)	Antibacterial - Macrolides
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Zithromax 500mg Tablets (by Haupt Pharma Latina S.r.l. S.S 156 Km 47,600 04100 Borgo San Michele Latina Italy.Marketed by: M/s Pfizer Inc, USFDA Approved)
	Detail of previous approval	Azysol 500mg Tablets, DRB 352
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
369	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Caliph Pharmaceuticals (Pvt) Ltd.** Plot 17, Special Industrial Zone (EPZ), Risalpur, KPK **(000748)**
	Application Form Dy. No / Tracking ID & date of submission	(3GN-DWW-Q8LY, 2026-08-19)
	Detail of Fee Submitted	93000, 2025-05-20,
	The proposed proprietary name / brand name	**SUNATEX 120MG INJECTION**
	Label Claim	Each Vial Contains: Artesunate 120mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1`s-As per SRO

	Shelf Life (Unit)	2 YearStore Below 30 Degree Celsius
	For generic drugs (me-too Status)	Armin Injection 120mg
	Pharmacotherapeutic Group of (API)	Data already approved in 353 MoM.
	Name, address of Manufacturing site:	Palpex pharmaceuticals (Pvt.) Ltd.-FD-46-A8, ST-1, Sector 38, and Korangi Creek Industrial Park Karachi, Pakistan-
	The status in reference regulatory authorities	Artesunate Injection 120mg Manufactured by Ryvis Pharma (Canada)
	Detail of previous approval	Arkante Injection 120mg in 353MoM.
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
370	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(NSS-LB2-X9SQ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-03,
	The proposed proprietary name / brand name	**ETRAMAY -2MGTABLETS**
	Label Claim	Each film-coated tablet contains: Etrasimod Arginine eq. to Etrasimod 2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Medizan Laboratoreis 354th meeting
	Pharmacotherapeutic Group of (API)	Immunosuppressants / Immunomodulatory agents.
	Name, address of Manufacturing site:	Medizan Laboratories (pvt)Ltd-PLOT-313 INDUSTRIAL TRIANGLES KAHUTA ROAD-
	The status in reference regulatory authorities	VELSIPITY™ (Etrasimod) tablets, for oral use Tablets: 2 mg Initial U.S. Approval: 2023 Distributed by: Pfizer Labs Division of Pfizer Inc. New York, NY 10001 www.pfizer.com. Study Reference:
	Detail of previous approval	354th meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the	

	same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
371	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd** Plot 710, Sundar Industrial Estate, Lahore **(000891)**
	Application Form Dy. No / Tracking ID & date of submission	(NU3-GXR-J3RB, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-30,
	The proposed proprietary name / brand name	**Lingolix**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's -As per SRO,2 x 10's -As per SRO,2x 7's -As per SRO,3 x 10's -As per SRO,4x 7's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Lingolix 100mg Tablet ,Medizan Registered
	Pharmacotherapeutic Group of (API)	non-peptide GnRH receptor antagonists (hypothalamic hormones)
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT) LTD -Plot No 313, Industrial triangle, Kahuta road, Islamabad-Pakistan-
	The status in reference regulatory authorities	MHRA Approved ,Yselty 100 mg film-coated tablets
	Detail of previous approval	Lingolix 100mg tablet ,M-351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
372	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd** Plot 710, Sundar Industrial Estate, Lahore **(000891)**
	Application Form Dy. No / Tracking ID & date of submission	(NYP-PSH-MQQV, 2026-08-19)

	Detail of Fee Submitted	97200, 2026-03-30,
	The proposed proprietary name / brand name	**Lingolix**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Lingolix 200mg tablet by medizan
	Pharmacotherapeutic Group of (API)	non-peptide GnRH receptor antagonists (hypothalamic hormones)
	Name, address of Manufacturing site:	M/s Medizan Laboratories (Pvt) Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Lingolix 200mg tablet (M 351)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
373	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(XSX-LTX-49VG, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**BETINE 20MG TABLETS**
	Label Claim	Each Tablet contains: Bilastine.....20mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	BILASEE 20MG TABLET BY HORIZON HEALTHCARE
	Pharmacotherapeutic Group of (API)	Antihistamines for systemic use
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd- Plot #33, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	343 DRB-M, Biltine 20mg Tablet
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
374	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(LXA-XMM-6ML6, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**MALT 30MG CAPSULE**
	Label Claim	Each Capsule contains: Iron (as Ferric Maltol) ... 30mg
	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)	Ferion 30mg Capsule by Horizon HealthCare (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Oral iron trivalent preparation
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd-Plot #33, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	347 DRB-M, Ferion 30mg Capsule
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
375	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**

	Application Form Dy. No / Tracking ID & date of submission	(RRG-UES-8S7S, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**RUPANE 10MG TABLETS**
	Label Claim	Each tablet contains: Rupatadine fumarate equivalent to Rupatadine 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,15's-As per SRO,20's-As per SRO,3's-As per SRO,30's-As per SRO,7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Rupataget Tablets 10mg BY 29-30/27,Korangi Industrial Area karachi
	Pharmacotherapeutic Group of (API)	Antihistamine
	Name, address of Manufacturing site:	Horizon Healthcare Pvt. Ltd-Plot #33, Sundar Industrial Estate, Lahore-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	343 DRB-M, Rupazon 10mg Tablet
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
376	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(QYL-6ZW-1U6S, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**C-Gest 10mg Tablet**
	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE.....10 MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	AS PER SRO-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	DUPHASTON 10 MG FILM-COATED TABLETS
	Pharmacotherapeutic Group of (API)	retrosteroid class
	Name, address of Manufacturing site:	M/S SKYWIN PHARMACEUTICAL-PLOT NO. 01/A, BADAR INDUSTRIAL ESTATE,

		PHASE-II, 18-KM, SHEIKHPURA ROAD LAHORE.-
	The status in reference regulatory authorities	USFDA APPROVED FORMULATION
	Detail of previous approval	Minutes of 336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
377	Case Category	Contract Manufacturing (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	(TUX-ESL-YZQ7, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Myno 2.5mg Tablets**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Miro 2.5mg Tablet (Reg No. 120270) by Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate, Lahore.-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg (Daiichi Sankyo Co., Ltd), PMDA
	Detail of previous approval	Mirogab 2.5mg Tablet (DRB 344th Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

	Approved	
378	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(8MT-ZUL-Z43B, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Delzee**
	Label Claim	Each gram of cream contains: Delgocitinib.....20mg (2.0%) (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm 15gm 20gm 30gm-As per SRO
	Shelf Life (Unit)	2 Yearstore at 20° to 25°C excursions permitted from 15ºC to 30ºC (59ºF to 86ºF) [see USP Controlled Room Temperature].
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Gansu Haotian Pharmaceutical Technology Co., Ltd. Address: No. 11 Chongqing Road, Baiyin District, Baiyin City, Gansu Province, China
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
379	Case Category	Contract Manufacturing (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	(PBN-7G6-1B31, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Myno 5mg Tablets**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Miro 5mg Tablet (Reg No. 120269) by Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Tarlige Tablets 5mg (Daiichi Sankyo Co., Ltd), PMDA
	Detail of previous approval	Mirogab 5mg Tablet (DRB 344th Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
380	Case Category	Contract Manufacturing (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	(V77-X2J-49SN, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Myno 10mg Tablets**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Miro 10mg Tablet (Reg No. 120268) by Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Tarlige Tablets 10mg (Daiichi Sankyo Co., Ltd), PMDA
	Detail of previous approval	Mirogab 10mg Tablet (DRB 344th Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
381	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	(VPZ-R53-P3L1, 2026-05-14)
	Detail of Fee Submitted	38700, 2025-12-15,
	The proposed proprietary name / brand name	**PruLo Tablet 2mg**
	Label Claim	Each film-coated tablet contains: Prucalopride Succinate equivalent to Prucalopride 2mg.
	Reference to Finished product specifications	As per Innovators Specification
	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).
	For generic drugs (me-too Status)	Pru-Cic 2mg Tablet
	Pharmacotherapeutic Group of (API)	Chronic idiopathic constipation (CIC).
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom 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)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	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	MOTEGRITY 2MG TABLET, TAKEDA PHARMS USA (Shire Development LLC)
	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 in Module 1; Pg#20
	Evaluation Remarks	
	Export facilitation	
	Decision	
	Approved	
382	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	(V22-HQ1-L889, 2026-03-31)
	Detail of Fee Submitted	38700, 2025-12-15,
	The proposed proprietary name / brand name	**PruLo Tablet 1mg**
	Label Claim	Each film -coated tablet contains: Prucalopride Succinate equivalent to Prucalopride 1mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled,20's-De-Controlled,30's-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 20°C - 2 5°C.
	For generic drugs (me-too Status)	Pru-Cic 1mg Tablet
	Pharmacotherapeutic Group of (API)	Chronic idiopathic constipation (CIC).
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Shandong Loncom 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)	Provided
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Provided
	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	MOTEGRITY 1MG TABLET, TAKEDA PHARMS 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	
	Export facilitation	
	Decision	
	Approved	
383	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(GXT-7MX-1MG8, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Omazee**
	Label Claim	Each film coated tablet contains: Omadacyclineas Tosylate..150mg AS PER INNOVATOR SPECS
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s 2x7s 1x14s 2x14s 1x10s 3x10s-As per SRO
	Shelf Life (Unit)	2 Yearstored at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.

	Pharmacotherapeutic Group of (API)	BrightGene Bio-Medical Technology Co., Ltd. Address: Building C25-C28, No.218 Xinghu Road, Suzhou Industrial Park, Suzhou, Jiangsu, China
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
384	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(9R9-554-BG3V, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Empro-N 375/20mg Tablet**
	Label Claim	Each modified release tablet contains: Naproxen.....375mg (Enteric coated Core) Esomeprazole as Magnesium Trihydrate.....20mg (Immediate Release Coat) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Glomov Tablets by Global Pharmaceutical
	Pharmacotherapeutic Group of (API)	Nonsteroidal Anti-inflammatory Drug (NSAID) and Proton Pump Inhibitor.
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Esoren , M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
385	Case Category	Contract Manufacturing (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	(GGB-QB6-HR3X, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Myno 15mg Tablets**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Miro 15mg Tablet (Reg No. 120267) by Nabiqasim Industries
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Tarlige Tablets 15mg (Daiichi Sankyo Co., Ltd), PMDA
	Detail of previous approval	Mirogab 15mg Tablet (DRB 344th Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
386	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(BRQ-8LM-2LVZ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Empro-N 500/20mg Tablet**
	Label Claim	Each modified release tablet contains: Naproxen.....500mg (Enteric coated Core)

		Esomeprazole as Magnesium Trihydrate.....20mg (Immediate Release Coat) (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Glomov Tablets by Global Pharmaceutical
	Pharmacotherapeutic Group of (API)	Nonsteroidal Anti-inflammatory Drug (NSAID) and Proton Pump Inhibitor.
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	MHRA Approved
	Detail of previous approval	Esoren , M-343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
387	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(45W-A1U-9SES, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Suzex**
	Label Claim	Each Film Coated Tablet Contains: Suzetrigine.....50mg (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s ,2x7s, 1x14s ,2x14s, 1x10s ,3x10s-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Neutan Pharma (Anhui) Co., Ltd. Address: No. 1018, Jin'an Road, Economic & Technology Development District, Suzhou, Anhui province 234001, China (CHN).
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354

	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
388	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(U7P-12Z-J4D5, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Vaadu**
	Label Claim	Each Film Coated Tablet Contains: Vadadustat.....150mg (As per innovator specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s ,2x7s, 1x14s ,2x14s, 1x10s ,3x10s-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd. Address: No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province., China Sales office: Hanyu Jingu, High tech Zone, Jinan City, Shandong Province
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
389	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(7ZN-REL-B3ES, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Vaadu**
	Label Claim	Each Film Coated Tablet Contains: Vadadustat.....450mg (As per Innovators specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s ,2x7s, 1x14s ,2x14s, 1x10s ,3x10s-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C. Protect from Heat & Light.
	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd. Address: No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province., China Sales office: Hanyu Jingu, High tech Zone, Jinan City, Shandong Province
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
390	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Horizon Healthcare (pvt.) ltd.** 35-A Small Industrial Estate - Taxila **(000856)**
	Application Form Dy. No / Tracking ID & date of submission	(AWV-MMS-AED1, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Vaadu**
	Label Claim	Each Film Coated Tablet Contains: Vadadustat.....300mg (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7s ,2x7s, 1x14s ,2x14s, 1x10s ,3x10s-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C. Protect from Heat & Light.

	For generic drugs (me-too Status)	Hamaz pharmaceuticals (pvt)Ltd.
	Pharmacotherapeutic Group of (API)	Shandong Kehui Pharmaceuticals Co., Ltd. Address: No. 9A1, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province., China Sales office: Hanyu Jingu, High tech Zone, Jinan City, Shandong Province
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals (Pvt)Ltd.-13-KM Bosan Road Lutafabad Multan-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
391	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(V2Y-EEW-1W5H, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Rose-A Tablet 5/10mg**
	Label Claim	Each Film Coated tablet contains: Rosuvastatin Calcium Equivalent to Rosuvastatin .....5mg Ezetimibe.....1
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) lTD-129-Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
392	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)**
	Application Form Dy. No / Tracking ID & date of submission	(A4B-JWD-D41D, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**XIPAN 100mg/5ml Suspension**
	Label Claim	Each 5ml of Dry Suspension, when reconstituted, Contains: Cefixime as Trihydrate USP..... 100mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Cebosh Dry Suspension (Bosch Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Cephalosporin (Third generation Antibiotic)
	Name, address of Manufacturing site:	SHAWAN PHARMACEUTICALS -Plot No. 37, Road NS 1, National Industrial Zone, RCCI Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	SUPREX SUSPENSION 100MG/5ML (LUPIN PHARMACEUTICALS INC. USA)
	Detail of previous approval	336th MInutes of meeting helad on 4th to 6th June,2024
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
393	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	(R95-N16-N9PS, 2026-01-30)
	Detail of Fee Submitted	93000.0, 220500 2025-06-04, 2025-11-19
	The proposed proprietary name / brand name	**Itracure 100mg Capsule**
	Label Claim	Itraconazole immediate release pellets eq. to ltraconazole... 100mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-Controlled,14's-Controlled,1x4's-Controlled,28's-Controlled,30's-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C
	For generic drugs (me-too Status)	Sporanox Capsule, Aspin Pharma, Karachi (012647).
	Pharmacotherapeutic Group of (API)	Antifungal
	Name, address of Manufacturing site:	M/s Hiranis Pharmaceuticals (Pvt.) Ltd.-Plot no. E-145 to 149, Northwestern Industrial Zone, Port Qasim, Karachi.-
	Name & address of API manufacturer	Alphamed Formulations 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	Provided
	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	ITRACONAZOLE 100 MG CAPSULES HARD, MHRA approved.
	GMP status of the firm	GMP Certificate No. 79/2023-DRAP (K) Valid till 14th Dec 2026
	Evidence of approval of manufacturing facility	Approved Section Letter No. F. 1-33/2009-Lic Dated 07th Feb 2014 is attached
	Evaluation Remarks	
	On 21 CFR compliance query the applicant has replied that: Regarding the use of a CFR-compliant system, it is submitted that at the time of testing of the submitted product Itracure 100mg Capsule, the batch under evaluation was a trial / development batch. Due to over-occupancy of the available 21 CFR-compliant HPLC systems, the stability testing of this trial batch was performed on a GxP-compliant HPLC system. However, we assure that upon registration of the product and initiation of commercial-scale manufacturing, all testing including routine QC and stability studies will be performed exclusively on 21 CFR Part 11–compliant HPLC systems to ensure enhanced data integrity, audit-trail compliance, and secure electronic data management.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
394	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Parkar Pharma** Plot No. 0/7-A, S.I.T.E, Area Kotri, Sindh **(000883)**
	Application Form Dy. No / Tracking ID & date of submission	(N1D-ZP6-V4NB, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-09,
	The proposed proprietary name / brand name	**Nalpar Injection 10mg/ml**
	Label Claim	Each 1ml ampoule contains: Nalbuphine Hydrochloride.....10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 5's-As per SRO

	Shelf Life (Unit)	2 YearStore at 15-30°C. Store in the original package in order to protect from light.Store at 15-30°C. Store in the original package in order to protect from light.Store at 15-30°C. Store in the original pa
	For generic drugs (me-too Status)	Kinz 10mg Injection
	Pharmacotherapeutic Group of (API)	N02AF02
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd-Plot no. K/201, SITE, Super Highway, Phase-II, Karachi.-
	The status in reference regulatory authorities	NUBAIN – (nalbuphine hydrochloride) injection, for intramuscular, subcutaneous, or intravenous use Reference: USA-FDA https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	Nalfort 10mg/ml Injection, Approved in DRB 336th DRB Dated 04th – 06th Jun. 2024 , page # 2865-2869
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
395	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Parkar Pharma** Plot No. 0/7-A, S.I.T.E, Area Kotri, Sindh **(000883)**
	Application Form Dy. No / Tracking ID & date of submission	(79M-P35-GEN7, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-09,
	The proposed proprietary name / brand name	**Nalpar Injection 20mg/ml**
	Label Claim	Each 1ml ampoule contains: Nalbuphine Hydrochloride.....20mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 5's-As per SRO
	Shelf Life (Unit)	2 YearStore at 15-30°C. Store in the original package in order to protect from light.
	For generic drugs (me-too Status)	Kinz 20mg Injection
	Pharmacotherapeutic Group of (API)	N02AF02
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd-Plot no. K/201, SITE, Super Highway, Phase-II, Karachi.-
	The status in reference regulatory authorities	NUBAIN – (nalbuphine hydrochloride) injection, for intramuscular, subcutaneous, or intravenous use Reference: USA-FDA https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	Nalfort 20mg/ml Injection, r Approved in DRB 343rd DRB Dated 03rd – 05th Dec. 2024 , page #

		1115.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
396	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(JLP-88T-1RXL, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-08,
	The proposed proprietary name / brand name	**Aksopol I 500mg/200mg Tablet**
	Label Claim	Each Film Coated tablet contains: Paracetamol .....500mg Ibuprofen.....200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	2x7's, 1x10's, 2x10's, 3x10's as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25-30ºC in a dry place
	For generic drugs (me-too Status)	Provas Duo Tablet 500mg/200mg (by SAMI Pharmaceuticals Pvt. Ltd.)
	Pharmacotherapeutic Group of (API)	Paracetamol (Analgesic and Antipyretics),Ibuprofen (Non-steroidal Anti-inflammatory Drug)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	Nuromol Dual Action Pain Relief 200mg/500mg tablets (by Reckitt Benckiser Healthcare International Ltd, Nottingham UK, MHRA Approved)
	Detail of previous approval	Ibuprofen-P 500mg+200mg Tablet, DRB 348
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

	Approved	
397	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**STANDARD DRUG COMPANY** Plot No. E-6-A, S.I.T.E **(000118)**
	Application Form Dy. No / Tracking ID & date of submission	(6E2-52T-6QMQ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-09,
	The proposed proprietary name / brand name	**Nalsan Injection 10mg/ml**
	Label Claim	Each 1ml ampoule contains: Nalbuphine Hydrochloride.....10mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 5's-As per SRO
	Shelf Life (Unit)	2 YearStore at 15-30°C. Store in the original package in order to protect from light.
	For generic drugs (me-too Status)	Kinz 10mg Injection
	Pharmacotherapeutic Group of (API)	N02AF02
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd-Plot no. K/201, SITE, Super Highway, Phase-II, Karachi.-
	The status in reference regulatory authorities	NUBAIN – (nalbuphine hydrochloride) injection, for intramuscular, subcutaneous, or intravenous use Reference: USA-FDA https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	Nalfort 10mg/ml Injection, Approved in DRB 336th DRB Dated 04th – 06th Jun. 2024 , page # 2865-2869
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
398	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**STANDARD DRUG COMPANY** Plot No. E-6-A, S.I.T.E **(000118)**
	Application Form Dy. No / Tracking ID & date of submission	(E72-4UQ-PXL5, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-09,
	The proposed proprietary name / brand name	**Nalsan Injection 20mg/ml**
	Label Claim	Each 1ml ampoule contains: Nalbuphine Hydrochloride.....20mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1ml x 5's-As per SRO

	Shelf Life (Unit)	2 YearStore at 15-30°C. Store in the original package in order to protect from light.
	For generic drugs (me-too Status)	Kinz 20mg Injection
	Pharmacotherapeutic Group of (API)	N02AF02
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd-Plot no. K/201, SITE, Super Highway, Phase-II, Karachi.-
	The status in reference regulatory authorities	NUBAIN – (nalbuphine hydrochloride) injection, for intramuscular, subcutaneous, or intravenous use Reference: USA-FDA https://www.accessdata.fda.gov/drugsatfda_docs/la
	Detail of previous approval	Nalfort 20mg/ml Injection, r Approved in DRB 343rd DRB Dated 03rd – 05th Dec. 2024 , page # 1115.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
399	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Fortune Pharma (Pvt.) LTD** Plot 20/K SITE,Super High Way Phase II Karachi **(000924)**
	Application Form Dy. No / Tracking ID & date of submission	(1VP-MY5-PR92, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-08,
	The proposed proprietary name / brand name	**Forxone**
	Label Claim	Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's or as per SRO-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	Rocephin Injection 500MG IM, Martin Dow
	Pharmacotherapeutic Group of (API)	Third-generation cephalosporin antibiotic
	Name, address of Manufacturing site:	Inventor Pharmaceuticals (Pvt) Ltd.-Plot No K/196 S.I.T.E (SHW) Karachi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Bectard Injection 500mg IM, DRB Meeting No. 331
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
400	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(B25-EXP-1DLE, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-24,
	The proposed proprietary name / brand name	**TELIDA 5mg TABLET**
	Label Claim	Each Film Coated Tablet Contains: Tadalafil (USP).....5 mg (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 Year20-25°C
	For generic drugs (me-too Status)	NA
	Pharmacotherapeutic Group of (API)	Phosphodiesterase-5 inhibitor (PDE5-I)
	Name, address of Manufacturing site:	M/s Wnsfeild Pharmaceuticals-Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	Telida 5mg Tablet | Minutes of 352nd Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
401	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(UNY-M67-572H, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-13,
	The proposed proprietary name / brand name	**CIALOR NRK 5mg Tablet**

	Label Claim	Each film-coated tablet contains: Tadalafil.....5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO,1x2's-As per SRO,1x4's-As per SRO,2x4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Dalafil 5mg Tablet Regn. Holder: M/s Solaris Life Sciences Private Limited, Regn. No. 132630
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 inhibitors Urologicals, Drugs used in erectile dysfunction..
	Name, address of Manufacturing site:	M/s Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Brand Name: Cialis 5mg Tablet SRA Registration Status: US FDA Approved New Drug Application (NDA): 021368 Company: Lilly del Caribe Inc
	Detail of previous approval	Dalafil 5mg Tablets, 352nd DRB Meeting.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
402	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Aurik Pharmaceuticals Pvt Ltd** PLOT # 6 & 7 ST # S-9 NATIONAL INDUSTRIAL ZONE, RAWAT, RAWALPINDI **(000802)**
	Application Form Dy. No / Tracking ID & date of submission	(8RR-ZQS-Y6X5, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-08,
	The proposed proprietary name / brand name	**NORTEST-N 5 MG TAB**
	Label Claim	Each Tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	2X10'S-As per SRO,3X10'S-As per SRO,5X10'S-As per SRO,6X10'S-As per SRO
	Shelf Life (Unit)	2 YearRoom Condition
	For generic drugs (me-too Status)	Primolut N Tablet 5mg of M/s Bayer plc (MHRA Approved)
	Pharmacotherapeutic Group of (API)	Synthetic progestational hormone
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road (000971)-
	The status in reference regulatory authorities	DRAP

	Detail of previous approval	Just-N 5mg Tablet Minutes of 347th meeting of Registration Board (28th – 30th April, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
403	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hamaz Pharmaceuticals (Pvt) Ltd.** 13-KM Bosan Road, Lutfabad **(000427)**
	Application Form Dy. No / Tracking ID & date of submission	(HXR-WPP-2HXD, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-08,
	The proposed proprietary name / brand name	**Penzee**
	Label Claim	Each gram of cream contains; Penciclovir.....10mg (1% w/w) (As per Innovator's specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm 15gm 20gm 30gm-As per SRO
	Shelf Life (Unit)	2 YearStore at 20º to 25ºC (68º to 77ºF).
	For generic drugs (me-too Status)	Horizon healthcare (Pvt)Ltd taxila
	Pharmacotherapeutic Group of (API)	Zhejiang Charioteer Pharmaceutical Co., Ltd. China Address: Tongyuan Creek, War Township, Xianju County, Taizhou City, Zhejiang Province, 317321
	Name, address of Manufacturing site:	Horizon healthcare (Pvt)Ltd. taxila-plot no 35 -A small industrial estate taxila-
	The status in reference regulatory authorities	complies
	Detail of previous approval	354
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
404	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(JT5-Z3U-89NT, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**Rose-A Tablet 10/10mg**
	Label Claim	Each film coated tablet contain: Rosuvastatin Calcium Equivalent to Rosuvastatin .....10mg Ezetimibe.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) lTD-Plot #129 Sunder Industrial Estate, raiwind Road, Lahore -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-352
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
405	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(9TZ-BT9-65B4, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-08,
	The proposed proprietary name / brand name	**Aksopol D 500mg/25mg Tablet**
	Label Claim	Each Film Coated tablet contains: Paracetamol .....500mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	2x7's, 1x10's, 2x10's, 3x10's, 6x10's, 10x10's as per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 25-30ºC in a dry place
	For generic drugs (me-too Status)	PANADOL NIGHT TABLET (by Haleon Pakistan Limited, Petro road, Jamshoro)

	Pharmacotherapeutic Group of (API)	Paracetamol (central analgesic effect that is mediated through activation of descending serotonergic pathways) , Diphenhydramine Hydrochloride (Antihistamines)
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	PANADOL PM, Acetaminophen and diphenhydramine hydrochloride Film coated tablet (by Haleon LLC USFDA Approved)
	Detail of previous approval	Peradol-D 500/25 mg Tablet, DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
406	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(QP7-SP5-UN38, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-13,
	The proposed proprietary name / brand name	**CIALOR NRK 20mg Tablet**
	Label Claim	Each film-coated tablet contains: Tadalafil..... 20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-Free of Cost,1x2's-As per SRO,1x4's-As per SRO,2x4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Dalafil 20mg Tablet Regn. Holder: M/s Solaris Life Sciences Private Limited, Regn. No. 132631
	Pharmacotherapeutic Group of (API)	Phosphodiesterase type 5 inhibitors Urologicals, Drugs used in erectile dysfunction..
	Name, address of Manufacturing site:	M/s Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Brand Name: Cialis 20mg Tablet SRA Registration Status: US FDA Approved New Drug Application (NDA): 021368 Company: Lilly del Caribe Inc
	Detail of previous approval	Dalafil 20mg Tablets, 352nd DRB Meeting.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
407	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(QS1-S2X-H6RJ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-13,
	The proposed proprietary name / brand name	**LEVITRA NRK 20mg Tablet**
	Label Claim	Each film-coated tablet contains: Vardenafil as Hydrochloride Trihydrate..... 20mg.
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO,1x2's-As per SRO,1x4's-As per SRO,1x6's-As per SRO,2x4's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Vardena 20mg Tablets Regn Holder: M/s Solaris Life Sciences Private Limited, Regn No. 132427
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction.
	Name, address of Manufacturing site:	M/s Solaris Life Sciences (Pvt.) Ltd.-Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	Brand Name: Levitra 20mg Tablet SRA Registration Status:US FDA Approved New Drug Application (NDA): 021400 Company: BAYER HLTHCARE Address: 100 Bayer BlvdWhippany, NJ, 079811544 United States
	Detail of previous approval	Vardena 20mg Tablets, Meeting No. 351st.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
408	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	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	(G2E-5TV-SHR2, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-14,
	The proposed proprietary name / brand name	**Urivoid 25mg Tablet**
	Label Claim	Each tablet contains: Bethanechol chloride ... 25mg (USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's-As per SRO,10 x 10's-As per SRO,2 x 10's-As per SRO,2 x 7's-As per SRO,3 x 10's-As per SRO,4 x 7's-As per SRO,5 x 10's-As per SRO
	Shelf Life (Unit)	2 Year15C - 30C
	For generic drugs (me-too Status)	Ucholine 10mg Tablet
	Pharmacotherapeutic Group of (API)	Cholinergic agonist (parasympathomimetic agent) & Direct-acting muscarinic receptor agonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	NDC 65162-573-10 USFDA Approved.
	Detail of previous approval	Xurovoid 25mg Tablet (M-344th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
409	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Go Pharmaceuticals (Pvt) Ltd** 5-km, Raiwind Manga Road Lahore **(001004)**
	Application Form Dy. No / Tracking ID & date of submission	(Z1J-YLQ-VD7J, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-21,
	The proposed proprietary name / brand name	**Dexole**
	Label Claim	Each Capsule contains: Dexlansoprazole (as dual delayed release pellets).....30mg As per innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30's -As per SRO
	Shelf Life (Unit)	2 YearStore below 30 centigrade. Protect from heat, moisture & sunlight
	For generic drugs (me-too Status)	Dexilant 30mg Capsule
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor (PPI)

	Name, address of Manufacturing site:	Variant Pharmaceuticals Pvt Ltd.-Plot no 5 M2 Pharmazone Sharqpur lahore-Road.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Minutes of 320th DRAP registration board meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
410	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(PZB-VXX-3M87, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-14,
	The proposed proprietary name / brand name	**Urivoid 10mg Tablet**
	Label Claim	Each Tablet contains: Bethanechol Chloride ... 10mg (USP specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 10's-As per SRO,10 x 10's-As per SRO,2 x 10's-As per SRO,2 x 7's-As per SRO,3 x 10's-As per SRO,4 x 7's-As per SRO,5 x 10's-As per SRO
	Shelf Life (Unit)	2 Year15C - 30C
	For generic drugs (me-too Status)	Ucholine 10mg Tablet
	Pharmacotherapeutic Group of (API)	Cholinergic agonist (parasympathomimetic agent) & Direct-acting muscarinic receptor agonist
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore-
	The status in reference regulatory authorities	NDC 65162-573-10 USFDA Approved. Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807
	Detail of previous approval	Xurovoid 10mg Tablet (M-344th)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
411	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(W6S-Z69-XB17, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-14,
	The proposed proprietary name / brand name	**Harry-P 90mg Tablet**
	Label Claim	Each film coated tablet contains: Etoricoxib... 90mg (As per Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 Year15C - 30C
	For generic drugs (me-too Status)	Starcox 90mg Tablet by GETZ PHARMA.
	Pharmacotherapeutic Group of (API)	selective cyclooxygenase-2 (COX-2) inhibitors
	Name, address of Manufacturing site:	SOLARIS LIFE SCIENCES (PVT.) LTD-Plot No. 08, StreetNo. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan-
	The status in reference regulatory authorities	Arcoxia 90mg Tablet; MHRA Approved.
	Detail of previous approval	Etoroxib 90mg Tablet (M-336)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
412	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(3A5-2QP-ZQ1N, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-15,
	The proposed proprietary name / brand name	**Megron 25mg Tablet**
	Label Claim	Each extended release Tablet contains: Mirabegron.....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 Year20-25°C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Mirabet 25mg Tab Manufacturer CCL Pharmaceuticals Strength 25mg Tablet Composition Each Extended Release Tablet contains: Mirabegron ……..25mg Registration Numbe
	Pharmacotherapeutic Group of (API)	a beta-3 adrenergic agonist
	Name, address of Manufacturing site:	M/S Welmark Pharmaceuticals-Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	Applied as Cross Refer Product against Already Approved CTD
	Detail of previous approval	MEGRON 25mg XR Tablets | Minutes of 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
413	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well & Well Pharma Pvt.Ltd** Plot No 07, Street S-8, RCCI, Rawat Rawalpindi **(000687)**
	Application Form Dy. No / Tracking ID & date of submission	(XYV-YTS-9U7Y, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-25,
	The proposed proprietary name / brand name	**WELLNIC CREAM**
	Label Claim	Each gram contains: Hydroquinone 40mg (4%) Fluocinolone Acetonide 0.1mg (0.01%) Tretinoin 0.5mg (0.05%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10g; 15g; 20g; 30g, 45gm-As per SRO
	Shelf Life (Unit)	2 YearStore below 30c
	For generic drugs (me-too Status)	Lazma cream By M/s Bio-Labs Ltd
	Pharmacotherapeutic Group of (API)	Data Already Approved in 349 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Tri-luma cream By Hill Dermaceuticals, Inc. (USFDA Approved)
	Detail of previous approval	Acknuma cream in 349MoM.
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the	

	same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
414	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(HD7-6NT-4NU5, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-02,
	The proposed proprietary name / brand name	**METHYSONE 40mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....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)	24 Monthbelow 25c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer Pakistan
	Pharmacotherapeutic Group of (API)	Glucocorticoids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Wenpred 40mg Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
415	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(ER1-VBG-3W3E, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-17,
	The proposed proprietary name / brand name	**SPARSEN 400MG TABLETS**

	Label Claim	Each film coated tablet contains: Sparsentan.....400 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree
	For generic drugs (me-too Status)	Partexx 400mg tablet by horizon health care pvt ltd
	Pharmacotherapeutic Group of (API)	Endothelin and angiotensin II receptor antagonist
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals Pvt. Ltd-13-Km, Lutafabad Bosan Road, Multan -
	The status in reference regulatory authorities	mhra approved
	Detail of previous approval	SPAREN 400MG TABLET IN 345 MEETING
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
416	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CRYSTOLITE PHARMACEUTICALS** Plot # 1 & 2, street S-2, National Industrial Zone Rawat, Islamabad **(000778)**
	Application Form Dy. No / Tracking ID & date of submission	(E59-JHY-BQS5, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-17,
	The proposed proprietary name / brand name	**SPARSEN 200MG TABLETS**
	Label Claim	Each film coated tablet contains: Sparsentan.....200 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,14's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 degree
	For generic drugs (me-too Status)	senpro 200mg tablet by horizon health care pvt ltd
	Pharmacotherapeutic Group of (API)	Endothelin and angiotensin II receptor antagonist
	Name, address of Manufacturing site:	Hamaz Pharmaceuticals Pvt. Ltd-13-Km, Lutafabad Bosan Road, Multan -
	The status in reference regulatory authorities	mhra approved
	Detail of previous approval	SPAREN 200MG TABLET IN 345 MEETING
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
417	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Tovida Pharmaceuticals (Pvt) Ltd** Plot No.7, Street No.S-07, RCCI Industrial Estate Islamabad **(000996)**
	Application Form Dy. No / Tracking ID & date of submission	(PV6-JWU-V886, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-17,
	The proposed proprietary name / brand name	**XIPAN 200mg/5ml Suspension**
	Label Claim	Each 5ml of Dry Powder for Suspension, when reconstituted, Contains: Cefixime as Trihydrate USP..... 200mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO -De-Controlled
	Shelf Life (Unit)	2 Year30C+-
	For generic drugs (me-too Status)	Cebosh Dry Suspension 200mg/5ml (Bosch Pharmaceuticals)
	Pharmacotherapeutic Group of (API)	Cephalosporin (Third generation Antibiotic)
	Name, address of Manufacturing site:	MS Shawan Pharmaceuticals -Plot No. 37, Road NS 1, National Industrial Zone, RCCI Rawat, Islamabad, Pakistan-
	The status in reference regulatory authorities	SUPREX SUSPENSION 200MG/5ML (LUPIN PHARMACEUTICALS INC. USA)
	Detail of previous approval	336th MInutes of meeting helad on 4th to 6th June,2024
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
418	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(4V9-YTA-DUZJ, 2026-08-19)

	Detail of Fee Submitted	97200, 2026-04-15,
	The proposed proprietary name / brand name	**Megron 50mg XR Tablet**
	Label Claim	Each extended release Tablet contains: Mirabegron.....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 Year20-25°C
	For generic drugs (me-too Status)	Brand Name of Approved Medicines Mirabet 50mg Tab Manufacturer CCL Pharmaceuticals Strength 50mg Tablet Composition Each Extended Release Tablet contains: Mirabegron ……..50mg Registration Numbe
	Pharmacotherapeutic Group of (API)	a beta-3 adrenergic agonist
	Name, address of Manufacturing site:	M/S Welmark Pharmaceuticals-Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar.-
	The status in reference regulatory authorities	https://www.medicines.org.uk/emc/product
	Detail of previous approval	MEGRON 50mg XR Tablets | Minutes of 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
419	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Standpharm Pakistan Pvt Ltd** 20 km ferozpur road lahore **(000051)**
	Application Form Dy. No / Tracking ID & date of submission	(R3P-W4L-HXE1, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-09,
	The proposed proprietary name / brand name	**MAXON 100mg Tablet**
	Label Claim	Each tablet contains: Avanafil.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature upto 25C
	For generic drugs (me-too Status)	Avala 100mg Tablets by MEDIZAN LABORATORIES (PVT.) LTD.
	Pharmacotherapeutic Group of (API)	CENTURY PHARMACEUTICAL LTD
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-

	The status in reference regulatory authorities	STENDRA 100mg Tablet Manufactured for VIVUS, Inc.
	Detail of previous approval	Avala 100mg Tablet approved in 351 meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
420	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(74Q-QBM-79PW, 2026-08-19)
	Detail of Fee Submitted	93000, 2025-04-22,
	The proposed proprietary name / brand name	**Fexime for Oral Suspension**
	Label Claim	Each 5mL (reconstituted) contains: Cefixime as trihydrate.....100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's (30mL) and 1's (60mL)-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°C
	For generic drugs (me-too Status)	Cefspan 100mg/5mL by Barret Hodgson
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	326 (14-16 March 2023) page No. 78-81
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
421	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**

	Application Form Dy. No / Tracking ID & date of submission	(NE7-B4T-A3S3, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-02,
	The proposed proprietary name / brand name	**Methysone 500mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....500MG (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Monthbelow 25c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer Pakistan
	Pharmacotherapeutic Group of (API)	Glucocorticoids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi -
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Wenpred 500mg Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
422	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Standpharm Pakistan Pvt Ltd** 20 km ferozpur road lahore **(000051)**
	Application Form Dy. No / Tracking ID & date of submission	(R1P-XM2-2U5A, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-09,
	The proposed proprietary name / brand name	**MAXON 50mg Tablet**
	Label Claim	Each tablet contains: Avanafil 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature upto 25C
	For generic drugs (me-too Status)	Avala 50mg Tablets by MEDIZAN LABORATORIES (PVT.) LTD.
	Pharmacotherapeutic Group of (API)	CENTURY PHARMACEUTICAL LTD
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	STENDRA 50mg Tablet Manufactured for VIVUS, Inc.
	Detail of previous approval	Avala 50mg Tablet approved in 351 meeting
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
423	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(9HV-UNV-UBZ8, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-02,
	The proposed proprietary name / brand name	**Methysone 125mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....125MG (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	24 Monthbelow 25c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer Pakistan
	Pharmacotherapeutic Group of (API)	Glucocorticoids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-Plot No. 31-32, Punjab Small Industrial Estate, Taxila, Rawalpindi-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Methysone 125mg sterile powder for injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
424	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CUREXA HEALTH (PVT.) LIMITED** 517 SUNDER INDUSTRIAL ESTSTE **(000864)**
	Application Form Dy. No / Tracking ID & date of submission	(JP6-G86-LA3M, 2026-08-19)

	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Hiclav Tablet 625mg**
	Label Claim	Each film coated tablet contains: Amoxicillin (as Trihydrate) 500mg Clavulanic acid (as Potassium Clavulanate) 125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30oC. Keep in a dry place. Keep out of reach of children. Protect from light.
	For generic drugs (me-too Status)	Stamentin 625mg Tablet by Stallion (Reg No. 121449)
	Pharmacotherapeutic Group of (API)	Combinations of Penicillins, including beta-lactamase inhibitors. ATC code: J01CR02
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Private) Limited-Plot No. 581-SUNDAR INDUSTRIAL ESTATE, LAHORE-
	The status in reference regulatory authorities	USFDA Approved Product Name: Amoxicillin and Clavulanate Potassium Manufacturer: Sandoz
	Detail of previous approval	Stamentin 625mg Tablet by Stallion, 335 DRB (25th April 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
425	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CUREXA HEALTH (PVT.) LIMITED** 517 SUNDER INDUSTRIAL ESTSTE **(000864)**
	Application Form Dy. No / Tracking ID & date of submission	(8UV-4Y8-E9LW, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Hiclav Tablet 375mg**
	Label Claim	Each film coated tablet contains: Amoxicillin (as Trihydrate) 250mg Clavulanic acid (as Potassium Clavulanate) 125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30oC. Keep in a dry place. Keep out of reach of children. Protect from light.
	For generic drugs (me-too Status)	Stamentin 375mg Tablet by Stallion (Reg No. 121450)

	Pharmacotherapeutic Group of (API)	Combinations of Penicillins, including beta-lactamase inhibitors. ATC code: J01CR02
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Private) Limited--, 581-SUNDAR INDUSTRIAL ESTATE, LAHORE-
	The status in reference regulatory authorities	USFDA Approved Product Name: Amoxicillin and Clavulanate Potassium Manufacturer: Sandoz
	Detail of previous approval	Stamentin 375mg Tablet by Stallion, 335 DRB (25th April 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
426	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(6US-SHM-VXD3, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Visunate-M 30mg Injection**
	Label Claim	Each vial contains: Artesunate 30mg (Intl. Ph. Specifications)
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Arcenate Injection 30mg Reg. no. 100927 M/s Sami Pharma Karachi.
	Pharmacotherapeutic Group of (API)	artemisinin-based antimalarial agent
	Name, address of Manufacturing site:	M/s Bio-Labs (Pvt.) Ltd. -Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	WHO recommended formulation.
	Detail of previous approval	Minutes of 331st Meeting of Registration Board held on 31st Oct – 2 nd Nov, 2023
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
427	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(HXL-H17-XPR7, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-14,
	The proposed proprietary name / brand name	**Upacure 15mg XR Tablet**
	Label Claim	Each film coated enteric release tablet contains: Upadacitinib hemihydrate eq. to Upadacitinib ... 15mg (Innovator's specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's-As per SRO,2 x 10's-As per SRO,2 x 7's-As per SRO,3 x 10's-As per SRO,4 x 7's-As per SRO,5 x 10's-As per SRO
	Shelf Life (Unit)	2 Year15C - 30C
	For generic drugs (me-too Status)	Upaget XR Tablet by GETZ PHARMA.
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitors
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Limited.-PLOT # 129, SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	Rinvoq (upadacitinib) 15mg Extended-release Tablet (IRELAND) USFDA Approved
	Detail of previous approval	Upacit 15mg XR Tablet (M-344)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
428	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(SV8-ZG5-J2GJ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**N-TERON 5MG TABELT**

	Label Claim	Each Tablet contains: Norethisterone 5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Plot #1 Al-badar Industrial Estate, 18KM Sheikhupura Raod, Lahore, Pakistan-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
429	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(TT3-6R2-67U8, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-06,
	The proposed proprietary name / brand name	**ES-TROL TABLET**
	Label Claim	Each of the 11 White Sugar coated tablets Contains Estradiol Valerate U.S.P.....2mg Each of the 10 Light Brown sugar coated tablets Contains Estradiol U.S.P.....2mg Norgestral U.S.P.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Skywin Pharmaceutical-Address: Plot #1 Albadar Industrial Estate, 8KM Sheikhupura Road, Lahore, Pakistan-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
430	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(ETE-U1M-8XRY, 2026-08-19)
	Detail of Fee Submitted	93000, 2025-04-22,
	The proposed proprietary name / brand name	**Oxicef 500 IV**
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	323 (6-8 Dec 2022) page No. 1384-1387
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
431	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(VP9-MQH-W9S6, 2026-08-19)
	Detail of Fee Submitted	93000, 2025-04-22,
	The proposed proprietary name / brand name	**Oxicef 250 IV**
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....250mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	323 (6-8 Dec 2022) page No. 1387-1390
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
432	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(GBQ-RP5-9WS8, 2026-08-19)
	Detail of Fee Submitted	93000, 2025-04-22,
	The proposed proprietary name / brand name	**Oxicef 1g IV**
	Label Claim	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone.....1g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-Controlled
	Shelf Life (Unit)	2 YearStore below 30 °C
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	323 (6-8 Dec 2022) page No. 1390-1392
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

	Approved	
433	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(S39-NTH-BMM9, 2026-08-19)
	Detail of Fee Submitted	93000, 2025-04-22,
	The proposed proprietary name / brand name	**Feximе Capsule**
	Label Claim	Each capsule contains: Cafixime as trihydrate.....400mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1x5's,1x10's, 2x5's As per SRO-Controlled
	Shelf Life (Unit)	2 Yearbelow 30°C
	For generic drugs (me-too Status)	Cefspan 400mg cap by Barret Hodgson
	Pharmacotherapeutic Group of (API)	Cephalosporin
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt Ltd-Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	326 (14-16 March 2023) page No. 74-76
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
434	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(M15-8HQ-U7ZA, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**PREGVOID TABLET 1.5mg**
	Label Claim	Each Tablet Contain: Levonorgestrel.....1.5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO,10's-As per SRO,2's-As per SRO,20's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	2 Year15°C - 30°C
	For generic drugs (me-too Status)	Emkit DS Tablet (Zafa Pharmaceutical)
	Pharmacotherapeutic Group of (API)	M/s Hunan KYF Pharmaceutical. Co., Ltd (China)

	Name, address of Manufacturing site:	M/s Skywin Pharmaceutical -Plot No. 01 , AI Badar Industrial Estate, Phase II , Sheikhupura Road, Lahore -
	The status in reference regulatory authorities	LEVONORGESTREL SANDOZ 1.5 MG EFG TABLET (Sandoz)
	Detail of previous approval	336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
435	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CUREXA HEALTH (PVT.) LIMITED** 517 SUNDER INDUSTRIAL ESTSTE **(000864)**
	Application Form Dy. No / Tracking ID & date of submission	(BYQ-PQ4-W7VL, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Hitaz Injection 4.5g**
	Label Claim	Each vial contains: Piperacillin (as Piperacillin Sodium) 4g Tazobactam (as Tazobactam Sodium) 0.5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30oC. Keep in a dry place. Keep out of reach of children. Protect from light.
	For generic drugs (me-too Status)	Pencital 4.5g Injection (Reg. No. 110312)
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Combinations of penicillins incl. beta-lactamase inhibitors; ATC code: J01C R05
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Private) Limited-Plot No. 581-SUNDAR INDUSTRIAL ESTATE, LAHORE-
	The status in reference regulatory authorities	USFDA Approved Product Name: Piperacillin and Tazobactam Manufacturer: Sandoz
	Detail of previous approval	PITZO 4.5g Injection, 308
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
436	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CUREXA HEALTH (PVT.) LIMITED** 517 SUNDER INDUSTRIAL ESTSTE **(000864)**
	Application Form Dy. No / Tracking ID & date of submission	(XSH-NVQ-UUHL, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Hitaz Injection 2.25g**
	Label Claim	Each vial contains: Piperacillin (as Piperacillin Sodium) 2g Tazobactam (as Tazobactam Sodium) 0.25g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30oC. Keep in a dry place. Keep out of reach of children. Protect from light.
	For generic drugs (me-too Status)	Pencital 2.25g Injection (Reg. No. 110311)
	Pharmacotherapeutic Group of (API)	Antibacterials for systemic use, Combinations of penicillins incl. beta-lactamase inhibitors; ATC code: J01C R05
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Private) Limited-Plot No. 581-SUNDAR INDUSTRIAL ESTATE, LAHORE-
	The status in reference regulatory authorities	USFDA Approved Product Name: Piperacillin and Tazobactam Manufacturer: Sandoz
	Detail of previous approval	PITZO 2.25g Injection, 308
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
437	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(B72-3A9-5JHM, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**STERON TABLET 5mg**

	Label Claim	Each tablet contains: Norethisterone.....5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO,1x5's-As per SRO,2x10's-As per SRO,3x10's-As per SRO,5x10's-As per SRO
	Shelf Life (Unit)	2 Year15°C - 30°C
	For generic drugs (me-too Status)	Primolut N Tablet 5mg (OBS Pharma (Pvt.) Ltd 108, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore)
	Pharmacotherapeutic Group of (API)	M/s Swati Spentose Private Limited
	Name, address of Manufacturing site:	M/s Skywin Pharmaceutical -Plot No. 01 , AI Badar Industrial Estate, Phase II , Sheikhupura Road, Lahore -
	The status in reference regulatory authorities	Primolut N Tablet 5mg (Bayer plc 400 South Oak Way, Reading, Berkshire, RG2 6AD)
	Detail of previous approval	DRB 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
438	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CUREXA HEALTH (PVT.) LIMITED** 517 SUNDER INDUSTRIAL ESTSTE **(000864)**
	Application Form Dy. No / Tracking ID & date of submission	(S2M-4PE-5PJP, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Hiclav BD Tablet 1g**
	Label Claim	Each film coated tablet contains: Amoxicillin (as Trihydrate) 875mg Clavulanic acid (as Potassium Clavulanate) 125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	6-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 30oC. Keep in a dry place. Keep out of reach of children. Protect from light.
	For generic drugs (me-too Status)	Stamentin 1g Tablet by Stallion (Reg No. 121451)
	Pharmacotherapeutic Group of (API)	Combinations of Penicillins, including beta-lactamase inhibitors. ATC code: J01CR02
	Name, address of Manufacturing site:	Stallion Pharmaceuticals (Private) Limited-Plot No. 581-SUNDAR INDUSTRIAL ESTATE, LAHORE-
	The status in reference regulatory authorities	USFDA Approved Product Name: Amoxicillin and Clavulanate Potassium Manufacturer: Sandoz

	Detail of previous approval	Stamentin 1g Tablet by Stallion, 335 DRB (25th April 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
439	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(U8V-JAV-623Y, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**GESTRON TABLET 10mg**
	Label Claim	Each film coated tablet contains: Dydrogesterone.....10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1x10's-As per SRO,1x5's-As per SRO,2x10's-As per SRO,3x10's-As per SRO,5x10's-As per SRO
	Shelf Life (Unit)	2 Year15°C - 30°C
	For generic drugs (me-too Status)	Duphaston 10mg Tablets Reg. No. 006654 Abbott Laboratories (Pakistan) Limited
	Pharmacotherapeutic Group of (API)	M/s Yangzhou Aurisco Pharmaceutical Co Ltd
	Name, address of Manufacturing site:	M/s Skywin Pharmaceutical -Plot No. 01 , AI Badar Industrial Estate, Phase II , Sheikhupura Road, Lahore -
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets (Mylan IRE Healthcare Limited)
	Detail of previous approval	DRB 336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
440	Case Category	Contract Manufacturing (Incharge Evaluation Cell)

	Name, address of Applicant.	**Aspin Pharma** Plot # 10 & 25 Sector 20 Korangi Industrial Area Karachi 74900 Pakistan **(000045)**
	Application Form Dy. No / Tracking ID & date of submission	(1U6-VDS-DS9Y, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-27,
	The proposed proprietary name / brand name	**Ellaspin 200mg Tablet**
	Label Claim	Ellaspin 200mg Tablet Each film coated tablet contains: Elagolix Sodium eq. to Elagolix.....200 mg (As per Innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 10's -De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	Egolix tablet (Reg. No. 120276)
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonist.
	Name, address of Manufacturing site:	AGP LIMITED-B-23-C, SINDH INDUSTRIAL TRADING ESTATE, (SITE), Karachi, Karachi West Site Town-
	The status in reference regulatory authorities	ORILISSA® elagolix (as elagolix sodium) tablets 150 mg and 200 mg, Health Canada
	Detail of previous approval	Endam Tablet approved in Minutes of 347th meeting of Registration Board (28th – 30th April, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
441	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(92L-JT4-5TTP, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Dena 20**
	Label Claim	Each film coated tablet contains: Vardenafil as HCl Trihydrate 20mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1x2's; 1x4's; 1x10's-Controlled
	Shelf Life (Unit)	2 YearThis medicinal product does not require any special storage conditions.

	For generic drugs (me-too Status)	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Company: Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan L
	Pharmacotherapeutic Group of (API)	Urologicals, Drugs used in erectile dysfunction, ATC code: G04BE09. Vardenafil is an oral therapy for the improvement of erectile function in men with erectile dysfunction
	Name, address of Manufacturing site:	M/S Medizan Laboratories (Pvt.)-Plot No. 313, ITE Kahuta Road, Islamabad-
	The status in reference regulatory authorities	LEVITRA® (Vardenafil HCl) tablets, for oral use Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Initial U.S. Approval: 2003 Company: Manufactured By: Bayer Healthcare Bayer Pharmaceutical Corporation 400 Morgan Lane, West Haven CT 06516 Made in Germany Marketed by: GSK GlaxoSmithKline Research Triangle Park NC 27709
	Detail of previous approval	Drug Registration Board Meeting(M-351) (Application ID: PZX-LDU-MJ97)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
442	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Aspin Pharma** Plot # 10 & 25 Sector 20 Korangi Industrial Area Karachi 74900 Pakistan **(000045)**
	Application Form Dy. No / Tracking ID & date of submission	(HRM-NUD-M5G3, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-27,
	The proposed proprietary name / brand name	**Ellaspin 150mg Tablet**
	Label Claim	Each film coated tablet contains: Elagolix Sodium eq. to Elagolix.....150 mg (As per Innovator's specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	3 x 14's -De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30°C
	For generic drugs (me-too Status)	Egolix tablet (Reg. No. 120275)
	Pharmacotherapeutic Group of (API)	gonadotropin-releasing hormone (GnRH) receptor antagonist.

	Name, address of Manufacturing site:	AGP LIMITED-B-23-C, SINDH INDUSTRIAL TRADING ESTATE, (SITE), Karachi, Karachi West Site Town-
	The status in reference regulatory authorities	ORILISSA® elagolix (as elagolix sodium) tablets 150 mg and 200 mg, Health Canada
	Detail of previous approval	Endam Tablet approved in Minutes of 347th meeting of Registration Board (28th – 30th April, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
443	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(J9V-3X2-MD8G, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-27,
	The proposed proprietary name / brand name	**Dydra 10mg Tablets**
	Label Claim	Each film coated tablet contains: Dydrogesterone 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 20's-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet by OBS Pakistan (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	• G — Genito urinary system and sex hormones • G03 — Sex hormones and modulators of the genital system • G03D — Progestogens • G03DB — Pregnenes • G03DB01 — Dydrogesterone
	Name, address of Manufacturing site:	Skywin Pharmaceuticals (Pvt.) Ltd.-Plot # 01, Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore. -
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets of Theramex Ireland Limited, Ireland (MHRA)
	Detail of previous approval	336th meeting of Registration Board (4th to 6th June, 2024)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product	

	formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
444	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(65Y-1Z6-5ZPA, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-07,
	The proposed proprietary name / brand name	**Nal-B Injection**
	Label Claim	Each 1ml ampoule contains: Nalbuphine hydrochloride 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Islam Pharmaceutical-7-km Pasrur Road Sialkot -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-317
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
445	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(24Y-LAG-7YRD, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**PREGVOID TABLET 0.75mg**
	Label Claim	Each Tablet Contains : Levonorgestrel.....0.75mg
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	1's-As per SRO,10's-As per SRO,2's-As per SRO,20's-As per SRO,5's-As per SRO
	Shelf Life (Unit)	2 Year15°C - 30°C
	For generic drugs (me-too Status)	Emkit Tablet (Zafa Pharmaceutical)
	Pharmacotherapeutic Group of (API)	M/s Hunan KYF Pharmaceutical. Co., Ltd.
	Name, address of Manufacturing site:	M/s Skywin Pharmaceutical -Plot No. 01 , AI Badar Industrial Estate, Phase II , Sheikhupura Road, Lahore -
	The status in reference regulatory authorities	Levonorgestrel Exeltis 0.75 mg EFG tablets (EXELTIS HEALTHCARE S.L)
	Detail of previous approval	336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
446	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(E94-8YR-EN5A, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-28,
	The proposed proprietary name / brand name	**Racedil 30mg Sachet**
	Label Claim	Each Sachet Contains: Racecadotril 30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Racedo 30mg sachet Manufacturer: Highnoon laboratories ltd Address: 17.5 K.M.Multan Road,Lahore-Pakistan
	Pharmacotherapeutic Group of (API)	antidiarrheals
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	ANSM France
	Detail of previous approval	Acetril, 347th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
447	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Welmed Pharmaceutical Industries (Pvt) Ltd.** Plot No. 108/1 Road No. R-2 I.E. Gadoon. **(000546)**
	Application Form Dy. No / Tracking ID & date of submission	(AZ6-5ZS-MDH8, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-17,
	The proposed proprietary name / brand name	**Noremed 5mg**
	Label Claim	Each tablet contains Norethisterone 5mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	3x 10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Primolut-N
	Pharmacotherapeutic Group of (API)	Synthetic hormone
	Name, address of Manufacturing site:	Skywin pharmaceuticals-Plot No. 01/A, Badar Industrial Estate, Phase-II, 18-KM, Sheikhpura road-
	The status in reference regulatory authorities	MHRA
	Detail of previous approval	Primosky-N 5mg, 347th meeting (Reg. no. 127778)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
448	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(ST1-JRW-1H9L, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-28,
	The proposed proprietary name / brand name	**Racedil 10mg Sachet**
	Label Claim	Each Sachet Contains; Racecadotril 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 30C
	For generic drugs (me-too Status)	Brand Name: Racedo 10mg sachet Manufacturer: Highnoon laboratories ltd Address: 17.5 K.M.Multan Road,Lahore-Pakistan
	Pharmacotherapeutic Group of (API)	antidiarrheals.
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	ANSM France
	Detail of previous approval	Acetril, 347th
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
449	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**
	Application Form Dy. No / Tracking ID & date of submission	(3LJ-RX8-LLEW, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-23,
	The proposed proprietary name / brand name	**DOREXANT 50MG TABLETS**
	Label Claim	Each film-coated tablet contains: Daridorexant Hydrochloride eq. to Daridorexant 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature below 30ºC.
	For generic drugs (me-too Status)	Darix 50mg Tablets M/s Medizan Laboratories, ISLAMABAD.
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No. 313, Industrial Triangle, Kahuta Road, ISLAMABAD-
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant) tablets 50mg Initial U.S. Approval: January 10, 2022 Distributed by: Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087
	Detail of previous approval	
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
450	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)**
	Application Form Dy. No / Tracking ID & date of submission	(EUV-ZBT-UN2U, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Cartin 500mg Injection**
	Label Claim	Each vial contains: Hydrocortisone Sodium Succinate equivalent to hydrocortisone..... 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	3 YearRoom Condition
	For generic drugs (me-too Status)	Cortizone injection by Global Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Glucocorticoid Corticosteroid with Anti-Inflammatory Action
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat Rawalpindi-
	The status in reference regulatory authorities	USFDA approved
	Detail of previous approval	BIOCORT 500mg Injection, Minutes of 307th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
451	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Solaris Life Sciences Private Limited,** Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, **(000992)**

	Application Form Dy. No / Tracking ID & date of submission	(ESA-BGH-VAMA, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-23,
	The proposed proprietary name / brand name	**DOREXANT 25MG TABLETS**
	Label Claim	Each film-coated tablet contains: Daridorexant Hydrochloride eq. to Daridorexant 25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore at temperature below 30ºC.
	For generic drugs (me-too Status)	Darix 25mg Tablets M/s Medizan Laboratories, ISLAMABAD.
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No. 313, Industrial Triangle, Kahuta Road, ISLAMABAD-
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant) tablets 25mg Initial U.S. Approval: January 10, 2022 Distributed by: Idorsia Pharmaceuticals US Inc. One Radnor Corporate Center, Suite 101 100 Matsonford Rd Radnor, PA 19087
	Detail of previous approval	Darix 25mg Tablets, DRB Meeting M-354 (Tracking ID No. TLU-Y1G-QTW5)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
452	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(349-H76-RT85, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Neurovin 15mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....15mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 15mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid

	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 15mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 15mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
453	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(TM9-2YY-UBBY, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Neurovin 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 10mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 10mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 10mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

454	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(NWH-B3U-SX9M, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Neurovin 5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 5mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 5mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
455	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Cell Health Sciences,** Plot No 217, Industrial Triangle, Kahuta Road, Islamabad **(000711)**
	Application Form Dy. No / Tracking ID & date of submission	(WVN-HYA-VNZQ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**Neurovin 2.5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 2.5mg Tablet of M/s Nabi Qasim

	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 2.5mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
456	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(26L-S82-GNLL, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Doic 180mg**
	Label Claim	Each film coated tablet contains: Bempedoic acid.....180mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO / DPC-Controlled
	Shelf Life (Unit)	2 YearThis medicinal product does not require any special storage conditions
	For generic drugs (me-too Status)	Brand Name: Bemzeox 180mg Tablet Registration holder: Horizon Healthcare (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Lipid Modifying agent
	Name, address of Manufacturing site:	M/S Medizan Laboratories (Pvt.)-Plot No. 313, ITE Kahuta Road, Islamabad-
	The status in reference regulatory authorities	Brand Name: Nexletol 180mg Tablets Registration holder: Esperion Therapeutics, Inc. 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108,USA FDA Approved Drug.
	Detail of previous approval	Tracking ID: SU8-E45-A4D3
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of	

	Form 5F. The firm has cross-referred a product approved in PRV vide SU8-E45-A4D3 dated 22 October 2025.	
	Decision	
	Approved Approved	
457	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(DVP-RE3-NJ1M, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Mythela 125mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....125mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Methyll 125mg Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
458	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(4ZN-XVG-AURY, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Evana**
	Label Claim	Each tablet contains: Avanafil 100mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1x2's; 1x4's; 1x10's-Controlled
	Shelf Life (Unit)	2 YearThis medicinal product does not require any special storage conditions
	For generic drugs (me-too Status)	Not Applicable, since this is a New Drug
	Pharmacotherapeutic Group of (API)	Avanafil belongs to the pharmacotherapeutic group of Urologicals; Drugs used in erectile dysfunction. Specifically, it is a phosphodiesterase type 5 (PDE5) inhibitor. Its mechanism of action involves inhibiting PDE5, which is an enzyme that plays a role in the development of erections.
	Name, address of Manufacturing site:	M/S Medizan Laboratories (Pvt.)-Plot No. 313, ITE Kahuta Road, Islamabad-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, for oral use Tablets: 50 mg, 100 mg, 200 mg Initial U.S. Approval: 2012 Company: Manufactured for VIVUS, Inc. Mountain View, CA 94040 Manufactured in Osaka Japan
	Detail of previous approval	Already approved (M-351) (Application ID: ZU1-HRR-6HTJ).
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID ZU1-HRR-6HTJ dated 24 December 2025.	
	Decision	
	Approved Approved	
459	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(7E5-5Z7-ANPT, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Mythela 1gm Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....1gm (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 Yearbelow 25c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE,

		TAXILA, RAWALPINDI-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Methyll 1gm Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
460	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)**
	Application Form Dy. No / Tracking ID & date of submission	(7A3-GZL-VZA1, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-16,
	The proposed proprietary name / brand name	**NEBIZIDE PLUS**
	Label Claim	Each Film Coated Tablet contains: Nebivolol Hydrochloride Eq. to Nebivolol.....5mg Hydrochlorothiazide.....
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 60's, 84's, 90's, 100's -As per SRO
	Shelf Life (Unit)	2 YearStore at 20°C to 25°C
	For generic drugs (me-too Status)	Genix Pharma (Pvt) Ltd (Gneb)
	Pharmacotherapeutic Group of (API)	Nebivolol (Zhejiang Huahai Pharmaceutical Co., Ltd) & Hydrochlorothiazide (Changzhou Pharmaceutical Factory)
	Name, address of Manufacturing site:	Genix Pharma (Pvt)Ltd.-44, 45B, KORANGI CREEK ROAD, Karachi.-
	The status in reference regulatory authorities	Menarini international (Lobivon Plus 5mg/ 25mg film coated tablets)
	Detail of previous approval	340
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
461	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(G4N-86T-JH3D, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-18,
	The proposed proprietary name / brand name	**Berinum 1gm Injection IV**
	Label Claim	Each vial contains: Meropenem 1gm (Blended with Sterile Sodium Carbonate) (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Meronem Injection by ICI Pakistan Ltd.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Name, address of Manufacturing site:	M/s Bio-Next Pharmaceuticals -Plot No. 50, St No. S-10, RCCI Industrial Estate Rawat Islamabad.-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	Minutes of 296th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
462	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(ZW2-4BR-45G6, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**Methidew 1g Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....1gm
	Reference to Finished product specifications	United States Pharmacopeia

	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Wenovo Pharmaceuitcals-Plot No. 31&32 Punjab Small Industrial Estate Taxila Rawalpindi -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
463	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(Y1H-AV2-Q6VH, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-30,
	The proposed proprietary name / brand name	**Merolin 2.5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 2.5mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 2.5mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
464	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(1GB-QRQ-L4JN, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-18,
	The proposed proprietary name / brand name	**Berinum Injection 500mg IV**
	Label Claim	Each vial contains: Meropenem (as trihydrate) 500mg blended with sodium carbonate....45.1mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Meronem Injection by ICI Pakistan Ltd.
	Pharmacotherapeutic Group of (API)	Carbapenem
	Name, address of Manufacturing site:	M/s Bio-Next Pharmaceuticals,-Plot No. 50, Street No. S-10, RCCI, Rawat-
	The status in reference regulatory authorities	Merrem Injection (USFDA Approved)
	Detail of previous approval	MENEPOR 500mg Injection IV, Minutes of 296th Meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
465	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(Q8Z-1ZT-6G66, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-01,
	The proposed proprietary name / brand name	**Methidew 500mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....500Mg

	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Wenovo Pharmaceuitcals-Plot No. 31&32 Punjab Small Industrial Estate Taxila Rawalpindi -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
466	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(P5B-72L-B7JB, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-30,
	The proposed proprietary name / brand name	**Merolin 5mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 5mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 5mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 5mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality	

	agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
467	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)**
	Application Form Dy. No / Tracking ID & date of submission	(8TU-VQ7-16MY, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-16,
	The proposed proprietary name / brand name	**NEBIZIDE PLUS**
	Label Claim	Each Film Coated Tablet contains: Nebivolol Hydrochloride Eq. to Nebivolol.....5mg Hydrochlorothiazide.....
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 10's, 14's, 20's, 28's, 30's, 56's, 60's, 84's, 90's, 100's -As per SRO
	Shelf Life (Unit)	2 YearStore at 20°C to 25°C
	For generic drugs (me-too Status)	Genix Pharma (Pvt) Ltd (Gneb)
	Pharmacotherapeutic Group of (API)	Nebivolol (Zhejiang Huahai Pharmaceutical Co., Ltd) & Hydrochlorothiazide (Changzhou Pharmaceutical Factory)
	Name, address of Manufacturing site:	Genix Pharma (Pvt)Ltd.-44, 45B, KORANGI CREEK ROAD, Karachi.-
	The status in reference regulatory authorities	Menarini international (Lobivon Plus 5mg/ 12.5mg film coated tablets)
	Detail of previous approval	340
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
468	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**

	Application Form Dy. No / Tracking ID & date of submission	(NEA-11J-UW82, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-13,
	The proposed proprietary name / brand name	**FIXIME 100mg/5ml Dry Suspension**
	Label Claim	Each 5mL of reconstituted suspension contains: Cefixime as trihydrate .....100mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Biozil 100mg/5mL Dry Suspension Bio-Labs (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Name, address of Manufacturing site:	M/s Bloom Pharmaceuticals (Pvt) Ltd.-Plot No. 30, Phase I and II, Industrial Estate Hattar-
	The status in reference regulatory authorities	Cefixime for Oral Suspension, 100mg/5mL (USFDA Approved)
	Detail of previous approval	M-316
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
469	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**SWERA PHARMACEUTICALS** PLOT# 27, STREET# S-4, INDUSTRIAL ESTATE, RAWAT **(000941)**
	Application Form Dy. No / Tracking ID & date of submission	(ZE4-ABT-NGDG, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-13,
	The proposed proprietary name / brand name	**FIXIME 200mg/5ml Dry Suspension**
	Label Claim	Each 5mL of reconstituted suspension contains: Cefixime as trihydrate .....200mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO / DPC -As per SRO
	Shelf Life (Unit)	2 YearBelow 30°C
	For generic drugs (me-too Status)	Biozil 200mg/5mL Dry Suspension
	Pharmacotherapeutic Group of (API)	Cephalosporin antibiotic
	Name, address of Manufacturing site:	M/s Bloom Pharmaceuticals Pvt Ltd.-Plot No. 30, Phase I and II, Industrial Estate Hattar-

	The status in reference regulatory authorities	Cefixime for Oral Suspension, 200mg/5mL (USFDA Approved)
	Detail of previous approval	M-316
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
470	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Maybush Pharmaceuticals (Pvt) Ltd** Plot # 249/A, Industrial Triangle, Kahuta Road Islamabad **(000501)**
	Application Form Dy. No / Tracking ID & date of submission	(1QT-VPE-6M6Y, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Cardano 0.5mg TABLETS**
	Label Claim	Each uncoated Tablet Contains; Cabergoline 0.5mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per sro-As per SRO
	Shelf Life (Unit)	2 Year30C
	For generic drugs (me-too Status)	Genome pharma 321th meeting
	Pharmacotherapeutic Group of (API)	Pharmacotherapeutic Group: Prolactine inhibitors WHO ATC Code: G02CB03
	Name, address of Manufacturing site:	Genome Pharmaceuticals (Pvt. Ltd)-Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK, Pakistan-
	The status in reference regulatory authorities	SRA Registration Status: Registered in UK Brand Name: Dostinex Tablets 0.5mg Manufacturer: Pfizer Limited Address: Ramsgate Road, Sandwich, Kent, CT13 9NJ
	Detail of previous approval	321th meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	

471	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Universal pharmaceuticals (pvt) Ltd** 131-A, Hayatabad industerial estate **(000545)**
	Application Form Dy. No / Tracking ID & date of submission	(MBZ-R2V-72MG, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-18,
	The proposed proprietary name / brand name	**Meno 1g Injection**
	Label Claim	Each vial contains: Meropenem Trihydrate Eq. to Meropenem.....1g (Blended with sodium Carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Dew-Max Pharmaceuticals (Pvt) Ltd -Plot No. 6 SS-4 National Industrial Zone Rawat Islamabad -
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
472	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)**
	Application Form Dy. No / Tracking ID & date of submission	(LRT-ZAQ-6EAA, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-01-28,
	The proposed proprietary name / brand name	**LOTENIX-T**
	Label Claim	Each ml contains: Loteprednol Etabonate.....5mg (0.5%) Tobramycin 0.3mg (0.3%)
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	5ml, 7.5ml, 10ml -As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Helix Pharma(Pvt.) Ltd. (Lotetab (Tobramycin +Loteprednol etabonate)3mg/5mg per ml)

	Pharmacotherapeutic Group of (API)	Loteprednol Etabonate (Aarti Industries Limited) & Tobrmycin (Chongqing Daxin Pharmaceutical Co., Ltd.)
	Name, address of Manufacturing site:	Genix Pharma (Pvt)Ltd.-44, 45B, KORANGI CREEK ROAD, Karachi.-
	The status in reference regulatory authorities	Bausch + Lomb Ireland Limited (Zylet)
	Detail of previous approval	340
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
473	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Universal pharmaceuticals (pvt) Ltd** 131-A, Hayatabad industerial estate **(000545)**
	Application Form Dy. No / Tracking ID & date of submission	(8NP-QQM-W98S, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-18,
	The proposed proprietary name / brand name	**Meno 500mg Injection**
	Label Claim	Each vial contains: Meropenem Trihydrate Eq. to Meropenem.....500mg (Blended with sodium Carbonate)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As Per SRO-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Dew-Max Pharmaceuticals (Pvt) Ltd -PLOT NO 6, STREET NO SS-4, MAIN INDUSTRIAL AREA G.T ROAD, RAWAT, Islamabad Islamabad Rural-
	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-312
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
474	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(WA8-U93-BB23, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**"Enprazol DS"**
	Label Claim	Each Modified release tablets contains:- Napreoxen .....500mg (as Enteric coated)ESOMEPRAZOLE AS MAGNESIUM TRIHYDRATE.....20MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Proposed Pack size: As per SRO / DPC-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C. Store in the original package in order to protect from light. Keep the bottle tightly closed in order to protect from moisture.
	For generic drugs (me-too Status)	Product Name: Glomov 20/500mg tablet Composition: Each modified release tablets contains: Naproxen… ..... 500mg (enteric coated core) Esomeprazole as magnesium trihydrate 20mg
	Pharmacotherapeutic Group of (API)	NSAID and proton pump inhibitor
	Name, address of Manufacturing site:	MIS Medizan Laboratories (Pvt.)-Plot No. 313, ITE Kahuta Road, Islamabad-
	The status in reference regulatory authorities	SRA Registration Status: USFDA approved Brand Name: Vimovo delayed release tablet 20/500mg Tablets Manufacturer: Dr. Reddy's Laboratories Limited Route of administration: Oral Dosage Form: Oral Tablets Country of Origin: USA
	Detail of previous approval	Already approved Tracking ID: MD5-JST-R8LA
	Evaluation Remarks	
	In light of Registration Board’s decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID MD5-JST-R8LA dated 24 October 2025.	
	Decision	
	Approved Approved	

475	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hudson Pharma (Pvt) Ltd** D-93, North Western Industrial Zone, Port Qasim Authority **(000842)**
	Application Form Dy. No / Tracking ID & date of submission	(NDJ-BUJ-2874, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Linzox**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO
	Shelf Life (Unit)	2 YearStore in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA Approved. https://products.mhra.gov.uk/product/?product=YSELTY
	Detail of previous approval	Lingolix 100mg Tablets; 351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
476	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Hudson Pharma (Pvt) Ltd** D-93, North Western Industrial Zone, Port Qasim Authority **(000842)**
	Application Form Dy. No / Tracking ID & date of submission	(PNB-AJV-EGZ5, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Linzox**
	Label Claim	Each film-coated tablet contains: Linzagolix Choline eq. to Linzagolix 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14s-As per SRO

	Shelf Life (Unit)	2 YearStore in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad, Pakistan-
	The status in reference regulatory authorities	MHRA Approved. https://mhraproducts4853.blob.core.windows.net/c
	Detail of previous approval	Lingolix 200mg Tablets; 351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
477	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(DGH-X5Z-AQNE, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-02-09,
	The proposed proprietary name / brand name	**Siagra Tablet**
	Label Claim	Each film coated tablet contains: Sildenafil Citrate eq. to Sildenafil 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	Proposed Pack size: As per SRO / DPC-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30°C. Store in the original package in order to protect from moisture.
	For generic drugs (me-too Status)	VIAGRA® (sildenafil citrate) tablets, for oral use Tablets: 25 mg, 50 mg, 100 mg Initial U.S. Approval: 1998 Pfizer Inc, NY, NY 10017 Company: Viagra (sildenafil citrate) registered trademarks of Pfiz
	Pharmacotherapeutic Group of (API)	Sildenafil citrate is a medication in the phosphodiesterase-5 inhibitor (PDE5- I) class of drugs. PDE5-I medications are used to treat erectile dysfunction and pulmonary arterial hypertension. Sildenafil works in the presence of sexual stimulation. Some common side effects of sildenafil include: headache, flushing, dyspepsia,

		nasal congestion, dizziness, nausea, hot flush, visual disturbance, cyanopsia, and vision blurred. Serious cardiovascular events, including myocardial infarction, unstable angina, and sudden cardiac death, have been reported in association with the use of sildenafil. Most of these events occurred during or shortly after sexual intercourse.
	Name, address of Manufacturing site:	M/S Medizan Laboratories (Pvt.)-Plot No. 313, ITE Kahuta Road, Islamabad-
	The status in reference regulatory authorities	VIAGRA® (sildenafil citrate) tablets, for oral use Tablets: 25 mg, 50 mg, 100 mg Initial U.S. Approval: 1998 Pfizer Inc, NY, NY 10017 Company: Viagra (sildenafil citrate) registered trademarks of Pfizer Inc. Distributed By; Pfizer Division of Pfizer Inc, NY, NY 10017
	Detail of previous approval	Already approved Tracking ID: 882-QQY-J4Y2
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID 882-QQY-J4Y2 dated 30 January 2026.	
	Decision	
	Approved Approved	
478	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Dew-Max Pharmaceuticals (Pvt) Ltd** Plot # 6, Street No. SS-4, Main Industrial Area, Rawat - Islamabad **(000889)**
	Application Form Dy. No / Tracking ID & date of submission	(L83-M93-XZWU, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**Betanox-G Cream**
	Label Claim	Each gram contains: Betamethasone Dipropionate (USP) Eq. to Betamethasone ..... 0.5mg (0.05%w/w) Gentamicin Sulphate (USP) Eq. to Gentamicin 1mg (0.1%w/w)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10gm-As per SRO,15gm-As per SRO,20gm-As per SRO
	Shelf Life (Unit)	2 Year15-30c
	For generic drugs (me-too Status)	Attached
	Pharmacotherapeutic Group of (API)	Attached
	Name, address of Manufacturing site:	Focus & Rulz Pharmaceuticals (Pvt) Ltd -Plot No.44 Industrial Triangle Kahuta Road Islamabad-

	The status in reference regulatory authorities	Attached
	Detail of previous approval	M-336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
479	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Scilife Pharma Private Limited** FD-57/58-A2, Korangi Creek Industrial Park (KCIP) **(000837)**
	Application Form Dy. No / Tracking ID & date of submission	(ND6-28S-P4HN, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-03-12,
	The proposed proprietary name / brand name	**Suzenax 50mg Tablet**
	Label Claim	Each film coated tablet contains: Suzetrigine..... 50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10x10's -As per SRO,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,4x10's-As per SRO,5x10's-As per SRO
	Shelf Life (Unit)	2 YearStore at 25°C (Excursions permitted between 15°C to 30°C).
	For generic drugs (me-too Status)	Suzemax 50mg Tablets, by Medizan Laboratories (Pvt) Ltd Approved in 354th RB Meeting Minutes
	Pharmacotherapeutic Group of (API)	Selective Na, 1.8 voltage gated sodium channel blocker
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt) Ltd -Plot No.313 Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	JOURNAVX (Suzetrigine) tablets, for oral use Tablets: 50 mg, Initial U.S. Approval: 2025 Manufactured for Vertex Pharmaceuticals Incorporated; 50 Northern Avenue, Boston, MA 02210
	Detail of previous approval	Suzemax 50mg Tablets (Suzetrigine), Approved in 354th RB MEETING MINUTES
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality	

	agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
480	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Jinnah Pharmaceuticals Pvt Ltd** 13 Km Lahore Road Multan **(000578)**
	Application Form Dy. No / Tracking ID & date of submission	(PJR-AZ3-1325, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Moxjin 400mg/250ml Infusion**
	Label Claim	Each Vial of 250ml contains: Moxifloxacin HCl equivalent to Moxifloxacin.....400mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ml vial-As per SRO
	Shelf Life (Unit)	2 YearDo not store below 15°C.
	For generic drugs (me-too Status)	Product Name Mofest 400mg/250ml Reg. no. 053227 Price: 370 Manufacturer: Sami Pharmaceuticals Pvt Ltd
	Pharmacotherapeutic Group of (API)	Quinolone antibacterials, fluoroquinolones
	Name, address of Manufacturing site:	Jaskan Pharmaceuticals (Pvt.) Ltd. -50-Sundar Industrial Estate, Lahore, Pakistan.-
	The status in reference regulatory authorities	Avelox 400mg/250ml (MHRA Approved)
	Detail of previous approval	DRB M-320 Reg No 115254as
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
481	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Medley Pharmaceuticals** 41-A PSIE Jhang Bahter Road ,Wah Cantt,Rawalpindi . **(000237)**
	Application Form Dy. No / Tracking ID & date of submission	(WE6-1RP-XVT8, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-25,
	The proposed proprietary name / brand name	**Maltoley 500mg/10ml Injection**
	Label Claim	Each 10ml contains: Iron as Ferric Carboxymaltose.....500mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	BOFERIN 500MG/10ML INJECTION (BOSCH PHARMACEUTICALS (Pvt.) Ltd)
	Pharmacotherapeutic Group of (API)	Iron replacement products
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-208-C Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	FERINJECT (VIFOR PHARMA)
	Detail of previous approval	Fermed Injection 500mg/10ml (Meeting No. 352) (Case No. 51)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
482	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Elvin Pharmaceuticals** 22 Km from Thokar Niaz Baig, 35 km Raiwind Road, Lahore **(000508)**
	Application Form Dy. No / Tracking ID & date of submission	(A24-SNZ-LN8Y, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-07,
	The proposed proprietary name / brand name	**FMC Maltose 500mg/10ml Injection**
	Label Claim	Each 10ml Contains: Iron as Ferric Carboxymaltose.....500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 YearStore at below 30 degree celcius
	For generic drugs (me-too Status)	BOFERIN 500MG/10ML INJECTION (BOSCH PHARMACEUTICALS (Pvt.) Ltd)
	Pharmacotherapeutic Group of (API)	Iron replacement products
	Name, address of Manufacturing site:	Hi-Med Pharmaceuticals-208-C Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	FERINJECT (VIFOR PHARMA)
	Detail of previous approval	Fermed Injection 500mg/10ml (Meeting No. 352) (Case No. 51)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
483	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat **(000886)**
	Application Form Dy. No / Tracking ID & date of submission	(HAU-2VA-QVD7, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**Clotazole-H CREAM**
	Label Claim	Each gm contains: Clotrimazole 10mg Hydrocortisone (as Acetate) 10mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10g; 15g; 20g; 30g-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Hydrozole Cream by GSK
	Pharmacotherapeutic Group of (API)	Data Already approved in 357 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Canesten HC Cream HPRA Approved
	Detail of previous approval	Tromatek-H Cream in 357 MoM.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
484	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Biogen Pharma** 8-KM, Chak Beli Road, Rawat, **(000639)**
	Application Form Dy. No / Tracking ID & date of submission	(V5A-MHB-3J54, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-28,
	The proposed proprietary name / brand name	**VIT-E 400MG CAPSULE**
	Label Claim	Each soft gelatin capsule contains: Dl alpa tocopheryl acetate .....400mg (USP Specifications)
	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 YearRoom Condition
	For generic drugs (me-too Status)	Evion 400mg soft gelatin capsule Manufactured by Martin Dow pharmceuticals
	Pharmacotherapeutic Group of (API)	Vitamin
	Name, address of Manufacturing site:	Biogen Life Science -8-km, Chakbeli Road, Rawat Rawalpindi-
	The status in reference regulatory authorities	Vitamin E Softgel Capsules FDA Approved
	Detail of previous approval	Tocogen 400mg Soft gelatin Capsules, Minutes of 345th meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
485	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Atco Laboratories Limited** B-18 SITE KARACHI **(000188)**
	Application Form Dy. No / Tracking ID & date of submission	(WX5-SW5-5SEL, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-04,
	The proposed proprietary name / brand name	**ATMIRO**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin (as Mirogabalin Besylate) 2.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,1x7's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,3x10's-De-Controlled,4x7's-De-Controlled
	Shelf Life (Unit)	2 YearDonot store and transport above 30 degree centrigrade
	For generic drugs (me-too Status)	Mirolin 2.5mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	M/s WIMITS PHARMACEUTICALS PVT. LIMITED-PLOT # 129, SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	Tarlige Tablets 2.5mg
	Detail of previous approval	Mirogab 2.5mg Tablet,DRB 344 held on 31st December 2024 -02nd January 2025
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant	

	application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
486	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(Q1S-YD4-NM9R, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Hydrona 100mg Injection**
	Label Claim	Each Vial Contains: Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....100mg (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 Yearbelow 25c
	For generic drugs (me-too Status)	CORTISONE 100mg INJECTION by Vision Pharma
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	HY KOR 100MG, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
487	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(Z24-ER7-Y6UA, 2026-08-19)

	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Hydrona 250mg Injection**
	Label Claim	Each Vial Contains: Hydrocortisone equivalent Hydrocortisone Sodium Succinate (USP).....250mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	CORTISONE 250mg INJECTION by Vision Pharma
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	HY KOR 250MG, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
488	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well & Well Pharma Pvt.Ltd** Plot No 07, Street S-8, RCCI, Rawat Rawalpindi **(000687)**
	Application Form Dy. No / Tracking ID & date of submission	(VEY-T6Z-J4B2, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**DESWEL Syrup 0.5mg/ml**
	Label Claim	Each ml of syrup contains: Desloratadine 0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Neo-Antial Syrup 0.5mg/ml Reg No 076064 M/s Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	second-generation tricyclic antihistamines
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	DRB-M-339 Reg No 124606 Manufacturer Caliph Pharma for Nicholas Pharma

	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
489	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(JVG-AJS-4UXD, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Mythela 40mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....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 Yearbelow 25c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Methyll 40mg Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
490	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**INVENTOR PHARMA PVT LTD** Plot No. K-196 S.I.T.E, Super Highway Phase-II **(000866)**

	Application Form Dy. No / Tracking ID & date of submission	(BUY-4HT-J4PM, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-22,
	The proposed proprietary name / brand name	**Insunate 120mg Injection**
	Label Claim	Each vial contains: Artesunate.....120mg
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	3 Year36 months for unopened vial. After reconstitution: the total in-use period should not exceed 1 hour.
	For generic drugs (me-too Status)	Brand Name: Misonate 120mg Injection Manufacturer /Registration Holder: Tabros Pharmaceuticals Registration Number: 083299
	Pharmacotherapeutic Group of (API)	P01BE03
	Name, address of Manufacturing site:	Palpex Pharmaceuticals (Pvt.) Ltd-Palpex Pharmaceuticals (Pvt.) Ltd Plot # FD-46-A8, Street - I, Sector 38, Korangi Creek Industrial Park, Karachi-
	The status in reference regulatory authorities	Reference Product: Arinate 120mg,for IV/IM use Registration holder: M/s DAFRA PHARMA Reference: US-FDA https://www.dafrapharma.com/wp-content/uploads/2025/05/DP-SmPC-Arinate-120_SARINJ120B_en_rev08-2022.pdf
	Detail of previous approval	Artesun Injection 120mg DRB 353rd DRB Dated 14th Jan. 2026 , page # 485
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
491	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Wallace Pharma Evolutions** Kala wala Stop 20-km, Lahore Jaranwala Road, Lahore. **(000951)**
	Application Form Dy. No / Tracking ID & date of submission	(6EB-1Q3-M8HL, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Mythela 500mg Injection**
	Label Claim	Each Vial Contains: Methylprednisolone as Sodium Succinate (USP).....500mg (Product complies USP Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Solu Medrol Injection by Pfizer
	Pharmacotherapeutic Group of (API)	Corticosteroids
	Name, address of Manufacturing site:	Wenovo Pharmaceuticals-PLOT # 31,32, PUNJAB SMALL INDUSTRIAL ESTATE, TAXILA, RAWALPINDI-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	Methyll 500mg Injection, DRB 339
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
492	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Atco Laboratories Limited** B-18 SITE KARACHI **(000188)**
	Application Form Dy. No / Tracking ID & date of submission	(4U5-MBM-9EY1, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-04,
	The proposed proprietary name / brand name	**ATMIRO Tablet 5mg**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin (as Mirogabalin Besylate) 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,1x7's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,3x10's-De-Controlled,4x7's-De-Controlled
	Shelf Life (Unit)	2 YearDonot store and transport above 30 degree centrigrade
	For generic drugs (me-too Status)	Mirolin 5mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	M/s WIMITS PHARMACEUTICALS PVT. LIMITED-PLOT # 129, SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	Tarlige Tablets 5mg
	Detail of previous approval	Mirogab 5mg Tablet,DRB 344 held on 31st December 2024 -02nd January 2025
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality	

	agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
493	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Atco Laboratories Limited** B-18 SITE KARACHI **(000188)**
	Application Form Dy. No / Tracking ID & date of submission	(Z3P-81B-TV26, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-04,
	The proposed proprietary name / brand name	**ATMIRO Tablet 10mg**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin (as Mirogabalin Besylate) 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-De-Controlled,1x7's-De-Controlled,2x10's-De-Controlled,2x7's-De-Controlled,3x10's-De-Controlled,4x7's-De-Controlled
	Shelf Life (Unit)	2 YearDonot store and transport above 30 degree centrigrade
	For generic drugs (me-too Status)	Mirolin 10mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	M/s WIMITS PHARMACEUTICALS PVT. LIMITED-PLOT # 129, SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	Tarlige Tablets 10mg
	Detail of previous approval	Mirogab 10mg Tablet,DRB 344 held on 31st December 2024 -02nd January 2025
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
494	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Obsons Pharmaceuticals** 209-S Quaid-e-Azam industrial estate, **(000416)**
	Application Form Dy. No / Tracking ID & date of submission	(7MY-RMP-Q75U, 2026-08-19)

	Detail of Fee Submitted	97200, 2026-04-30,
	The proposed proprietary name / brand name	**Tazopime 4.5 g Injection**
	Label Claim	Each vial contains: Piperacillin (as Sodium) 4.0g Tazobactam (as Sodium) 0.5g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 x 1's-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Inzalin TZ 4.5g Injection
	Pharmacotherapeutic Group of (API)	β-Lactamase inhibitor
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Badar Industrial Estate, Phase II, Sheikhupura Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Inzalin TZ 4.5g Injection, 335
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
495	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(GNV-ELU-8ZDV, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**DYDRONIX TABLET**
	Label Claim	Each film coated tablet contains: Dydrogesterone 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-De-Controlled
	Shelf Life (Unit)	3 Yearas required
	For generic drugs (me-too Status)	Dydrogest 10mg Tablet by OBS Pakistan (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones
	Name, address of Manufacturing site:	SKYWIN PHARMACEUTICALS-Plot #01,Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets by Mylan IRE Healthcare Limited HPRA of Ireland
	Detail of previous approval	TABLET D-GEST 10 MG approved in DRB -336th held on 4-6 June 2024
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
496	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Obsons Pharmaceuticals** 209-S Quaid-e-Azam industrial estate, **(000416)**
	Application Form Dy. No / Tracking ID & date of submission	(5YR-ZG6-G6TM, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-30,
	The proposed proprietary name / brand name	**Ferricure 500 mg/10 mL Injection**
	Label Claim	Each 10 mL contains: Ferric carboxymaltose Eq.to Elemental Iron 500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's x 10 mL-As per SRO
	Shelf Life (Unit)	2 YearStore at room temperature
	For generic drugs (me-too Status)	Carbosky 500mg/10ml Injection
	Pharmacotherapeutic Group of (API)	Ferric carboxymaltose injection is in a class of medications called iron replacement products.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Badar Industrial Estate, Phase II, Sheikhupura Road, Lahore, Pakistan.-
	The status in reference regulatory authorities	MHRAA Approved
	Detail of previous approval	Carbosky 500mg/10ml Injection, 347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
497	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(7LH-AAS-77VA, 2026-08-19)

	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Runib Tablet 5mg**
	Label Claim	Each Film Coated Tablet Contains: Tofacitinib Citrate eq. to Tofacitinib 5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-De-Controlled
	Shelf Life (Unit)	4 Yearas required
	For generic drugs (me-too Status)	Tofamit 5mg Tablet BY Wimits Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Janus kinase (JAK) inhibitor
	Name, address of Manufacturing site:	WIMITS PHARMACEUTICALS (PVT). LTD - Plot No. 129 Sunder Industrial Estate Lahore, Pakistan. -
	The status in reference regulatory authorities	Xeljanz Tablet by Pfizer Ireland
	Detail of previous approval	Tofamit 5mg Tablet Approved in DRB 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
498	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(UHX-AXR-P5ZQ, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Doriva 25mg Tablets**
	Label Claim	Each film coated tablet contains: Daridorexant Hydrochloride eq. to Daridorexant 25mg
	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)	Not Applicable
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad-Pakistan-
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant) tablets, for oral use 25mg Tablet by Idorsia Pharmaceuticals US Inc. (US-FDA)

	Detail of previous approval	Darix 25mg Tablet, 354th meeting of Registration Board (4th to 5th March, 2026)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
499	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(R17-7W1-997Y, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Lynza 100mg Tablets**
	Label Claim	Each film coated tablet contains: Linzagolix Choline eq. to Linzagolix..... 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's; 2x7's; 2x10's; 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Lizohil 100mg Tablet of Hilton Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	M/s Medizan Laboratories (Pvt) 1td.-Plot No.313 Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	Yselty 100 mg film-coated tablets, for oral use by Theramex Ireland Limited
	Detail of previous approval	Lingolix 100mg Tablets, 351 Meeting of Registration Board (23rd – 24th September, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

	Approved	
500	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(PZE-6YJ-TDTV, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Doriva 50mg Tablets**
	Label Claim	Each film coated tablet contains: Daridorexant Hydrochloride eq. to Daridorexant 50mg
	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)	Not Applicable
	Pharmacotherapeutic Group of (API)	Dual Orexin Receptor Antagonist (DORA)
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad-Pakistan-
	The status in reference regulatory authorities	QUVIVIQ (Daridorexant) tablets, for oral use 50mg Tablet by Idorsia Pharmaceuticals US Inc. (US-FDA)
	Detail of previous approval	Darix 50mg Tablet, 354th meeting of Registration Board (4th to 5th March, 2026)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
501	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(PX8-T6V-W1J7, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Lynza 200mg Tablets**
	Label Claim	Each film coated tablet contains: Linzagolix Choline eq. to Linzagolix..... 200mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1x10's; 2x7's; 2x10's; 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30°C.
	For generic drugs (me-too Status)	Lizohil 200mg Tablet of Hilton Pharma (Pvt) Limited
	Pharmacotherapeutic Group of (API)	Belongs to hypothalamic hormones, specifically non-peptide GnRH receptor antagonists used as anti-gonadotropins
	Name, address of Manufacturing site:	M/s Medizan Laboratories (Pvt) 1td.-Plot No.313 Industrial Triangle Kahuta Road Islamabad-
	The status in reference regulatory authorities	Yselty 200 mg film-coated tablets, for oral use of Theramex Ireland Limited
	Detail of previous approval	Lingolix 200mg Tablets, 351 Meeting of Registration Board (23rd – 24th September, 2025)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
502	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(6AN-ZXR-EPPL, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Velmod 2mg Tablets**
	Label Claim	Each film coated tablet contains: Etrasimod Arginine eq. to Etrasimod 2mg
	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)	Not Applicable
	Pharmacotherapeutic Group of (API)	Immunosuppressants / Immunomodulatory agents. L04AE05
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad-Pakistan-
	The status in reference regulatory authorities	VELSIPITY™ (Etrasimod) tablets, for oral use 2mg Tablets by Pfizer Labs (US-FDA)
	Detail of previous approval	Etra 2mg Tablet, 354th meeting of Registration Board (4th to 5th March, 2026)
	Evaluation Remarks	

	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
503	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(E1X-GXH-LJBS, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Golix 150mg Tablets**
	Label Claim	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix 150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 14's and As per SRO-As per SRO
	Shelf Life (Unit)	2 YearAs required
	For generic drugs (me-too Status)	ORLIX 150mg Tablets by Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore.
	Pharmacotherapeutic Group of (API)	As previously submitted
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd.,. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Orilissa (Elagolix) 150mg tablet by AbbVie Inc. North Chicago, IL 60064
	Detail of previous approval	ORLIX 150mg Tablets, DRB 343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
504	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(857-55B-J89E, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Golix 200mg Tablets**
	Label Claim	Each film coated tablet contains: Elagolix Sodium equivalent to Elagolix 200mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 14's and As per SRO-As per SRO
	Shelf Life (Unit)	2 YearAs required
	For generic drugs (me-too Status)	ORLIX 200mg Tablets by Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sunder Industrial Estate Raiwind Road, Lahore.
	Pharmacotherapeutic Group of (API)	As previously submitted
	Name, address of Manufacturing site:	Wimits Pharmaceuticals (Pvt) Ltd.,. -Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore-
	The status in reference regulatory authorities	Orilissa (Elagolix) 200mg tablet by AbbVie Inc. North Chicago, IL 60064
	Detail of previous approval	ORLIX 200mg Tablets, DRB- 343rd
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
505	Case Category	Export Facilitation (Incharge Evaluation Cell)
	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	(PDZ-1ZT-7AWE, 2026-03-02)
	Detail of Fee Submitted	97200, 2025-12-30,
	The proposed proprietary name / brand name	**FENTIN 3MG/2.5ML Inhalation SUSPENSION**
	Label Claim	Each single 2.5ml ampoule contains: Ensifentrine.....3mg (as per *Innovator_s Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearBelow 25 C
	For generic drugs (me-too Status)	N/A
	Pharmacotherapeutic Group of (API)	PDE3 and PDE4 inhibitor
	Name, address of Manufacturing site:	M/S Weather Folds Pharmaceuticals, Hattar-Plot no. 69/2, Phase II, Industrial Estate, Hattar, KPK -

	The status in reference regulatory authorities	https://www.fda.gov/media/182289/download
	Detail of previous approval	
	Evaluation Remarks	
	Export facilitation glass ampoule whereas innovator's product is filled into a unit dose low density polyethylene (LDPE) plastic ampule.	
	Decision	
	Deferred Registration Board deferred the case for following innovator's product packaging and re-submission of data.	
506	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Carer Pharmaceuticals industries** Plot no.27, Main Road Rawat Industrial Estate, Rawat **(000925)**
	Application Form Dy. No / Tracking ID & date of submission	(J51-GP4-DY99, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-30,
	The proposed proprietary name / brand name	**Vistarone 10mg tablet**
	Label Claim	EACH FILM COATED TABLET CONTAINS: DYDROGESTERONE ..... 10 MG
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's ,20,30's-As per SRO
	Shelf Life (Unit)	2 YearStore between 15C-30C
	For generic drugs (me-too Status)	DUPHASTON 10 MG FILM-COATED TABLETS
	Pharmacotherapeutic Group of (API)	GENITO URINARY SYSTEM AND SEX HORMONES.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals -Plot # 01, Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore. -
	The status in reference regulatory authorities	USFDA Approved
	Detail of previous approval	Dydrosky 10mg tablet, Meeting NO : 336
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
507	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat **(000886)**

	Application Form Dy. No / Tracking ID & date of submission	(75D-Z6M-NNU5, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**TRINIC CREAM**
	Label Claim	Each gram contains: Hydroquinone 40mg (4%) Fluocinolone Acetonide 0.1mg (0.01%) Tretinoin 0.5mg (0.05%)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10g; 15g; 20g; 30g, 45gm-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Lazma cream M/s Bio-Labs Pharma Pakistan
	Pharmacotherapeutic Group of (API)	Data Already approved in 349 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Tri-Luma Cream, USFDA Approved
	Detail of previous approval	Acknuma cream in 349 MoM.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
508	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat **(000886)**
	Application Form Dy. No / Tracking ID & date of submission	(6NZ-E8T-19QA, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**CLOTAZOLE CREAM 1% w/w**
	Label Claim	Each gram contains: Clotrimazole 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	15gm-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Clotrim Cream by M/s ZAFA Pharma Pakistan
	Pharmacotherapeutic Group of (API)	Data Already approved in 348 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Canesten Cream BAYER Plc (UK) Limited , EMC Approved
	Detail of previous approval	Tromatek Topical Cream 1% w/w in 348 MoM
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
509	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat **(000886)**
	Application Form Dy. No / Tracking ID & date of submission	(X2Y-LQQ-AZRB, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**CLOTAZOLE LOTION 1% w/v**
	Label Claim	Each ml contains: Clotrimazole 10mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml,60ml,100ml,120ml,-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Stiemazol 1%w/v Lotion by GSK
	Pharmacotherapeutic Group of (API)	Data Already approved in 353 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Clotrimazole Topical Solution ,FDA Approved
	Detail of previous approval	Tromatek Lotion 1% w/v in 353 MoM
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
510	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Atco Laboratories Limited** B-18 SITE KARACHI **(000188)**
	Application Form Dy. No / Tracking ID & date of submission	(6LU-Z9V-N9BS, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-04,
	The proposed proprietary name / brand name	**ATMIRO Tablet 15mg**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin (as Mirogabalin Besylate) 15mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10’s-De-Controlled,1x7's-De-Controlled,2x10’s-De-Controlled,2x7’s-De-Controlled,3x10’s-De-Controlled,4x7’s-De-Controlled
	Shelf Life (Unit)	2 YearDonot store and transport above 30 degree centrigrade
	For generic drugs (me-too Status)	Mirolin 15mg Tablet
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	M/s WIMITS PHARMACEUTICALS PVT. LIMITED-PLOT # 129, SUNDER INDUSTRIAL ESTATE LAHORE-
	The status in reference regulatory authorities	Tarlige Tablets 15mg
	Detail of previous approval	Mirogab 15mg Tablet,DRB 344 held on 31st December 2024 -02nd January 2025
	Evaluation Remarks	
	In light of Registration Board’s decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
511	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat **(000886)**
	Application Form Dy. No / Tracking ID & date of submission	(124-GRQ-WX6E, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**CLOTAZOLE Vaginal CREAM 10% W/W**
	Label Claim	Each gram contains: Clotrimazole 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	5gm-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Canesten 10%w/w vaginal Cream M/s Bayer Health Care
	Pharmacotherapeutic Group of (API)	Data Already approved in 348 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Canesten Thrush Internal Cream 10% w/w vaginal , MHRA Approved
	Detail of previous approval	Tromatek Vaginal Cream 10% w/w in 348 MoM
	Evaluation Remarks	
	In light of Registration Board’s decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the	

	Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
512	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Nicholas Pharmaceuticals** Plot 34, Street SS-2, National Industrial Zone, Rawat **(000886)**
	Application Form Dy. No / Tracking ID & date of submission	(5G1-MDZ-3DTR, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-20,
	The proposed proprietary name / brand name	**CLOTAZOLE Vaginal TABLET**
	Label Claim	Each vaginal tablet contains: Clotrimazole 500mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Canesten vaginal Tablet By Bayer Health Care
	Pharmacotherapeutic Group of (API)	Data Already approved in 348 MoM
	Name, address of Manufacturing site:	Caliph Pharmaceuticals (Pvt) Ltd -Plot No. 17, Special Industrial Zone (EPZ), Risalpur -
	The status in reference regulatory authorities	Clotrimazole 500mg vaginal Tablet, MHRA Approved
	Detail of previous approval	Tromatek Vaginal Tablet in 348 MoM
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
513	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sapient Pharma** 123/S Quaid E Azam Industrial Estate Kot Lakhpat **(000207)**
	Application Form Dy. No / Tracking ID & date of submission	(53T-5AD-16Z8, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-05,
	The proposed proprietary name / brand name	**Merolin 10mg Tablet**
	Label Claim	Each Film Coated Tablet contains: Mirogabalin Besylate equivalent to Mirogabalin.....10mg

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Miro 10mg Tablet of M/s Nabi Qasim
	Pharmacotherapeutic Group of (API)	Gabapentinoid
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Tarlige Tablets 10mg of M/s Daiichi Sankyo Co., Ltd (PMDA Approved)
	Detail of previous approval	Mirogab 10mg Tablet approved in 344th Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
514	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(7HN-2V5-2BN7, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-21,
	The proposed proprietary name / brand name	**Swidol Night 500/25mg Tablet**
	Label Claim	Each film coated tablet contains: Paracetamol.....500mg Diphenhydramine Hydrochloride.....25mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	10x10's -As per SRO,1x10's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,6x10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name & Strength: PANADOL NIGHT TABLET, Manufactured by : Haleon Pakistan Limited, Petaro road, Jamshoro
	Pharmacotherapeutic Group of (API)	Paracetamol: Analgesics and antipyretics, Diphenhydramine Hydrochloride :Antihistamines
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals (Pvt.) Ltd. -Plot No. 129, Sundar Industrial Estate Raiwind Road Lahore Pakistan-
	The status in reference regulatory authorities	Brand Name & Strength: Panadol Night or Panadol Night Pain, Market authorization :Haleon UK Trading Limited, Marketing

		authorisation number: PL 44673/0076, Reference Regulatory Authority: MHRA approved.
	Detail of previous approval	Peradol-D 500/25 mg Tablet, 343rd DRB Meeting.
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
515	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Well Care Pharmaceuticals** A/7 PSIE **(000465)**
	Application Form Dy. No / Tracking ID & date of submission	(5GD-WR4-W8RX, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-01-30,
	The proposed proprietary name / brand name	**Vonowell Tab 10mg**
	Label Claim	Each Film Coated Tablet Contains:- Vonoprazan Fumarate eq. to Vonoprazan 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x7's; 2x7's; 4x7's; 3x10's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30%
	For generic drugs (me-too Status)	Vonopran 20 10mg Tablet Shaigan Pharmaceuticals (Pvt) Ltd 110204
	Pharmacotherapeutic Group of (API)	Proton pump inhibitor
	Name, address of Manufacturing site:	Jinnah Pharmaceuticals Pvt.Ltd-13-KM Lahore Road Multan-
	The status in reference regulatory authorities	PMDA Japan Approved)
	Detail of previous approval	PRVC Letter Reg No 131739 against ref J17-QE9-RL9Y
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID J17-QE9-RL9Y dated 23 April 2026.	
	Decision	
	Approved Approved	

516	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd** Plot 710, Sundar Industrial Estate, Lahore **(000891)**
	Application Form Dy. No / Tracking ID & date of submission	(QP6-SEY-WE25, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-14,
	The proposed proprietary name / brand name	**Avala Tablet 50mg**
	Label Claim	Each tablet Contains: Avanafil.....50mg
	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,5's-De-Controlled,50's-De-Controlled,6's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30oC.
	For generic drugs (me-too Status)	Avala 50mg Tablet, Medizan Laboratories.
	Pharmacotherapeutic Group of (API)	CENTURY PHARMACEUTICAL LTD.
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, VIVUS LLC (USFDA)
	Detail of previous approval	Avala 50mg Tablet, 351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
517	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd** Plot 710, Sundar Industrial Estate, Lahore **(000891)**
	Application Form Dy. No / Tracking ID & date of submission	(RJU-8Q7-693W, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-14,
	The proposed proprietary name / brand name	**Avala Tablet 100mg**
	Label Claim	Each tablet Contains: Avanafil.....100mg
	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,5's-De-Controlled,50's-De-Controlled,6's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30oC.
	For generic drugs (me-too Status)	Avala 100mg Tablet, Medizan Laboratories.
	Pharmacotherapeutic Group of (API)	CENTURY PHARMACEUTICAL LTD.
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	STENDRA™ (avanafil) tablets, VIVUS LLC (USFDA)
	Detail of previous approval	Avala 100mg Tablet, 351
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
518	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd** Plot 710, Sundar Industrial Estate, Lahore **(000891)**
	Application Form Dy. No / Tracking ID & date of submission	(XVN-785-V98Z, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-14,
	The proposed proprietary name / brand name	**Tofamit Tablet 5mg**
	Label Claim	Each film coated tablet Contains: Tofacitinib citrate eq. to Tofacitinib.....5mg
	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,5's-De-Controlled,50's-De-Controlled,6's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30oC.
	For generic drugs (me-too Status)	Tofamit 5mg Tablet., M/s Medizan Laboratories (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Shandong XierKangtai Pharmaceuticals Co., Ltd.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-

	The status in reference regulatory authorities	XELJANZ (Tofacitinib) tablets, PF PRISM CV (USFDA)
	Detail of previous approval	Tofamit, 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
519	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**CCL Pharmaceuticals (Pvt.) Ltd** Plot 710, Sundar Industrial Estate, Lahore **(000891)**
	Application Form Dy. No / Tracking ID & date of submission	(GD8-GAL-QSXB, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-14,
	The proposed proprietary name / brand name	**Tofamit Tablet 10mg**
	Label Claim	Each film coated tablet Contains: Tofacitinib citrate eq. to Tofacitinib.....10mg
	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,5's-De-Controlled,50's-De-Controlled,6's-De-Controlled,7's-De-Controlled,8's-De-Controlled
	Shelf Life (Unit)	2 YearDo not store above 30oC.
	For generic drugs (me-too Status)	Tofamit 10mg Tablet., M/s Medizan Laboratories (Pvt) Ltd.
	Pharmacotherapeutic Group of (API)	Shandong XierKangtai Pharmaceuticals Co., Ltd.
	Name, address of Manufacturing site:	M/s Wimits Pharmaceuticals Pvt. Limited.-Plot # 129, Sunder Industrial Estate Lahore.-
	The status in reference regulatory authorities	XELJANZ (Tofacitinib) tablets, PF PRISM CV (USFDA)
	Detail of previous approval	Tofamit, 343
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
520	Case Category	Contract Manufacturing (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	(EA5-X1U-EAU6, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-15,
	The proposed proprietary name / brand name	**Injex Plus Injection**
	Label Claim	Each vial contains: Ceftazidime 2 gram (Equivalent to 2.635 grams sterile ceftazidime pentahydrate/sodium carbonate) and Avibactam 0.5 grams (Equivalent to 0.551 grams sterile avibactam Sodium).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-Controlled,10's-Controlled
	Shelf Life (Unit)	2 YearStore below 30°
	For generic drugs (me-too Status)	Zavicefta (Ceftazidime 2gm/ Avibactum 0.5gm) Powder for concentrate for solution for infusion; Reg No. 106848
	Pharmacotherapeutic Group of (API)	Anti- Bacterial; Ceftazidime [cephalosporin antibiotics] Avibactam [beta-lactamase inhibitors]
	Name, address of Manufacturing site:	M/S NovaMed Pharmaceuticals (Pvt) Ltd.-28-KM, Ferozepur Road, Lahore.-
	The status in reference regulatory authorities	Avycaz 2g/0.5g Injection Company: GlaxoSmithKline Manufacturing S.p.A. Verona, 37135 Italy.
	Detail of previous approval	Avidim Injection 2.5gm approved in 331st DRB Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
521	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Seraph Pharmaceutical** Plot No 210, Industrial Triangle Kahuta Road, Islamabad. **(000860)**
	Application Form Dy. No / Tracking ID & date of submission	(AN9-QWB-7TQ7, 2026-08-19)

	Detail of Fee Submitted	97200, 2026-05-14,
	The proposed proprietary name / brand name	**Vagitin tablet Vaginal**
	Label Claim	Each tablet contains: Metronidazole.....500mg Neomycin Sulphate.....65000IU Nystatin 100000IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30C
	For generic drugs (me-too Status)	Brand Name: Megyne Vaginal Tablets Manufacturer: Nabiqasim Industries (Pvt.) Ltd. Address: 5th Floor, Commerce Center, Hasrat Mohani Rd, New Chali, Karachi, Karachi City, Sindh Pakistan.
	Pharmacotherapeutic Group of (API)	Antibacterial & Antifungal agent for Vaginal Infections
	Name, address of Manufacturing site:	Name: Solaris Life Sciences (Pvt.) Ltd-Address: Plot # 08, Street No. S-1, RCCI, Industrial Estate Rawat, Rawalpindi - Pakistan.-
	The status in reference regulatory authorities	ANSM France
	Detail of previous approval	Numet , 357th Meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
522	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(PWN-PXS-Y31R, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-21,
	The proposed proprietary name / brand name	**Caryza 1.5mg Capsule**
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....1.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,1x5's-As per SRO,1x6's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Caripz 1.5mg Capsule, Manufacturer Name: GENIX PHARMA

		PRIVATE LIMITED, Approved in 324th DRB Meeting
	Pharmacotherapeutic Group of (API)	Psycholeptics, other antipsychotics
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01 Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Brand Name & Strength: VRAYLAR (cariprazine) 1.5mg capsules, Distributed by: AbbVie, Inc. North chicago, IL 60064 USA, Reference Regulatory Authority: USFDA approved
	Detail of previous approval	Carip 1.5mg Capsule, Minutes for 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
523	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(7EE-78E-865V, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-21,
	The proposed proprietary name / brand name	**Caryza 3mg Capsule**
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....3mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,1x5's-As per SRO,1x6's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Caripz 3mg Capsule Manufacturer: M/s. Genix Pharma Private Limited. Approved in 324th DRB meeting.
	Pharmacotherapeutic Group of (API)	Psycholeptics, other antipsychotics
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01 Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Brand Name & Strength: VRAYLAR (cariprazine) 3mg capsules, Distributed by: AbbVie, Inc. North chicago, IL 60064 USA,

		Reference Regulatory Authority: USFDA approved
	Detail of previous approval	Carip 3mg Capsule, Minutes for 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
524	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(9YE-L4N-T1SB, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-21,
	The proposed proprietary name / brand name	**Caryza 4.5mg Capsule**
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....4.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,1x5's-As per SRO,1x6's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's -As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Caripz 4.5mg Capsule Manufacturer: M/s. Genix Pharma Private Limited. Approved in 324 th DRB meeting.
	Pharmacotherapeutic Group of (API)	Psycholeptics, other antipsychotics
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01 Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Brand Name & Strength: VRAYLAR (cariprazine) 4.5mg capsules, Distributed by: AbbVie, Inc. North chicago, IL 60064 USA, Reference Regulatory Authority: USFDA approved
	Detail of previous approval	Carip 4.5mg Capsule, Minutes for 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the	

	above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
525	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(LUQ-TVN-9G97, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-07,
	The proposed proprietary name / brand name	**Dazrox 30mg Capsule**
	Label Claim	Each Capsule contains: Dexlansoprazole.....30mg (as dual Delayed released Pellets)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dextop 30mg Capsule of M/s Searle
	Pharmacotherapeutic Group of (API)	Dexlansoprazole belongs to a class proton pump inhibitor
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Dexilant 30mg capsule of M/s Takeda Pharmaceuticals America, Inc. (USFDA Approved)
	Detail of previous approval	Dexin 30mg Capsule approved in 331st Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
526	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(DW8-RB7-6P16, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-21,

	The proposed proprietary name / brand name	**Caryza 6mg Capsule**
	Label Claim	Each Capsule contains: Cariprazine Hydrochloride equivalent to Cariprazine.....6mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's-As per SRO,1x5's-As per SRO,1x6's-As per SRO,2x10's-As per SRO,2x7's-As per SRO,3x10's-As per SRO,4x7's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Caripz 6mg Capsule Manufacturer: M/s. Genix Pharma Private Limited. Approved in 324th DRB meeting.
	Pharmacotherapeutic Group of (API)	Psycholeptics, other antipsychotics
	Name, address of Manufacturing site:	M/s Skywin Pharmaceuticals-Plot No. 01 Al Badar Industrial Estate, Phase II Sheikhupura Road Lahore-
	The status in reference regulatory authorities	Brand Name & Strength: VRAYLAR (cariprazine) 6mg capsules, Distributed by: AbbVie, Inc. North chicago, IL 60064 USA, Reference Regulatory Authority: USFDA approved
	Detail of previous approval	Carip 6mg Capsule, Minutes for 343rd meeting of Registration Board
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
527	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Sarco Chemicals Industries** 17-Km. Lahore Road Multan **(000203)**
	Application Form Dy. No / Tracking ID & date of submission	(WMT-E53-MU5R, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-07,
	The proposed proprietary name / brand name	**Dazrox 60mg Capsule**
	Label Claim	Each Capsule contains: Dexlansoprazole.....60mg (as dual Delayed released Pellets)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x10's, 2x7's, 2x10's, 4x7's, 3x10's As per SRO-De-Controlled
	Shelf Life (Unit)	2 YearStore at room temperature below 30
	For generic drugs (me-too Status)	Dexin 60mg Capsule of M/s Searle

	Pharmacotherapeutic Group of (API)	Dexlansoprazole belongs to a class proton pump inhibitor
	Name, address of Manufacturing site:	Wimits Pharmaceuticals Pvt. Ltd.-Plot No.129, Sundar Industrial Estate, Riwind Road, Lahore-
	The status in reference regulatory authorities	Dexilant 60mg capsule of M/s Takeda Pharmaceuticals America, Inc. (USFDA Approved)
	Detail of previous approval	Dexin 60mg Capsule approved in 331st Meeting
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
528	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(W9Z-SJW-DLHT, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-08,
	The proposed proprietary name / brand name	**Visunate-M 60mg Injection**
	Label Claim	Each vial contains: Artesunate..... .....60mg (Intl. Ph. Specifications)
	Reference to Finished product specifications	The International Pharmacopeia
	Proposed Pack Size	1's-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Arcenate Injection 60mg Reg. no. 100928 M/s Sami Pharma Karachi.
	Pharmacotherapeutic Group of (API)	Artemisinin and derivatives, plain ATC Code: P01BE03
	Name, address of Manufacturing site:	M/s Bio-Labs (Pvt.) Ltd. -Plot No. 145, Industrial Triangle Kahuta Road, Islamabad.-
	The status in reference regulatory authorities	WHO recommended formulation.
	Detail of previous approval	Asunate 60mg IV Injection, 331st Meeting of Registration Board held on 31st Oct – 2 nd Nov, 2023
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality	

	agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
529	Case Category	Contract Manufacturing (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	(5Z2-5AX-SQ4R, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**Suzee 50mg Tablets**
	Label Claim	Each film-coated tablet contains: Suzetrigine ..... 50mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's -As per SRO,14's-As per SRO,2's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,40's-As per SRO,50's-As per SRO,6's-As per SRO,60's-As per SRO,70's-As per SRO,8's-As per SRO,80's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Suzemax 50mg Tablets, By: Medizan Laboratories (Pvt.)- Approved in 354th DRB Meeting
	Pharmacotherapeutic Group of (API)	Selective $Na_v1.8$ voltage-gated sodium channel blocker
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	JOURNAVX (Suzetrigine) tablets (FDA)
	Detail of previous approval	Suzemax 50mg Tablets (DRB 354th Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
530	Case Category	Contract Manufacturing (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	(834-W51-EETG, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-11,
	The proposed proprietary name / brand name	**Danilon 10mg Tablets**
	Label Claim	Each film coated tablet contains: Dydrogesterone..... 10 mg (USP Specifications)
	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 YearStore Below 30°C
	For generic drugs (me-too Status)	Dydrova Tablet 10mg, Reg. No. 132849, By: Martin Dow Limited
	Pharmacotherapeutic Group of (API)	Genito Urinary system and sex hormones.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot No. 01, Al Badar Industrial Estate, Phase II Sheikhupura Road, Lahore-Pakistan-
	The status in reference regulatory authorities	Duphaston 10 mg film-coated tablets ® is Approved in HPRA of Ireland.
	Detail of previous approval	D-GEST 10mg Tablet (336th DRB Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
531	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Crown Pharmaceuticals** Plot 286, Kahuta industrial Triangle, Kahota Road, Islamabad **(000456)**
	Application Form Dy. No / Tracking ID & date of submission	(HT4-XMW-QNHU, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-13,
	The proposed proprietary name / brand name	**Keto-Pro 30mg/ml Injection**
	Label Claim	Each 1ml ampoule contains: Ketorolac Tromethamine USP.....30mg USP Specs
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1ml×5's-De-Controlled
	Shelf Life (Unit)	2 YearBelow 30C Degree
	For generic drugs (me-too Status)	Toradol Injection 30mg/ml by M/s Barrett Hodgson Pakistan (Pvt.) Ltd. Reg. No. 015000
	Pharmacotherapeutic Group of (API)	Anti-inflammatory, non-steroid

	Name, address of Manufacturing site:	M/s Islam Pharmaceuticals-7KM Pasrur Road Sialkot-
	The status in reference regulatory authorities	Ketorolac Tromethamine injection 30mg/ml by M/s Peckforton Pharmaceuticals Limited Crewe Hall, Crewe, Cheshire, CW1 6UL, United Kingdom, MHRA Approved.
	Detail of previous approval	Troket 30mg/ml Injection, Minutes of 326th meeting of Registration Board (14th to 16th March, 2023)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
532	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(GL4-TDQ-TXRH, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**ESTRAWIM**
	Label Claim	Each of the 11 sugar coated tablet contains: Estradiol valerate .....2mg Each of the 10 light brown sugar coated tablet contains: Estradiol valerate .....2mg Norgestrel.....0.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1x21's, 3x21's-As per SRO
	Shelf Life (Unit)	2 YearStore at 20°C to 25°C
	For generic drugs (me-too Status)	Bayer Weimar GmbH und Co., KG, Weimar, Germany (PROGYLUTON)
	Pharmacotherapeutic Group of (API)	Estradiol Valerate (Zhejiang Xianju Junye Pharmaceutical Co., Ltd.) AND Norgestral(Swati Spentose Private Limited.)
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot no.1, Al Badar Industrial Estate Phase II, Sheikhupura Road Lahore.-
	The status in reference regulatory authorities	Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702 (PROGYLUTON)
	Detail of previous approval	347
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to	

	submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
533	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**M/s Daneen Pharma (Pvt) Ltd** Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, **(000688)**
	Application Form Dy. No / Tracking ID & date of submission	(WPX-5M4-J64V, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-01-28,
	The proposed proprietary name / brand name	**TURA**
	Label Claim	Each film coated tablet contains: Lurasidone hydrochloride.....80mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	4's,7's, 10's, 14's, 20's, 28's,30's & 60's-As per SRO
	Shelf Life (Unit)	2 Yearstore at 20'C-25'C
	For generic drugs (me-too Status)	Helix Pharma (Lurisa)
	Pharmacotherapeutic Group of (API)	Jiangsu Yongan Pharmaceutical Co., Ltd
	Name, address of Manufacturing site:	Genix Pharma Pvt Ltd-44-45-B,Korangi creek Road Karachi-
	The status in reference regulatory authorities	Sunovion Pharmaceuticals Inc, USA
	Detail of previous approval	Lura Tablet 80mg, 336 Meeting No
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
534	Case Category	Contract Manufacturing (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	(9HV-12V-J8EX, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-11,

	The proposed proprietary name / brand name	**Ubro 50mg Tablets**
	Label Claim	Each tablet contains: Ubrogepant Trihydrate eq. to Ubrogepant...50mg (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10's-As per SRO,100's-As per SRO,12's-As per SRO,14's-As per SRO,16's-As per SRO,2's-As per SRO,20's-As per SRO,28's-As per SRO,30's-As per SRO,4's-As per SRO,40's-As per SRO,50's-As per SRO,6's-As per SRO,60's-As per SRO,70's-As per SRO,8's-As per SRO,80's-As per SRO,90's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Ubro 50mg Tablets, By Medizan Laboratories (Approved in 354th DRB Meeting)
	Pharmacotherapeutic Group of (API)	CGRP antagonist
	Name, address of Manufacturing site:	Medizan Laboratories (Pvt.) Ltd.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	UBRELVY (Ubrogepant) tablets (FDA)
	Detail of previous approval	Ubro 50mg Tablet (Approved in 354th DRB Meeting)
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
535	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**STANDARD DRUG COMPANY** Plot No. E-6-A, S.I.T.E **(000118)**
	Application Form Dy. No / Tracking ID & date of submission	(5UX-8SD-WGVM, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-12,
	The proposed proprietary name / brand name	**standzole 20mg Capsule**
	Label Claim	Each capsule contains: Omeprazole enteric coated Pellets E.q to omeprazole.....20mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C.
	For generic drugs (me-too Status)	Brand Name: Risek 20mg Capsule Manufacturer /Registration Holder: Getz Pharma (Private) Ltd. Registration Number: 019364
	Pharmacotherapeutic Group of (API)	A02BC01
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd-M/s Fortune Pharma Pvt. Ltd Plot No K/201 S.I.T.E. (SHW) Phase II, Karachi, Pakistan.-

	The status in reference regulatory authorities	Reference Product: Omeprazole 20 mg gastro-resistant capsule,for oral use. Reference: MHRA https://mhraproducts4853.blob.core.windows.net/c
	Detail of previous approval	Case No. 701, 343rd DRB Dated 03rd – 05th Dec. 2024 , page # 670-675
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
536	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**STANDARD DRUG COMPANY** Plot No. E-6-A, S.I.T.E **(000118)**
	Application Form Dy. No / Tracking ID & date of submission	(G4R-VHB-WY7D, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-12,
	The proposed proprietary name / brand name	**standzole 40mg Capsule**
	Label Claim	Each capsule contains: Omeprazole Enteric Coated Pellets E.q. to Omeprazole..... 40mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	2 YearDo not store above 25°C.
	For generic drugs (me-too Status)	Brand Name: Risek 40mg Capsule Manufacturer /Registration Holder: Getz Pharma (Private) Ltd. Registration Number: 019364
	Pharmacotherapeutic Group of (API)	A0
	Name, address of Manufacturing site:	Fortune Pharma Pvt. Ltd-M/s Fortune Pharma Pvt. Ltd Plot No K/201 S.I.T.E. (SHW) Phase II, Karachi, Pakistan.-
	The status in reference regulatory authorities	Reference Product: Omeprazole 40mg hard gastro-resistant capsules, for oral use. Reference: MHRA https://mhraproducts4853.blob.core.windows.net/c
	Detail of previous approval	Case No. 702, 343rd DRB Dated 03rd – 05th Dec. 2024 , page # 675-680
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	

	Decision	
	Approved Approved	
537	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Zamko Pharmaceuticals (Pvt) Ltd.** 641-A, Sunder Industrial Estate, Raiwind Road, **(000890)**
	Application Form Dy. No / Tracking ID & date of submission	(LGJ-AW1-JU6U, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-13,
	The proposed proprietary name / brand name	**PRODEX 30mg Capsule**
	Label Claim	Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets.....30mg (Product complies Innovators Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Razodex Capsule by Getz Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	DEXZEN 30mg Capsule, DRB 330
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
538	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Zamko Pharmaceuticals (Pvt) Ltd.** 641-A, Sunder Industrial Estate, Raiwind Road, **(000890)**
	Application Form Dy. No / Tracking ID & date of submission	(ZL6-P4N-SPRD, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-05-13,
	The proposed proprietary name / brand name	**PRODEX 60mg Capsule**
	Label Claim	Each Capsule Contains: Dexlansoprazole as Dual Delayed Release Pellets.....60mg (Product complies Innovators Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO

	Shelf Life (Unit)	2 Yearbelow 25c
	For generic drugs (me-too Status)	Razodex Capsule by Getz Pharma
	Pharmacotherapeutic Group of (API)	Proton Pump Inhibitor
	Name, address of Manufacturing site:	Wezen Pharmaceuticals-Plot No. 23 & 24, S-1, RCCI, Industrial Estate, Rawat. -
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	DEXZEN 60mg Capsule, DRB 330
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Approved	
539	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	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	(BTY-RGW-ET8H, 2026-08-19)
	Detail of Fee Submitted	97200, 2026-04-20,
	The proposed proprietary name / brand name	**GENDROX**
	Label Claim	Each ml contains: Medroxyprogesterone Acetate.....150mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	25's x 1ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Global Pharmaceuticals (Pvt.) ltd.(MEDROXY DEPO 150 mg|ml Injection 1ml)
	Pharmacotherapeutic Group of (API)	HANGZHOU SHUYUAN PHARMACEUTICAL TECHNOLOGY CO.LTD.
	Name, address of Manufacturing site:	Skywin Pharmaceuticals-Plot no.1, Al Badar Industrial Estate Phase II, Sheikhupura Road Lahore.-
	The status in reference regulatory authorities	PFIZER Pharmaceuticals (DEPO-PROVERA)
	Detail of previous approval	336
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	

	Approved Approved	
540	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saaaf Pharmaceuticals** Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 **(000637)**
	Application Form Dy. No / Tracking ID & date of submission	(X2R-769-WA15, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-24,
	The proposed proprietary name / brand name	**Tablet Sildifin 100mg**
	Label Claim	Each Tab contains Sildinafil as Citrate 100mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25c
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No2, street No. N-3,National Industrial Zone, Rawat.-
	The status in reference regulatory authorities	NA
	Detail of previous approval	Selden100mg, 343rd DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Product was added in additional agenda. However, now is present in main agenda.	
541	Case Category	Contract Manufacturing (Incharge Evaluation Cell)
	Name, address of Applicant.	**Saaaf Pharmaceuticals** Risalpur, Nowshera, Khyber Pakhtunkhwa 23200 **(000637)**
	Application Form Dy. No / Tracking ID & date of submission	(JT1-SYN-VTTA, 2025-05-09)
	Detail of Fee Submitted	93000.0, 2025-01-24,
	The proposed proprietary name / brand name	**Tablet Sildifin 50mg**
	Label Claim	Each Tablet contains Sildinafil as citrate 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	2 YearBelow 25c
	For generic drugs (me-too Status)	Available
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Gray's Pharmaceuticals-Plot No2, street No. N-3,National Industrial Zone, Rawat.-

	The status in reference regulatory authorities	NA
	Detail of previous approval	Selden, 343rd DRB meeting
	Evaluation Remarks	
	In light of Registration Board's decision taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June, 2023, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved Product was added in additional agenda. However, now is present in main agenda.	
542	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(3Z9-TEE-977E, 2025-06-19)
	Detail of Fee Submitted	37000.0, 2025-03-13,
	The proposed proprietary name / brand name	**Terb 125mg Tablet**
	Label Claim	Each tablet contains: Terbinafine as Hydrochloride.....125mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's, 30's-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Terbin 125mg tablet, Registration Holder: M/s Martin Dow Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SYNERGENE ACTIVE INGREDIENTS PVT LTD., Address: Unit-[,Plot No:59-D, Jawaharlal Nehru Pharma City, Parawada (V), Parawada Mandal, Vi sakhapatnam District - 53 021, Andhra Pradesh, India
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Brand Name: LAMISIL 125mg (as hydrochloride) tablet, Marketing Authorization holder: Novartis Pharmaceuticals Australia Pty Ltd, PO Box 101, NORTH RYDE, NSW, 1670 Australia, Regulatory Authority: TGA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	The firm is using a Waters HPLC system equipped with Empower 2 software for stability studies. However, the applicant has stated that "the system is not 21 CFR compliant".	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
543	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(P3P-JVV-93HZ, 2025-05-09)
	Detail of Fee Submitted	37000.0, 2025-03-13,
	The proposed proprietary name / brand name	**Terb 250mg Tablet**
	Label Claim	Each tablet contains: Terbinafine as Hydrochloride.....250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10’s, 30’s-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Terbin 250mg tablet, Registration Holder: M/s Martin Dow Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SYNERGENE ACTIVE INGREDIENTS PVT LTD., Address: Unit-[,Plot No:59-D, Jawaharlal Nehru Pharma City, Parawada (V), Parawada Mandal, Vi sakhapatnam District - 53 021, Andhra Pradesh, India
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Brand Name: LAMISIL 250mg (Terbinafine as hydrochloride) tablet, Marketing Authorization holder: Novartis Pharmaceuticals Australia Pty Ltd, PO Box 101, NORTH RYDE, NSW, 1670 Australia, Regulatory Authority: TGA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm is using a Waters HPLC system equipped with Empower 2 software for stability studies. The applicant has stated that the system is not 21 CFR compliant.	
	Decision	

	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
544	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(PJR-V4B-W53D, 2025-06-19)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	**Terb 1% w/w Cream**
	Label Claim	Each gram of cream contains: Terbinafine as Hydrochloride.....10mg (1%w/w)
	Reference to Finished product specifications	Any Other
	Proposed Pack Size	10g-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Lamisil 1% cream, Registration Holder: M/s GSK (Pakistan) Limited, Registration No.: 013210
	Pharmacotherapeutic Group of (API)	Antifungals for systemic use
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. SYNERGENE ACTIVE INGREDIENTS PVT LTD., Address: Plot No:59-D, Jawaharlal Nehru Pharma City, Parawada (V), Parawada Mandal, Vi sakhapatnam District - 53 021, Andhra Pradesh, India
	Detail of stability batches of drug product	T037, T038, T039
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Lamisil 1% w/w Cream, Marketing Authorization Holder: Karo Pharma AB, Regulatory Authority: EMA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The firm is using a Waters HPLC system equipped with Empower 2 software for stability studies. The applicant has stated that the system is not 21 CFR compliant.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
545	Case Category	Routine (Iqra Aftab)

	Name, address of Applicant.	**SHAWAN PHARMACEUTICALS** PLOT # 37, NS-1. NATIONAL INDUSTRIAL ZONE. RAWAT **(000627)**
	Application Form Dy. No / Tracking ID & date of submission	(HSX-MJP-7HU7, 2025-04-10)
	Detail of Fee Submitted	37000.0, 2024-12-16,
	The proposed proprietary name / brand name	**Terbin**
	Label Claim	: Each tablet contains: Terbinafine HCl.....125mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearRome Temperature
	For generic drugs (me-too Status)	Lamisil, M/s NOVARTIS PHARMA (PAK) LTD
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/s. Synergene Active Ingredients Private Limited Address: Unit-II, Plot No.59-D, Jawaharlal Nehru Pharma City, Parawada(V&M), Anakapalli District -531021, Andhra Pradesh, India.
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Approved by US FDA USFDA approves Alembic's Ketorolac tromethamine injection USP
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant has stated that the system is not 21 CFR compliant.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
546	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Kanel Pharma** Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat **(000758)**
	Application Form Dy. No / Tracking ID & date of submission	(NHE-BBE-8JGZ, 2025-05-15)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	**Kanafil 250mg**
	Label Claim	Each tablet contains: Terbinafine as Hcl.....250mg USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO

	Shelf Life (Unit)	2 Yearbelow 30° C
	For generic drugs (me-too Status)	LAMISIL 250mg Tablets
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Synergene Active Ingredients Pvt. Ltd., Unit-II
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	US Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Same chromatograms for both strengths Terbinafine 125mg and 250mg with only change in area. (Tailing factor, retention time, peak height and theoretical plates are same.	
	Decision	
	Rejected Registration Board decided to reject the instant application, considering that the firm had submitted same chromatograms for both strengths Terbinafine 125mg and 250mg with only change in area. (Tailing factor, retention time, peak height and theoretical plates are same).	
547	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Kanel Pharma** Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat **(000758)**
	Application Form Dy. No / Tracking ID & date of submission	(Y3D-D7H-XUG6, 2025-05-15)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	**Kanafil**
	Label Claim	Each tablet contains; Terbinafine as Hcl.....125mg USP Specifications
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30° C
	For generic drugs (me-too Status)	LAMISIL 125mg Tablets
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Synergene Active Ingredients Pvt. Ltd., Unit-II
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	US Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Same chromatograms for both strengths Terbinafine 125mg and 250mg with only change in area. (Tailing factor, retention time, peak height and theoretical plates are same).	
	Decision	
	Rejected Registration Board decided to reject the instant application, considering that the firm had submitted same chromatograms for both strengths Terbinafine 125mg and 250mg with only change in area. (Tailing factor, retention time, peak height and theoretical plates are same).	
548	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Regal Pharmaceuticals** Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat **(000839)**
	Application Form Dy. No / Tracking ID & date of submission	(41A-S6V-13MD, 2025-03-11)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-29, 2025-01-23
	The proposed proprietary name / brand name	**Rectam 125mg Tablets**
	Label Claim	Each film coated tablet contains Terbinafine HCl 125 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearRoom Temprature
	For generic drugs (me-too Status)	Sabifin 125mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symergene Active Ingredients Pvt.Ltd.,
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Applicant has stated their audit trail is not activated.	
	Decision	
	Deferred	

	Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
549	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Regal Pharmaceuticals** Plot No. 2-A, Street No. S-5 National Industrial Zone RCCI Rawat **(000839)**
	Application Form Dy. No / Tracking ID & date of submission	(S3M-W6J-X4H7, 2025-03-11)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-29, 2025-01-23
	The proposed proprietary name / brand name	**Rectam 250mg Tablets**
	Label Claim	Each film coated Tablet contains Terbinafine HCl 250mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 YearRoom Temprature
	For generic drugs (me-too Status)	Sabifin 250mg Tablet
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symergene Active Ingredients Pvt.Ltd.,
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Applicant has stated their audit trail is not activated.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
550	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	**Kanel Pharma** Plot No. 6, Street No. SS-3, National Industrial Zone, Rawat **(000758)**
	Application Form Dy. No / Tracking ID & date of submission	(71D-QZN-33P4, 2025-04-21)
	Detail of Fee Submitted	37000.0, 2025-03-12,
	The proposed proprietary name / brand name	**Kanafil**
	Label Claim	Each Gram Contains: Terbinafine as Hcl....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Yearbelow 30° C
	For generic drugs (me-too Status)	CUTIS 1% lotion (Tabros Pharma)

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	M/S Synergene Active Ingredients Pvt. Ltd., Unit-II
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Approved by Sweden
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Chromatograms are identical to that submitted by M/s Medera.	
	Decision	
	Rejected Registration Board decided to reject the instant application, considering that the firm had submitted the exactly same chromatograms that had been submitted by M/s. Medera Pharmaceuticals (Pvt) Ltd along with its registration application.	
551	Case Category	Routine (Iqra Aftab)
	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	(Y3X-LE2-8UUP, 2025-05-12)
	Detail of Fee Submitted	37000.0, 2025-04-08,
	The proposed proprietary name / brand name	**Zemark Dry Suspension**
	Label Claim	Each 5ml of reconstituted suspension contains Azithromycin dihydrate equivalent to Azithromycin 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1s-As per SRO
	Shelf Life (Unit)	2 Year15° to 30°C
	For generic drugs (me-too Status)	Azomax Suspension of M/S Sandoz Pharma
	Pharmacotherapeutic Group of (API)	Macrolide Antiobiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Citi pharma
	Detail of stability batches of drug product	Data provided in Module III, Section-3.2 P-8.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Documents attached in Module III, Section-3.2 P-8.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Data provided in Module III, Section-3.2 P2.2B.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Data provided in Module III, in Drug Substance part.
	The status in reference regulatory authorities	Zithromax Suspension FDA Approved.

	GMP status of the firm	Suspension Section approved by DRAP, certificate attached in Module I, Section-1.3.5.
	Evidence of approval of manufacturing facility	Section Approved by DRAP, certificate attached in Module I, Section 1.3.5.
	Evaluation Remarks	
	The chromatograms of stability studies are same for filled and 6month analysis with only change in date.	
	Decision	
	Rejected Registration Board decided to reject the instant application considering that the firm had submitted same chromatograms for the filled-stage analysis and the 6-month stability analysis, with only the date being changed.	
552	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar **(000995)**
	Application Form Dy. No / Tracking ID & date of submission	(ZZE-PWB-UVY5, 2025-02-12)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-29, 2024-10-22
	The proposed proprietary name / brand name	**Levset 500MG Tablet**
	Label Claim	Each Film Coated Tablet contains: Levofloxacin hemihydrate Equivalent to Levofloxacin..... 500 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Ambient
	For generic drugs (me-too Status)	Leflox Tablet by Getz
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	JIANGXI DADI PHARMACEUTICAL limited CO.
	Detail of stability batches of drug product	3 batches: 2000 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Leflox Tablet: PE and CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New DML dated 10-05-2024
	Evidence of approval of manufacturing facility	10-05-2024: New DML issuance letter specifies Tablet (General) section
	Evaluation Remarks	
	The pharmaceutical equivalence results are identical for both tablet strengths, i.e., 250 mg and 500 mg.	
	Decision	
	Rejected	

	Registration Board decided to reject the instant application on the basis that the firm had submitted identical pharmaceutical equivalence results for both tablet strengths, i.e., 250 mg and 500 mg.	
553	Case Category	New Section (Iqra Aftab)
	Name, address of Applicant.	**Steris Pharmaceuticals** Plot No 9 Near Synpac Hattar Private Industrial Estate Haripur Road Hattar **(000995)**
	Application Form Dy. No / Tracking ID & date of submission	(92U-4T3-NDN4, 2025-03-25)
	Detail of Fee Submitted	30000.0, 7000.0 2024-08-29, 2024-10-22
	The proposed proprietary name / brand name	**Levset 250MG Tablet**
	Label Claim	Each Film Coated Tablet contains: Levofloxacin hemihydrate Equivalent to Levofloxacin..... 250 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10s-As per SRO
	Shelf Life (Unit)	2 Year(s)Ambient
	For generic drugs (me-too Status)	Leflox Tablet by Getz
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	JIANGXI DADI PHARMACEUTICAL limited CO.
	Detail of stability batches of drug product	3 batches: 2000 Tablet
	Documents for the procurement of API with approval from DRAP (in case of Import)	Not submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Leflox Tablet: PE and CDP performed
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Not submitted
	The status in reference regulatory authorities	MHRA Approved
	GMP status of the firm	New DML dated 10-05-2024
	Evidence of approval of manufacturing facility	10-05-2024: New DML issuance letter specifies Tablet (General) section
	Evaluation Remarks	
	The pharmaceutical results are identical for both tablet strengths, i.e., 250 mg and 500 mg.	
	Decision	
	Rejected Registration Board decided to reject the instant application on the basis that the firm had submitted identical pharmaceutical equivalence results for both tablet strengths, i.e., 250 mg and 500 mg.	
554	Case Category	Routine (Iqra Aftab)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(TH5-TW2-QVAP, 2025-02-07)
	Detail of Fee Submitted	37000.0, 2024-11-11,
	The proposed proprietary name / brand name	**Flonex 150mg Capsule**

	Label Claim	Each Capsule contains: Fluconazole.....150mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Diflucan capsule 150mg by Pfizer Laboratories (011828)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	RUTU CHEMICALS. Plot No.2924/2, Road No.29, Phase – III, G.I.D.C Panoli, Dist. Bharuch, Gujrat, INDIA
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	Diflucan® 150 mg hard capsules Pfizer Limited Ramsgate Road Sandwich, Kent CT13 9NJ United Kingdom approved by EMA/MHRA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The system is not 21 CFR compliant.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
555	Case Category	Routine (Iqra Aftab)
	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	(U3H-A4Z-N6D4, 2025-05-11)
	Detail of Fee Submitted	37000.0, 2024-12-02,
	The proposed proprietary name / brand name	**ITRACON 100MG CAPSULE**
	Label Claim	Each Capsule contains Itraconazole pellets eq.to Itraconazole ..... 100 mg (USP specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	4's-As per SRO
	Shelf Life (Unit)	24 MonthAt room temperature below 25 degree centigrade
	For generic drugs (me-too Status)	Sporanox 100 mg cap by Aspin Pharma Pvt. Ltd, Registration Number 012647
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Surge Laboratories Pvt. Ltd. 10th KM, Faisalabad Road Bikhi, District Sheikhupura

	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	ITRACONAZOLE 100mg CAPSULES by Laboratorios LICONSA, S.A. Avda, MHRA approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The applicant's HPLC system is not 21 CFR compliant.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
556	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	**Akson Pharmaceuticals (Pvt) Ltd** Plot No. 9-B/1&2, street No.D-1, Old Industrial estate, Mirpur, Azad Kashmir **(000486)**
	Application Form Dy. No / Tracking ID & date of submission	(ZUD-7DV-2MG5, 2025-04-18)
	Detail of Fee Submitted	93000.0, 9400 2025-03-07, 2026-08-12
	The proposed proprietary name / brand name	**Akset 2% Ointment**
	Label Claim	Each gram ointment contains: Fusidic Acid (as Fusidate Sodium) .....20mg (Innovator Spec's)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	as per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)15- 25°C
	For generic drugs (me-too Status)	Fudic Ointment 2%
	Pharmacotherapeutic Group of (API)	Data approved in M-344
	Name, address of Manufacturing site:	Solaris Life Sciences (Pvt.) Ltd-Plot No. 08, Street No. S-1, RCCI, Industrial Estate, Rawat, Rawalpindi-PAKISTAN.-
	The status in reference regulatory authorities	. Fucidin 20mg Ointment (Registered in MHRA UK
	Detail of previous approval	M-344
	Evaluation Remarks	
	Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
	Decision	
	Approved	

	Firm shall submit following prior issuance of Registration letter. Declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F.	
557	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	**GMP Pharmaceuticals** 28-Km Sheikhupura Road Lahore **(000815)**
	Application Form Dy. No / Tracking ID & date of submission	(8RQ-3SS-D72W, 2025-02-11)
	Detail of Fee Submitted	75000.0, 18000.0 2024-07-04, 2024-10-02
	The proposed proprietary name / brand name	**VONZEM**
	Label Claim	Each film coated tablet contains Vonoprazan as fumarate equivalent to Vonoprazan ..... 10mg.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)30 - 40 * c
	For generic drugs (me-too Status)	Me too
	Pharmacotherapeutic Group of (API)	Data Already approved in M-335
	Name, address of Manufacturing site:	Self Manufacturing
	The status in reference regulatory authorities	US FDA
	Detail of previous approval	
	Evaluation Remarks	
	Overwriting of vonoprazan strength from 45 mg to 10mg in differential fee challan. Pre-registration fee is required for change status for data already approved from No to Yes. Undertaking is required. The data is already approved in M-335 meeting.	
	Decision	
	Approved Firm shall submit following prior issuance of Registration letter. 1. Declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. 2. Quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. 3. Pre-registration fee as per the latest fee SRO.	
558	Case Category	Contract Manufacturing (Iqra Aftab)
	Name, address of Applicant.	**Welcome Pakistan Trading Pharma (Pvt) Ltd** Chakri Interchange, Gangawala **(000987)**
	Application Form Dy. No / Tracking ID & date of submission	(SDX-QR9-GT85, 2025-05-30)
	Detail of Fee Submitted	93000.0, 2024-12-07,
	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)Store below 25c
	For generic drugs (me-too Status)	Ucid 2% Cream by Ciba Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Data already approved in M-357.
	Name, address of Manufacturing site:	Winbrains Research Laboratories-Plot No. 69/1, Phase I-II, Industrial Area, Hattar.-
	The status in reference regulatory authorities	UK MHRA
	Detail of previous approval	
	Evaluation Remarks	
	Data already approved in M-357.Pre-registration fee is required for change in data already approved from No to Yes.	
	Decision	
	Approved Firm shall submit following prior issuance of Registration letter. 1. Declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. 2. Quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. 3. Pre-registration fee as per the latest fee SRO.	
559	Case Category	Contract Manufacturing (Iqra Aftab)
	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	(7AV-1V8-DQBZ, 2024-09-30)
	Detail of Fee Submitted	93000.0, 2024-09-21,
	The proposed proprietary name / brand name	**OLP 1mg/ml Eye Drops**
	Label Claim	Each ml Contains: Olopatadine as Hydrochloride (USP).....1mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	As per SRO-As per SRO
	Shelf Life (Unit)	2 Year(s)Stability 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)	Opat Opthalmic Solution Alza Pharmaceuticals 081624
	Pharmacotherapeutic Group of (API)	Data Already Approved M-352
	Name, address of Manufacturing site:	M/S Winbrains Research Laboratories, -Plot no. 69/1, Block B, Phase I & II, Industrial Estate, Hattar, KPK -
	The status in reference regulatory authorities	https://www.accessdata.fda.gov/drugsatfda_docs/l
	Detail of previous approval	

	Evaluation Remarks	
	Following deficiencies were communicated to the applicant. Provide the section approval letter along with valid DML and GMP certificates for both the drug substance and drug product manufacturers. Submit the contract agreement. Provide stability data of the API till claimed shelf life. Specify which innovator/reference drug product the applied drug product is qualitatively similar to. For average volume or minimum fill, state the limits in volume units rather than percentages. Submit drug substance import documents, such as the clearance certificate or DRAP-attested invoice. Clearly mention the retest date or expiry date of the drug substance. Include the test for water loss as part of the specifications. Include assay of preservative at both release and shelf-life specification. Add particulate matter testing to the specifications. Include drop size and viscosity tests in the specifications and ensure they are performed. Two different stability summary data sheets (T-01 and T-001) with different batch sizes have been submitted, clarify. Submit in-use stability study data. Clarify the standards of different concentrations in the zero-time (initial) analysis. Identification by UV has not been performed for the drug product. The injection volume specified in USP is 30 µL, whereas 20 µL has been used for both API and DP testing, justify. The stated storage condition is 4–25°C, while the stability study conditions differ, justify. A peak has been observed at RT 0.5 in the attached chromatogram (305), justify. Verify the attached chromatograms using the audit trail and provide supporting snapshots. Provide the test method of the API as used by the drug product manufacturer. As the data is already approved as stated by the applicant, the firm shall submit requisite pre-registration variation fee as per the latest SRO and declaration as per contract policy notification F.No. 1-2/2022-DMC dated:13,June,2023.The following tests to be made part of DP specifications: water loss, assay of preservative at both release and shelf-life specification, add particulate matter testing, drop size and viscosity tests in the specifications and in-use stability studies.	
	Decision	
	Approved Firm shall submit following prior issuance of Registration letter. 1. Declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. 2. Quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. 3. Pre-registration fee as per the latest fee SRO.	
560	Case Category	Routine (Iqra Aftab)
	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	(2NY-A2D-EUUW, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	**RACIFIX 30mg Sachet**
	Label Claim	Each Sachet contains: Racecadotril.....30mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	As per SRO/DPC-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30C
	For generic drugs (me-too Status)	RECADA Children Sachet t,Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Submitted.
	Name, address of Manufacturing site:	Self Manufacturing

Name & address of API manufacturer	Symed Labs Limited
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	Hidrasec Children 30mg Granules for oral Suspension Abbottt Healthcare products Ltd.
GMP status of the firm	Submitted.
Evidence of approval of manufacturing facility	Submitted.

Evaluation Remarks

Query	Response
Support the gradient elution flow of API by monograph. Justify run time of 50 minutes.	We, Symed Labs Limited the manufacturer of API Racecadotril hereby confirm that, As per Ph.Eur monograph Gradient program was up to 35 minutes , we extended runtime to 50 minutes with initial gradient program (i.e. initial gradient program Pump A:60% and Pump B:40%) for stabilise system to avoid Gradient flow fluctuations during immediate changes from (20 :80) at 35 minutes to (60:40) at 0.01 minutes in next injection. The note point for the same is mentioned in STP.
The retention time as per attached chromatograms of API is not about 16 minutes as mentioned in Monograph.	Retention time (RT) of rececadotril mentioned about 16 min. As per pharmacopeia definition "About" mean± 10%. So the retention may vary from 14.4 min to 17.6 min. We, Symed Labs Limited the manufacturer of API Racecadotril hereby confirm that, the shift of the Retention time (RT) is due to the usage of column ie, Hibar Purospher STAR RP-18 e 250 mm x 4.6 mm, 5-um or equivalent.
Justification is required for not using polyacrylate dispersion 30 per cent.	In the proposed formulation, taste masking has been effectively achieved using alternative excipients, Sucralose. Therefore, the inclusion of polyacrylate dispersion is not considered necessary. The developed formulation demonstrates acceptable product performance, and comparative dissolution and stability studies confirm that the omission of this excipient does not adversely affect the quality of the product. Polyacrylate dispersion is a non-pharmacologically active excipient and does not contribute to the therapeutic efficacy of the product. Its role in the innovator formulation is limited to taste masking of Racecadotril. In the proposed formulation, taste masking has been effectively achieved using alternative excipients, Sucralose. Therefore, the inclusion of polyacrylate dispersion is not considered necessary. The developed formulation demonstrates acceptable product performance, and comparative dissolution and Stability studies

		confirm that the omission of this excipient does not adversely affect the quality of the product.

Decision

Deferred

Deferred for revision of formulation as per the innovator product and accordingly submit the revised pharmaceutical development data along with stability studies.

561	Case Category	Routine (Iqra Aftab)
	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	(M77-SUY-7L5L, 2024-08-28)
	Detail of Fee Submitted	30000.0, 2024-05-16,
	The proposed proprietary name / brand name	**RACIFIX 10mg Sachet (Racecadotril)**
	Label Claim	Each Sachet contains: Racecadotril.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 x 10's-As per SRO
	Shelf Life (Unit)	2 Year(s)Store below 30 C
	For generic drugs (me-too Status)	RECADA Infant Sachet 10mg by M/s Sami Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Submitted.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Symed Labs Limited
	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	Hidrasec Infant 10mg Graunles for oral Suspension by M/s Abbott Healthcare products Ltd
	GMP status of the firm	Submitted.
	Evidence of approval of manufacturing facility	Submitted.

Evaluation Remarks

Query	Response
Support the gradient elution flow of API by monograph. Justify run time of 50 minutes.	We, Symed Labs Limited the manufacturer of API Racecadotril hereby confirm that, As per Ph.Eur monograph Gradient program was up to 35 minutes , we extended runtime to 50 minutes with initial gradient program (i.e. initial gradient program Pump A:60% and Pump B:40%) for stabilise system to avoid Gradient flow fluctuations during immediate changes

	from (20 :80) at 35 minutes to (60:40) at 0.01 minutes in next injection. The note point for the same is mentioned in STP.
The retention time as per attached chromatograms of API is not about 16 minutes as mentioned in Monograph.	Retention time (RT) of rececadotril mentioned about 16 min. As per pharmacopeia definition "About" mean± 10%. So the retention may vary from 14.4 min to 17.6 min. We, Symed Labs Limited the manufacturer of API Racecadotril hereby confirm that, the shift of the Retention time (RT) is due to the usage of column ie, Hibar Purospher STAR RP-18 e 250 mm x 4.6 mm, 5-um or equivalent.
Justification is required for not using polyacrylate dispersion 30 per cent.	In the proposed formulation, taste masking has been effectively achieved using alternative excipients, Sucralose. Therefore, the inclusion of polyacrylate dispersion is not considered necessary. The developed formulation demonstrates acceptable product performance, and comparative dissolution and stability studies confirm that the omission of this excipient does not adversely affect the quality of the product. Polyacrylate dispersion is a non-pharmacologically active excipient and does not contribute to the therapeutic efficacy of the product. Its role in the innovator formulation is limited to taste masking of Racecadotril. In the proposed formulation, taste masking has been effectively achieved using alternative excipients, Sucralose. Therefore, the inclusion of polyacrylate dispersion is not considered necessary. The developed formulation demonstrates acceptable product performance, and comparative dissolution and Stability studies confirm that the omission of this excipient does not adversely affect the quality of the product.

	Decision	
	Deferred Deferred for revision of formulation as per the innovator product and accordingly submit the revised pharmaceutical development data along with stability studies.	
562	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	(31L-LJW-MHAJ, 2024-09-18)
	Detail of Fee Submitted	75000.0, 75000.0 2024-08-06, 2024-09-06
	The proposed proprietary name / brand name	**Plop Forte**
	Label Claim	Each ml contains: 7.76 mg olopatadine hydrochloride equivalent to 7 mg olopatadine. OR Olopatadine HCl eq. to Olopatadine 0.7%
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	2.5 ml, 5 ml and 10 -As per SRO
	Shelf Life (Unit)	2 Year(s)Store between 2°C - 25°C
	For generic drugs (me-too Status)	Not Applicable
	Pharmacotherapeutic Group of (API)	Submitted.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	FLAX LABORATORIESPRIVATE LIMITED, B-29/1,MIDC Mahad, Birvadi village,Dist:-Raigad, Maharashtra, India-402301
	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)	Attach stress studies of API.
	The status in reference regulatory authorities	Pazeo 0.7% (7 mg) Ophthalmic Solution by Novartis Pharmaceuticals Canada Inc.
	GMP status of the firm	Submitted.
	Evidence of approval of manufacturing facility	Submitted.
	Evaluation Remarks	
	Decision	
	Approved	
563	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	(ERJ-834-P4Q1, 2026-05-16)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Ensillin-G Oral Liquid**

	Label Claim	Each 100 ml contains: Enrofloxacin ....10g Aminophyllin..... 4g Guaiphenesin.....10g
	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-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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
564	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	(PU2-UZ2-TJWM, 2026-05-15)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Doxytos-60 Oral Powder**
	Label Claim	Each 100gm contains: Tylosin Tartrate .....20g Doxycycline Hcl.....40g
	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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
565	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	(QLG-6XE-MSJE, 2026-05-18)
	Detail of Fee Submitted	38700, 2026-05-18,
	The proposed proprietary name / brand name	**Omox 60 Oral Powder**
	Label Claim	Each 100 gm contains: Amoxicillin Trihydrate ..... 60g 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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
566	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	(DBG-18N-NDZ7, 2026-05-15)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Doxytos-45 Oral Powder**
	Label Claim	Each 100gm contains: Tylosin Tartrate.....20g Doxycycline Hcl.....25g
	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	

	The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
567	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	(6HY-Q5M-56AD, 2026-05-15)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Doxitocin-TC Oral Powder**
	Label Claim	Each 100gm contains: Tylosine Tartate 10gm Doxycycline HCl.....20gm Colistin Sulphate .3gm Bromhexine HCL.....1gm
	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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
568	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	(53B-BDU-4ZDW, 2026-05-15)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Doxitocin Oral Powder**
	Label Claim	Each 100gm contains: Tylosine Tartate .....10gm Doxycycline HCl .....20gm Colistin Sulphate .....48MIU Bromhexine HCL.....0.5gm
	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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
569	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	(RPW-QNR-P9B8, 2026-05-16)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Coliflox-Plus Oral liquid**
	Label Claim	Each 100ml contains Enrofloxacin ..... 20gm Colistin Sulphate.....45MIU
	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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
570	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**ONE HEALTH PHARMA** Plot# 28/2-A, SITE Kotri, sindh. **(000993)**
	Application Form Dy. No / Tracking ID & date of submission	(1T8-Z9Z-T3JY, 2024-05-16)
	Detail of Fee Submitted	30000.0, 2024-05-09,
	The proposed proprietary name / brand name	**Onemizole 3 % Oral liquid**
	Label Claim	Each mL contains Levamisole HCL BP 30 mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	1.0 L-De-Controlled,10.0 L-De-Controlled,100 mL-De-Controlled,15.0 L-De-Controlled,2.5 L-De-Controlled,25.0 L-De-Controlled,250 mL-De-Controlled,5.0 L-De-Controlled,50 mL-De-Controlled,500 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore at Cool and Dry Place, Protect From Heat and Sunlight
	For generic drugs (me-too Status)	Mallworm-DS (058929) Mallard

	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Inspection for Grant of DML Conclusion Remarks are "GOOD"
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
571	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	(NVE-V5S-5AZ6, 2026-05-15)
	Detail of Fee Submitted	38700, 9400 2026-05-14, 2026-07-22
	The proposed proprietary name / brand name	**Doxitocin-30 Oral Powder**
	Label Claim	Each 100gm contains: Tylosine Tartate .....10gm Doxycycline HCl .....20gm Colistin Sulphate.....50MIU Bromhexine HCL.....5gm
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 kg-De-Controlled,100 gm-De-Controlled,1000 gm-De-Controlled,50 gm-De-Controlled,500 gm-De-Controlled,5kg-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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
572	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	(QWB-7WA-XWXT, 2026-05-18)
	Detail of Fee Submitted	38700, 2026-05-18,
	The proposed proprietary name / brand name	**Amoxico 20 Oral Powder**
	Label Claim	Each 100 gm contains: Amoxicillin Trihydrate.....20g Colistin Sulphate 80MIU
	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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
573	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	(MQA-PTU-1LTT, 2026-05-15)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Doxitocin Forte Oral Powder**
	Label Claim	Each 100gm contains Tylosine Tartate .....20gm Doxycycline HCl.....40gm Colistin Sulphate.....50MIU Bromhexine HCL.....1gm
	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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
574	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	(JMD-3SP-WJWD, 2026-05-15)
	Detail of Fee Submitted	38700, 2026-05-14,
	The proposed proprietary name / brand name	**Doxitocin-T Plus Oral Powder**

	Label Claim	Each 100gm contains: Tylosine Tartate .....20gm Doxycycline HCl .....40gm Colistin Sulphate.....6gm 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	
	The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
	Decision	
	Approved	
575	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	(DSM-PQ4-9QT3, 2026-05-18)
	Detail of Fee Submitted	38700, 2026-05-18,
	The proposed proprietary name / brand name	**Neotetramox Oral Powder**
	Label Claim	Each gram 1000 gram contain: Amoxicillin as Trihydrate...100gm Colistin Sulphate ..... 50gm Neomycin Sulphate ..... 200gm (Innovator's Specs)
	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	
576	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	(B6N-B7J-Z8PS, 2026-05-18)
	Detail of Fee Submitted	38700, 2026-05-18,
	The proposed proprietary name / brand name	**Amoxico C Oral Powder**
	Label Claim	Each 100 gm contains: Amoxicillin as trihydrate ..... 15g Colistin Sulphate.....550MIU
	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 The firm shall submit fee Rs. 9400/- for specification correction before issuance of registration letter	
577	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	(ZBL-PLW-ZTAL, 2026-05-18)
	Detail of Fee Submitted	38700, 2026-05-18,
	The proposed proprietary name / brand name	**Amoxico Ultra Oral Powder**
	Label Claim	Each 100 gram contain: Amoxicillin as Trihydrate.....20g Colistin Sulphate.....5MIU
	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	
	Firm has submitted revised formulation in another application this formulation me-too does not exist, submitted for rejection please.	
	Decision	

	Rejected As the combination in this strength is not available.	
578	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(97W-9LM-2P4U, 2024-10-11)
	Detail of Fee Submitted	37000.0, 2024-09-24,
	The proposed proprietary name / brand name	**KANASONE INJECTION**
	Label Claim	Each ml contains (As Per Innovators Spec.) Kanamycin Sulphate .....50mg Colistine Sulphate .....100,000IU Neomycin Sulphate.....50mg Dexamethasone Sodium Phospahte .....0.5 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	KONODEX INJECTION (052347) ALINA COMBINE KARACHI
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The panel recommends grant of DML
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Sub-committee recommended such formulations.	
	Decision	
	Approved	
579	Case Category	Routine (Muhammad Sarfraz Nawaz)
	Name, address of Applicant.	**Skymed Healthcare Private Limited** House No:2, Gor-1 near Chamba House Lahore, Pakistan. **(05-352-0063-038947D)**
	Application Form Dy. No / Tracking ID & date of submission	(JBP-7T4-5QBN, 2024-08-21)
	Detail of Fee Submitted	300000.0, 2024-04-03,
	The proposed proprietary name / brand name	**Axfol Injection**
	Label Claim	Propofol Injection BP 1% W/V 200mg/20ml
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	pack of 5-As per SRO
	Shelf Life (Unit)	24 Month2 to 25 degree celsius
	For generic drugs (me-too Status)	Generic (Diprivan)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Naprod Life Sciences Pvt. Ltd.-G-17/1, M.I.D.C. Tarapur Industrial Area, Boisar, Dist- Palghar-401506 India.-India
	Pharmaceutical Equivalence and Comparative Dissolution Profile	

	Name, address of Marketing Authorization Holder:	Naprod Life Sciences Pvt. Ltd., G-17/1, M.I.D.C. Tarapur Industrial Area, Boisar, Dist - Palghar-401506 India., India
	Details of Certificates (CoPP/FSC/cGMP):	
	Details of Authorization Letter :	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	US FDA(document attached herewith)
	Evaluation Remarks	
	Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
	Decision	
	Approved	
580	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	(JRM-NXJ-WB54, 2026-08-03)
	Detail of Fee Submitted	97200, 2026-05-05,
	The proposed proprietary name / brand name	**Bitrilva 24mg/26mg Tablets**
	Label Claim	Each film coated tablet contains: Sacubitril ..... 24mg Valsartan 26mg
	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 24mg/26mg by FEROZSONS Laboratories Limited (Reg. No. 097079)
	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 # 2N1 and 2N139 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 24/26mg 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 24mg/26mg 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	
581	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Biogen Life Sciences** 8-KM, Chak Beli Road, Rawat, **(000911)**
	Application Form Dy. No / Tracking ID & date of submission	(X8M-X1Q-APHM, 2024-07-25)
	Detail of Fee Submitted	30000.0, 2024-03-01,
	The proposed proprietary name / brand name	**GENOCIN 500 mg INJECTION IV**
	Label Claim	Each vial contains: Vancomycin as HCl 500mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)Room Condition
	For generic drugs (me-too Status)	Vanzy 500mg Injection
	Pharmacotherapeutic Group of (API)	Antibiotic
	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. 350309
	Detail of stability batches of drug product	Three batches of 250 vials each
	Documents for the procurement of API with approval from DRAP (in case of Import)	API loan from Ms English pharma without timely intimation to DRAP, hence may be verified accordingly
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE data submitted against Vancomycin 500 injection of Ms Abbott
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Submitted as per zone IV-A conditions
	The status in reference regulatory authorities	VANCOCIN CP vancomycin 500mg (500,000IU as hydrochloride) powder for injection vial. TGA
	GMP status of the firm	Submitted
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	i. The firm has submitted copies of GMP and DML of the applicant valid at the time of submission but are expired now, the firm shall submit valid GMP and DML before issuance of the registration letter. ii. API loan from Ms English pharma without timely intimation to DRAP, hence, may be verified accordingly.	
	Decision	
	Approved The firm shall submit the following before issuance of registration letter: i. copies of valid GMP and DML of the applicant ii. API loan verification.	
582	Case Category	Contract Manufacturing (Najia Saleem)
	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	(UQR-8P3-DR4R, 2024-08-20)
	Detail of Fee Submitted	75000.0, 2024-06-26,
	The proposed proprietary name / brand name	**C-Kolin 250mg/2ml Injection**
	Label Claim	Each Ampoule (2mL) Contains: Citicoline as Sodium Salt (USP).....250Mg (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)	Coliwan Injection 250mg by Swan Pharma
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Wnsfeild Pharmaceuticals-Plot No. 122, Phase-V, Block-A, Industrial Estate, Hattar, KPK. -
	The status in reference regulatory authorities	ANSM France
	Detail of previous approval	
	Evaluation Remarks	
	The firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved in 357th meeting of the Registration Board and submitted undertaking and requested to consider this product as cross-referred already approved data. Hence, the firm shall submit fee Rs. 9400/- before issuance of registration letter.	
	Decision	
	Approved The firm shall submit fee Rs. 9400/- as applicable on cross-referred cases, before issuance of registration letter.	
583	Case Category	Contract Manufacturing (Najia Saleem)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(3BV-YVR-LYT5, 2025-02-13)
	Detail of Fee Submitted	93000.0, 2025-01-13,
	The proposed proprietary name / brand name	**FATYSAF 100mg TABLETS**
	Label Claim	Each film-coated tablet contains: Resmetirom ..... 100mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	REZDIFFRA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad.-
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the	

	same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID E9Z-Q9V-U6T3 dated 10 June 2026. Moreover, the firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved and requested to consider this product as cross-referred already approved data. Hence, the firm shall submit fee Rs. 9400/- before issuance of registration letter.	
	Decision	
	Approved The firm shall submit fee Rs. 9400/- as applicable on cross-referred cases, before issuance of registration letter.	
584	Case Category	Contract Manufacturing (Najia Saleem)
	Name, address of Applicant.	**Saffron Pharmaceuticals** 19-Km Sheikhupura Road **(000616)**
	Application Form Dy. No / Tracking ID & date of submission	(TBR-4PA-Q2WX, 2025-03-04)
	Detail of Fee Submitted	93000.0, 2025-01-13,
	The proposed proprietary name / brand name	**FATYSAF 60mg TABLETS**
	Label Claim	Each film-coated tablet contains: Resmetirom ..... 60mg (As per Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	14's-As per SRO
	Shelf Life (Unit)	24 MonthDo not store above 30°C.
	For generic drugs (me-too Status)	REZDIFFRA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	MEDIZAN LABORATORIES (PVT.) LTD.-Plot No.313, Industrial Triangle, Kahuta Road Islamabad. -
	The status in reference regulatory authorities	USFDA
	Detail of previous approval	
	Evaluation Remarks	
	In light of Registration Board's decisions taken in its 324th meeting and notified vide F.No.1-2/2022-DMC dated 13th June 2023, and 350th Meeting held on 29th – 30th July, 2025, the instant application is being presented for consideration of the Board as an application for cross-reference of already approved data on Form 5F. Applicants need to submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure and fulfill other conditions mentioned in the above-mentioned notification. Furthermore, quality agreement under Rule 20-A of the Drugs (LR&A) Rules, 1976 is also needed as part of module-1 of Form 5F. The firm has cross-referred a product approved in PRV vide TID BL2-P8U-3AVQ dated 30 April 2026. Moreover, the firm initially selected "No" but later on replied in response to a query that their contract manufacturing product has been approved and requested to consider this product as cross-referred already approved data. Hence, the firm shall submit fee Rs. 9400/- before issuance of registration letter.	
	Decision	
	Approved The firm shall submit fee Rs. 9400/- as applicable on cross-referred cases, before issuance of registration letter.	

585	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Lucky Core Industries Limited** 32/2A, Phase-III, Industrial Estate, Hattar **(000363)**
	Application Form Dy. No / Tracking ID & date of submission	(GU7-RLJ-W32R, 2024-09-25)
	Detail of Fee Submitted	37000.0, 9400 2024-09-10, 2026-07-06
	The proposed proprietary name / brand name	**Sunplus Injection**
	Label Claim	Each Ampoule Contains: Vitamin D3 (Cholecalciferol) .....200,000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1's-As per SRO
	Shelf Life (Unit)	2 Year(s)store below 30˚C
	For generic drugs (me-too Status)	Indrop D Vitamin D3 (Cholecalciferol) 200,000IU Manufactured by Neutro Pharma (Pvt). Ltd. Lahore
	Pharmacotherapeutic Group of (API)	vitamin
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Sichuan Province Yuxin Pharmaceutical Co., Ltd Address: No. 51, West Section of Changjiang Road, Economic Development District (South District), Shifang City, Sichuan Province, China 61840
	Detail of stability batches of drug product	3 batches of 2000 ampoules each
	Documents for the procurement of API with approval from DRAP (in case of Import)	License to import drugs (form-6), batch certificate (form-7), commercial invoice and packing list are submitted
	Pharmaceutical Equivalence and Comparative Dissolution Profile	PE against Indrop D
	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=66597083
	GMP status of the firm	
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	The firm has not submitted clearance certificate/ ADC attested commercial invoice however, only license to import drugs (form-6), batch certificate (form-7), commercial invoice and packing list are submitted.	
	Decision	
	Approved with IM and oral route of administration.	
586	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(TUW-3D1-ZRW3, 2025-09-26)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	**Brivatam 50mg/5ml Injection**

	Label Claim	Each 5ml contains: Brivaracetam.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	5’s x 1ml-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Cubriva Injection, Registration Holder: M/s Genix Pharma
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. PORTON PHARMA SOLUTIONS.LTD, Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221 China.
	Detail of stability batches of drug product	Batch # T052, T053, T054 are attached in Dossier
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Briviact 10 mg/ml solution for injection/infusion, Marketing Authorization Holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, Regulatory Authority: MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table titled Brivaracetam Injection as System Administrator-Project Audit trail without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
587	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(3Y5-8R6-LJET, 2025-09-30)
	Detail of Fee Submitted	37000.0, 9400 2025-04-21, 2026-07-23
	The proposed proprietary name / brand name	**Brivatam 100mg Tablet**
	Label Claim	Each film coated tablet contains: Brivaracetam.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 14’s, 28’s, 56’-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Brivace 100mg Tablet , Registration Holder: M/s Hilton Pharmaceuticals
	Pharmacotherapeutic Group of (API)	antiepileptics, other antiepileptics

	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. PORTON PHARMA SOLLUTIONS.LTD, Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221, China.
	Detail of stability batches of drug product	Batch # T049, T050, T051 are attached in Dossier
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Briviact 100mg film-coated tablets, Marketing Authorization holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, Regulatory Authority: MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table titled Brivaracetam Tablet as System Administrator-Project Audit trail without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
588	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(GA2-RZ7-T7PR, 2025-09-25)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	**Brivatam 10mg Tablet**
	Label Claim	Each film coated tablet contains: Brivaracetam.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 14’s, 28’s, 56’-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Brivace 10mg Tablet, Registration Holder: M/s Hilton Pharmaceuticals
	Pharmacotherapeutic Group of (API)	antiepileptics, other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. PORTON PHARMA SOLLUTIONS.LTD, Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221, China.
	Detail of stability batches of drug product	Batch No. T037, T038, T039 are attached in Dossier

	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Briviact 10 mg film-coated tablets, Marketing Authorization holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, Regulatory Authority: MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table titled Brivaracetam Tablet as System Administrator-Project Audit trail without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
589	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(NYQ-VGN-W7DP, 2025-10-02)
	Detail of Fee Submitted	37000.0, 9400 2025-04-21, 2026-07-23
	The proposed proprietary name / brand name	**Brivatam 25mg Tablet**
	Label Claim	Each film coated tablet contains: Brivaracetam.....25mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7’s, 14’s, 28’s, 56’-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Brivace 25mg tablet, Registration Holder: M/s Hilton Pharmaceuticals
	Pharmacotherapeutic Group of (API)	Antiepileptics, other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. PORTON PHARMA SOLLUTIONS.LTD, Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221 China.
	Detail of stability batches of drug product	Batch No. T040,T041, T042 are attached in Dossier
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier

	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Briviact 25 mg film-coated tablets, Marketing Authorization holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, Regulatory Authority: MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table titled Brivaracetam Tablet as System Administrator-Project Audit trail without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
590	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(JNB-TBL-1PR4, 2025-10-06)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	**Brivatam 75mg Tablet**
	Label Claim	Each film coated tablet contains: Brivaracetam.....75mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 14's, 28's, 56'-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Brivace 75mg tablet, Registration Holder: M/s Hilton Pharmaceuticals
	Pharmacotherapeutic Group of (API)	antiepileptics, other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. PORTON PHARMA SOLLUTIONS.LTD, Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221, China.
	Detail of stability batches of drug product	Batch # T046, T047, T048 are attached in Dossier
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Briviact 75mg film-coated tablets, Marketing Authorization holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, Regulatory Authority: MHRA Approved

	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table titled Brivaracetam Tablet as System Administrator-Project Audit trail without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
591	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(3UR-NDA-RWPT, 2025-09-30)
	Detail of Fee Submitted	37000.0, 9400 2025-04-21, 2026-07-23
	The proposed proprietary name / brand name	**Brivatam 50mg Tablet**
	Label Claim	Each film coated tablet contains: Brivaracetam.....50mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	7's, 14's, 28's, 56'-As per SRO
	Shelf Life (Unit)	2 YearStore Below 30°C
	For generic drugs (me-too Status)	Brand Name: Brivace 50mg Tablet, Registration Holder: M/s Hilton Pharmaceuticals
	Pharmacotherapeutic Group of (API)	antiepileptics, other antiepileptics
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. PORTON PHARMA SOLLUTIONS.LTD, Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221, China.
	Detail of stability batches of drug product	Batch no. T043, T044, T045 are attached in Dossier
	Documents for the procurement of API with approval from DRAP (in case of Import)	Attached in Dossier
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Attached in Dossier
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in Dossier
	The status in reference regulatory authorities	Brand Name: Briviact 50mg film-coated tablets, Marketing Authorization holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom, Regulatory Authority: MHRA Approved
	GMP status of the firm	Valid
	Evidence of approval of manufacturing facility	Attached in Dossier
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table titled Brivaracetam Tablet as System Administrator-Project Audit trail without any details for verification of submitted chromatograms.	

	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
592	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(BMB-AD7-SZUT, 2025-10-10)
	Detail of Fee Submitted	37000.0, 2025-04-21,
	The proposed proprietary name / brand name	**Brivatam 10mg/ml Oral Solution**
	Label Claim	Each ml contains: Brivaracetam.....10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	60ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Brand Name: Brivera10mg/ml Oral solution., Manufacturer: M/s Genix Pharmaceuticals.
	Pharmacotherapeutic Group of (API)	Name: M/s. PORTON PHARMA SOLLUTIONS LTD., Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221 China.
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	Name: M/s. PORTON PHARMA SOLLUTIONS LTD., Address: 1 Fine Chemical Zone Chongqing Chem Ind Park Changshou Chongqing 401221 China.
	Detail of stability batches of drug product	Attached in 3.2.P.8.3 of Module 3.
	Documents for the procurement of API with approval from DRAP (in case of Import)	Commercial Invoice is provided Along with Stability Data.
	Pharmaceutical Equivalence and Comparative Dissolution Profile	Pharmaceutical Equivalence is provided in 3.2.P.2.2 of Module 3.
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	Attached in 2.3.S.7.1 of Module 3.
	The status in reference regulatory authorities	Brand Name: Briviact 10 mg/ml oral solution., Marketing Authorization holder: UCB Pharma Limited 208 Bath Road Slough Berkshire SL1 3WE United Kingdom., Regulatory Authority: MHRA Approved
	GMP status of the firm	Attached in 1.3.5 of Module 1
	Evidence of approval of manufacturing facility	Attached in 1.3.5 of Module 1
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table titled Brivaracetam syrup as System Administrator-Project Audit trail without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	

593	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**Swiss Pharmaceuticals Pvt. Ltd.** A/159, S.I.T.E.-II, Super Highway **(000438)**
	Application Form Dy. No / Tracking ID & date of submission	(5BJ-VZH-M6SQ, 2024-07-01)
	Detail of Fee Submitted	30000.0, 2024-05-30,
	The proposed proprietary name / brand name	**KAIRDON 1mg/1ml Syrup**
	Label Claim	Each ml contains: Risperidone.....1mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	120ml-As per SRO,30ml-As per SRO,60ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Risp Oral Solution 1mg/ml by M/s Adamjee Pharmaceuticals Pvt Ltd.
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Self Manufacturing
	Name & address of API manufacturer	N/A
	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	Risperdal® 1 mg/ml oral solution Janssen Pharmaceutica N.V. Turnhoutseweg 30, 2340 Beerse, Belgium EMA Approved
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has stated in the dossier that the firm has Waters HPLC with Empower software for stability studies currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
594	Case Category	Routine (Najia Saleem)
	Name, address of Applicant.	**BAKER & BAKER PHARMACEUTICALS PVT LTD** PLOT NO 43,44,45,48,49-C SMALL INDUSTRIAL ESTATE BHIMBER AJK. **(001026)**
	Application Form Dy. No / Tracking ID & date of submission	(115-LQE-57X4, 2026-04-11)
	Detail of Fee Submitted	38700, 2026-04-08,
	The proposed proprietary name / brand name	**CLINDO ORAL LIQUID**
	Label Claim	Each Liter contains: Enrofloxacin.....100 g N-Acetyl L-Cystine.....186 g Propylene

		Glycol.....100 g Benzyl Alcohol.....20 mg (As per innovator's specifications).
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 250ml, 500ml, 1Litre-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature, in a dry place. Protect from direct sunlight. Keep the container tightly closed.
	For generic drugs (me-too Status)	PENPROL SOLUTION (063718)
	Pharmacotherapeutic Group of (API)	Antibiotic, anti-inflammatory, antioxidant
	Name, address of Manufacturing site:	--
	GMP status of the firm	New DML
	Evidence of approval of manufacturing facility	submitted
	Evaluation Remarks	
	Target species: Poultry (broilers, layers) Calves Goats & sheep	
	Decision	
	Approved	
595	Case Category	Contract Manufacturing (Najia Saleem)
	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	(MRS-TPW-YLAT, 2024-06-11)
	Detail of Fee Submitted	75000.0, 9400 2023-05-04, 2026-07-06
	The proposed proprietary name / brand name	**Vomfran 4mg**
	Label Claim	Each film coated tablet contains: Ondansetron as Hydrochloride Dihydrate 4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10's-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Onseron Tablets 4mg (Ondansetron as Hydrochloride dihydrate) by Indus pharma Regn. No. 053448
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A/159, S.I.T.E. II , Super Highway, Karachi – Pakistan-
	Name & address of API manufacturer	
	Detail of stability batches of drug product	
	Documents for the procurement of API with approval from DRAP (in case of Import)	
	Pharmaceutical Equivalence and Comparative Dissolution Profile	
	Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	
	The status in reference regulatory authorities	ZOFRAN 4mg Tablet (Ondansetron as hydrochloride dihydrate) by Novartis Pharmaceuticals UK Limited 2n
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
596	Case Category	Contract Manufacturing (Najia Saleem)
	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	(WG9-34T-VWLU, 2024-10-10)
	Detail of Fee Submitted	93000.0, 2024-09-25,
	The proposed proprietary name / brand name	**Vomfran 4mg/5ml**
	Label Claim	Each 5ml contains: Ondansetron (as Ondansetron Hydrochloride Dihydrate).....4mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-As per SRO
	Shelf Life (Unit)	2 YearStore below 30°C
	For generic drugs (me-too Status)	Onseron Syrup (Ondansetron HCl) by Indus Pharma (Pvt.) Ltd. Regn. No.: 058677
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	Swiss Pharmaceuticals Pvt. Ltd.-A/159, S.I.T.E. II , Super Highway, Karachi – Pakistan-
	Name & address of API manufacturer	None
	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	ZOFRAN ORAL SOLUTION by M/s. GlaxoSmithKline Research Triangle Park, NC 27709, Approved by: US FDA
	GMP status of the firm	
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	The firm has stated in the dossier that currently the system is not 21 CFR Compliant; upon clarification the firm has then submitted a table without any details for verification of submitted chromatograms.	
	Decision	
	Deferred Registration Board deferred the instant case to devise a mechanism for disposal of such cases wherein the data is complete, however, the HPLC system is not 21 CFR compliant.	
597	Case Category	Routine (Noor Ul Ain Arshia)

Name, address of Applicant.	**Healthtek Pvt. Ltd.** Plot No.14, Sector 19, Korangi Industrial Area Karachi - Pakistan **(000618)**
Application Form Dy. No / Tracking ID & date of submission	(GWL-H4A-J793, 2024-10-25)
Detail of Fee Submitted	30000.0, 7000.0 2024-08-01, 2024-10-24
The proposed proprietary name / brand name	**2SUM 1.5g Injection IV/IM**
Label Claim	Each vial contains: Cefoperazone Sodium Eq. to Cefoperazone.....1000mg Sulbactam Sodium Eq. to Sulbactam.....500mg
Reference to Finished product specifications	As per Innovators Specification
Proposed Pack Size	1's-As per SRO
Shelf Life (Unit)	2 Year(s)Store Below 30 Degree Celsius
For generic drugs (me-too Status)	Cefpran 1.5g Injection
Pharmacotherapeutic Group of (API)	Antibiotics (Cephalosporin)
Name, address of Manufacturing site:	Self Manufacturing
Name & address of API manufacturer	Suzhou Dawnrays Pharmaceutical Co., Ltd., No.22 Tianling Road, Wuzhong Economic Development District, Suzhou, Jiangsu Province, People's Republic of China,Suzhou Dawnrays Pharmaceutical Co., Ltd., No.22 Tianling Road, Wuzhong Economic Development District, Suzhou, Jiangsu Province, People's Republic of China
Detail of stability batches of drug product	3 Batches Size 1L 130 vials
Documents for the procurement of API with approval from DRAP (in case of Import)	Form-6 Computerized No: K-2889286421268 Date of issue: 11-Jan-2024
Pharmaceutical Equivalence and Comparative Dissolution Profile	Cefpran 1.5gm Injection marketed by ontech corporation B. No: 230701
Stability Studies of Drug Substance/Product (Conditions & duration of Stability studies)	IV-A
The status in reference regulatory authorities	Sulperazone*
GMP status of the firm	Certificate no 29/2025-DRAP dated 14-03-25
Evidence of approval of manufacturing facility	No F.2-10/2003-Lic (Vol-II)dated 26-december-2024 mentioning dry powder injection section

Evaluation Remarks

The case was previously approved in 357th Meeting of Registration Board. However, while processing for issuance of registration letter, approval status of applied formulation could not be verified from reference regulatory authorities adopted by the Registration Board in its 276th meeting. In support of their request, the applicant has submitted that: Sulperazone (Cefoperazone 1 g + Sulbactam 0.5 g) 1.5g Injection was previously available in Italy and later on the Marketing Authorization was lapsed due to non-commercialization and was not withdrawn due to any safety, efficacy, quality, or benefit-risk-related concerns. Rationale and usage of 1.5 G Sulbactam/Cefoperazone: The 1.5g (500mg/1g) formulation has a well-established role in specific patient populations, particularly immunocompromised febrile neutropenic cancer patients and bone marrow transplant recipients, where higher Cefoperazone exposure with a lower sulbactam dose may be clinically appropriate. Dose adjustment is recommended in patients with significant renal impairment (creatinine clearance <30 mL/min). Patients with creatinine clearance of 15-30 mL/min should receive a maximum of 1 g sulbactam every 12 hours (2 g/day), while those with creatinine clearance <15 mL/min should receive a maximum of 500 mg Sulbactam every 12 hours (1 g/day).

	A review of regulatory documents issued by the United States Food and Drug Administration (US FDA), World Health Organization (WHO), European regulatory documents, and publicly available regulatory information demonstrate that: There is no regulatory evidence that Cefoperazone or Cefoperazone/Sulbactam has been withdrawn because of an unacceptable safety profile. WHO confirms that Cefoperazone/Sulbactam continues to be marketed in numerous countries worldwide and describes its efficacy and safety profile as well established through decades of clinical use. Therefore, the absence of marketing authorization in certain developed countries reflects commercial strategy, historical regulatory decisions, changing prescribing practices and antimicrobial stewardship rather than a regulatory determination that the medicine is unsafe. Based on the above scientific evidence, it is respectfully submitted that the proposed Cefoperazone/Sulbactam 1.5 g (500 mg/1 g) formulation is consistent with internationally accepted clinical practice and approved prescribing information. The case was present in the hard agenda and has now been included in the E-App.	
	Decision	
	Rejected Registration Board rejected the registration application of "2SUM 1.5g Injection IV/IM; GWL-H4A-J793" submitted by M/s Healthtek Pvt. Ltd., Plot No.14, Sector 19, Korangi Industrial Area Karachi on the grounds that formulation in the applied strength is not available in the RRA's. Accordingly, the decision taken by the Board in its 357th meeting with respect to registration of "2SUM 1.5g Injection IV/IM" shall stand revoked.	
598	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	(QSH-WD4-PYEE, 2026-03-02)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	**Bupak Injection**
	Label Claim	Each ml Contains .....Buparvaquone 50 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in Cool and Dry place Below 25 C
	For generic drugs (me-too Status)	Bupralex Injection Reg # 033264 Star laboratories lahore
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
599	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	(TUU-6TX-BSZ9, 2026-03-02)

	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	**Dicarb Injection**
	Label Claim	Each ml Contains:- Imidocarb Dipropionate 120 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in Cool and Dry place Below 25 C
	For generic drugs (me-too Status)	Durazol Injection Reg # 078204 Mylab Bahawalpur
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
600	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	(XAZ-RMV-GPNB, 2026-03-02)
	Detail of Fee Submitted	38700, 2026-02-20,
	The proposed proprietary name / brand name	**Dicarb Injection**
	Label Claim	Each ml Contains:- Imidocarb Dipropionate 120 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in Cool and Dry place Below 25 C
	For generic drugs (me-too Status)	Durazol Injection Reg # 078204 Mylab Bahawalpur
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
601	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	(YZN-D3S-P3B9, 2025-12-19)
	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Sipracol Injection 100 mL**
	Label Claim	Sipramycin Adipate..... 32 MIU Colistin Sulfate .....10 MIU
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)Store Cool and Dry place below 25 Degree Centigrade
	For generic drugs (me-too Status)	Sipracol 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	Present
	Evaluation Remarks	
	Decision	
	Approved	
602	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	(Y35-YXT-34D1, 2026-03-06)
	Detail of Fee Submitted	38700, 2026-03-05,
	The proposed proprietary name / brand name	**SPECLIN ORAL POWDER**
	Label Claim	Each 100gm Contains: Lincomycin as HCL ... 5gm Spectinomycin HCL .....7.5gm Spiramycin Adipate ..... 2.5gm Bromhexine HCL ..... 0.5gm As per Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25ºC
	For generic drugs (me-too Status)	Lexob Oral Power of M/s. QAS International (Reg. No. 118391)
	Pharmacotherapeutic Group of (API)	Antibiotic & Mucolytic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

603	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	(U66-669-7GD7, 2026-03-06)
	Detail of Fee Submitted	38700, 2026-03-05,
	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 Specification
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25ºC
	For generic drugs (me-too Status)	Genta-Prim Injection (50ml) of M/s. Inshal Pharmaceutical Industries, Islamabad. (Reg. No. 080520)
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
604	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	(PDS-LW2-JZ2W, 2026-03-03)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**Tonic Injection**
	Label Claim	Each ml Contain: Etilefrin ... 0.2mg Caffeine ... 10mg Sodium Salicylate ... 7mg Novaminsulfon ... 40mg Nicotinamide ... 0.3mg Calcium Gluconate ... 100mg Magnesium Gluconate ... 10mg Boric Acid ... 10mg Sorbitol ... 200mg Sodium Oxybenzyl Phosphinic Acid ... 5mg Methyl Parahydroxy Benzoate ... 0.7mg As per Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	500ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	GESITONE INJECTION of M/s. Selmore Pharma (Reg. No. 057001)
	Pharmacotherapeutic Group of (API)	

	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	As per letter No. F. 5-1/2019-Lic dated 28th August, 2023, firm has been granted approval of Liquid Injection Section Vet. (General) Liquid Injectable Section Vet (Steroid) Liquid Injectable Penicillin (Vetrinary), firm has applied pack size of 500ml. The said letter suggest that the firm has approval only for SVP. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant section (LVP) through Licensing Division before the approval of applied formulation. Submitted for consideration of Board, please.	
	Decision	
	Deferred Deferred for the clarification of section approval from Licensing Division.	
605	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	(B23-UJ1-Q7J1, 2026-03-03)
	Detail of Fee Submitted	38700, 2026-02-25,
	The proposed proprietary name / brand name	**Tonic Injection**
	Label Claim	Each ml Contain: Etilefrin ... 0.2mg Caffeine ... 10mg Sodium Salicylate ... 7mg Novaminsulfon ... 40mg Nicotinamide ... 0.3mg Calcium Gluconate ... 100mg Magnesium Gluconate ... 10mg Boric Acid ... 10mg Sorbitol ... 200mg Sodium Oxybenzyl Phosphinic Acid ... 5mg Methyl Parahydroxy Benzoate ... 0.7mg As per Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	250ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	GESITONE INJECTION of M/s. Selmore Pharma (Reg. No. 057001)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Not Applicable For verification of manufacturing facility.	
606	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	(AV7-N8U-4Y1P, 2026-03-07)
	Detail of Fee Submitted	38700, 2026-03-05,
	The proposed proprietary name / brand name	**CURE-CRD INJECTION**
	Label Claim	Each ml contains: - Tylosin Tartrate ... 50mg Colistin Sulphate ... 0.20mg Streptomycin Sulphate ... 100mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 YearBelow 25ºC
	For generic drugs (me-too Status)	CONTROL-CRD INJECTION of M/s. Breeze Pharma. (Reg. No. 071050)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
607	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	(7N2-UMY-ASUU, 2026-03-06)
	Detail of Fee Submitted	38700, 2026-03-05,
	The proposed proprietary name / brand name	**ETHATOX POWDER**
	Label Claim	Each Kg Contains: Sodium Benzoate ... 500gm Ethanol Beta Amino Phosphoric Acid ... 100gm Vitamin A ... 10 MIU Vitamin K3 ... 1.0gm Vitamin E ... 2.5gm Vitamin C ... 2.5gm As per Innovator's Specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	De-Controlled-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25ºC
	For generic drugs (me-too Status)	Betatox Powder of M/s. Selmore Pharma (Reg. No. 046660)
	Pharmacotherapeutic Group of (API)	Vitamin and Antioxidant
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfacotry
	Evidence of approval of manufacturing facility	present
	Evaluation Remarks	
	Decision	

	Approved	
608	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	(3W6-PN1-1ZVA, 2026-03-07)
	Detail of Fee Submitted	38700, 2026-03-05,
	The proposed proprietary name / brand name	**CURE-CRD INJECTION**
	Label Claim	Each ml contains: - Tylosin Tartrate ... 50mg Colistin Sulphate ... 0.20mg Streptomycin Sulphate ... 100mg (As per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25ºC
	For generic drugs (me-too Status)	CONTROL-CRD INJECTION of M/s. Breeze Pharma. (Reg. No. 071050)
	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	
609	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	(3EU-MYR-2A47, 2026-03-07)
	Detail of Fee Submitted	38700, 2026-03-05,
	The proposed proprietary name / brand name	**CURE-CRD INJECTION**
	Label Claim	Each ml contains: - Tylosin Tartrate ... 50mg Colistin Sulphate ... 0.20mg Streptomycin Sulphate ... 100mg (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)	CONTROL-CRD INJECTION of M/s. Breeze Pharma. (Reg. No. 071050)
	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	
610	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(1M7-M1B-J3YM, 2026-01-16)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**KETOSON 10% liquid Injection**
	Label Claim	Each ml contains (BP Spec.) Ketoprofen BP 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	KETOJET INJECTION (102085) Breeze Pharma
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
611	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(AYY-77B-9JDG, 2026-01-17)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**MagXin 5% Liquid Injection**
	Label Claim	Each ml contains (USP) Flunixin meglumin USP 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	Harry Mine Liquid INJECTION HAAROLDS PHARMA PVT. LTD.(109029)

	Pharmacotherapeutic Group of (API)	Analgesic, Anti-Inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
612	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	(1EV-M89-PGHQ, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**AEROXSEL SOLUTION**
	Label Claim	Each ml contains: Norfloxacin 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ML-De-Controlled,10L-De-Controlled,25L-De-Controlled,5L-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at room temperature (15-25 °C) Protect from heat, light and Moisture. Store in the original container. Keep all medicines out of the reach of children
	For generic drugs (me-too Status)	NOROXSEL SOLUTION Reg# 044945
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	PASS
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 Litre.	
613	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(RX8-456-5APR, 2026-02-23)
	Detail of Fee Submitted	97200, 2026-02-17,
	The proposed proprietary name / brand name	**Citi Amoxi 80% Water Soluble Powder**
	Label Claim	Each 100 gm contain: Amoxicillin as Trihydrate..... 80 gm BP Specifications
	Reference to Finished product specifications	British Pharmacopeia

	Proposed Pack Size	100gm-De-Controlled, 1Kg-De-Controlled,10Kg-De-Controlled,2.5Kg-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at or below 25°C.
	For generic drugs (me-too Status)	Dokamox 80% Water Soluble Powder For Oral Route by ORIENT ANIMAL HEALTH PVT LTD
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	M/S Oxford Health Care -Plot No. 12 & 13 , Street No. SS-1, RCCI Industrial Estate ,Rawat.-
	GMP status of the firm	GMP is valid till 18-01-2029
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	The applicant firm did not possess approval from the CLB for the manufacture of veterinary products.	
	Decision	
	Deferred According to S.R.O 1347(I)/2021 dated 15 October, 2021, contract manufacturing shall be allowed between human to human and veterinary to veterinary drugs only.	
614	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(5VM-Z71-582W, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	**D-2 OX PLUS SUSPENSION**
	Label Claim	Each 100ml contain: Oxyclozanide ..... 6.25% Oxfendazole ..... 2.265% Cobalt Chloride ..... 0.167% Sodium Selenite ..... 0.05% (As Per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	OXFASHEL PLUS SUSPENSION (063885)
	Pharmacotherapeutic Group of (API)	Anthelmentic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 Litre.	
615	Case Category	Routine (Sabahat Zehra)

	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(9XU-192-U3H7, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	**WOUNDER DRENCH**
	Label Claim	Each 100ml Contains: Ivermectin ..... 0.2G Albendazole ..... 10G Triclabendazole ..... 12G (As Per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,2.5 Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	LEVAMECTIN ORAL LIQUID
	Pharmacotherapeutic Group of (API)	Anthelmentic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 Litre.	
616	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(RE5-N21-JBTD, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	**DM Clozan suspension**
	Label Claim	Each 1000ml contain: Oxyclozanide ..... 34G (As Per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,2.5 Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	ANTI-FLUKE (063661) AVICENNA LABORATERIES
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present

	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 Litre	
617	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(XW6-L9R-VHTP, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	**DO FEN Maars Drench**
	Label Claim	Each 100ml Contains: Oxfendazole ..... 2.265g Cobalt Sulphate ..... 0.382g Selenium ..... 0.035g (As Per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	ORAZOLE SC Drench (029606) Selmore Pharma
	Pharmacotherapeutic Group of (API)	Anthelmentic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 Litre.	
618	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(Z17-QBP-H7YJ, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-21,
	The proposed proprietary name / brand name	**DM ZAN Oral Suspension**
	Label Claim	Each 100ml contain: Oxyclozanide ..... 3.0% Levamisole ..... 1.5% Cobalt Chloride ..... 0.075% Sodium Selenite ..... 0.035% (As Per Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100ml-De-Controlled,2.5Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	NILZACON SUPER SUSPENSIO (075754)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 Litre.	
619	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(BNE-R2U-7D1R, 2026-01-16)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**DM-CIN**
	Label Claim	Each 100gm powder contains (Innovator's Spec.) Neomycin Sulphate (BP)..... 70g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100g-De-Controlled,250g-De-Controlled,25g-De-Controlled,500g-De-Controlled,5kg-De-Controlled,kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	Neomycin- 70% POWDER (075694) ATTABAK PHARMA
	Pharmacotherapeutic Group of (API)	Anti-Bacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg.	
620	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	(55L-BYS-178J, 2025-08-26)
	Detail of Fee Submitted	37000.0, 2025-07-29,
	The proposed proprietary name / brand name	**Malvit -C Oral Powder**
	Label Claim	Each 100gm contains : Paracetamol .....2gm Vitamin C .....20GM Calcium Carbonate .....4.5gm Magnesium Sulphate .....3.5gm Potassium Chloride 4gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg -De-Controlled,2.5kg -De-Controlled,250gm-De-Controlled,500gm -De-Controlled
	Shelf Life (Unit)	2 Year(s)20 -25 *C
	For generic drugs (me-too Status)	Spin -C Powder (078239)
	Pharmacotherapeutic Group of (API)	Analgesic
	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	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1kg.	
621	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	(LQB-BYJ-8B7E, 2025-10-10)
	Detail of Fee Submitted	38700, 2025-09-22,
	The proposed proprietary name / brand name	**CINCOL POWDER**
	Label Claim	Each kg contains : Oxytetracyclin HCL .....300GM, Neomycin Sulphate .....150gm, , Florfenicol.....100gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0km-De-Controlled,100gm-De-Controlled,2.5kg-De-Controlled,250gm-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)30 C
	For generic drugs (me-too Status)	Stenop Powder / Reg : 089846
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Kindly see in inspection report
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	

	Decision	
	Approved Approved up to 1 kg.	
622	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	(LS8-JQ4-J1QG, 2026-03-13)
	Detail of Fee Submitted	38700, 2025-11-18,
	The proposed proprietary name / brand name	**ASVIT Oral Powder**
	Label Claim	Each 100gm Contains : Acetylsalicylic acid .....6.7gm Ascorbic acid (Vit - C) .....20 gm As per innovator Specification 's
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg-De-Controlled,2.5 kg -De-Controlled,250 gm -De-Controlled,500 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)25 C - 30C
	For generic drugs (me-too Status)	ACEVIT -- C ,A & K Pharmaceuticals Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
623	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	(VGJ-8T4-NZ1D, 2025-08-26)
	Detail of Fee Submitted	37000.0, 2025-07-29,
	The proposed proprietary name / brand name	**Noline Oral Liquid (Vet)**
	Label Claim	Each 100ml Contains : Aminophylline .....8gm Guaifenesin.....20gm Norfloxacin.....20gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Liter -De-Controlled,2.5 Liters -De-Controlled,250ml -De-Controlled,5 Liters -De-Controlled,500ml -De-Controlled
	Shelf Life (Unit)	2 Year(s)20 -25 *C
	For generic drugs (me-too Status)	Noramin -G Liquid (044976)

	Pharmacotherapeutic Group of (API)	Antibiotic
	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	
	Decision	
	Approved Approved up to 1 litre.	
624	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	(XQV-H5V-RVSX, 2026-01-12)
	Detail of Fee Submitted	38700, 2025-11-18,
	The proposed proprietary name / brand name	**ANCIN -ST Oral Suspension**
	Label Claim	Each 100 ml contains : Enrofloxacin .....7500 , Sulphamethoxy Pyridazine .....7500, Sulphamethazine.....5000mg , Trimethoprim 2500mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 liter-De-Controlled,2.5 liter-De-Controlled,250ml -De-Controlled,5 Liter-De-Controlled,500ml -De-Controlled
	Shelf Life (Unit)	2 Year(s)25C to 30C
	For generic drugs (me-too Status)	Cinafas Oral Suspension / Intervac(Pvt)Ltd Lahore
	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	
	The applied formulation contains four antibiotics, under review of sub-committee on veterinary drugs.	
	Decision	
	Deferred For submission of valid international references in support of their product, if available.	
625	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**FORZA ROMA PHARMACEUTICAL PVT LTD** PLOT NO 330, PHASE 2 INDUSTRIAL CITY FIEDMC CHAK JHUMRA, FAISALABAD **(001020)**

	Application Form Dy. No / Tracking ID & date of submission	(GPP-8JP-ZPN1, 2026-03-04)
	Detail of Fee Submitted	38700, 2026-03-04,
	The proposed proprietary name / brand name	**VERGINA F.R.**
	Label Claim	Each gram contains Virginiamycin 12 mg, Choline Chloride 100 mg, DL Methionine 50 mg, L-Lysine 25 mg, Vitamin D3 2 mg, Vitamin E 9 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 kg HDPE JAR-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30 degree
	For generic drugs (me-too Status)	ACME PHARMACEUTICAL RAWAT
	Pharmacotherapeutic Group of (API)	Growth Promotor
	Name, address of Manufacturing site:	--
	GMP status of the firm	NEW GRANTED LICENCE
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
626	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(GUA-WT1-D1EG, 2026-01-17)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**MagXin 5% Liquid Injection**
	Label Claim	Each ml contains (USP) Flunixin meglumin USP 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	Harry Mine Liquid INJECTION (109028) HAAROLDS PHARMA PVT. LTD.
	Pharmacotherapeutic Group of (API)	Analgesic, Anti-Inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

627	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(MD6-PRA-W1YX, 2026-01-17)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**MagXin 5% Liquid Injection**
	Label Claim	Each ml contains (USP) Flunixin meglumin USP 50mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	Harry Mine Liquid INJECTION HAAROLDS PHARMA PVT. LTD.HAAROLDS PHARMA PVT. LTD.(1 09027)
	Pharmacotherapeutic Group of (API)	Analgesic, Anti-Inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	present
	Evaluation Remarks	
	Decision	
	Approved	
628	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(ANY-5LA-NTJ7, 2026-01-16)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**KETOSON 10% liquid Injection**
	Label Claim	Each ml contains (BP Spec.) Ketoprofen BP..... 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	KETOJET INJECTION (102085)
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	

	Approved	
629	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**DMAARSON PHARMACTUICALS** PLOT 17, SS-2 RCCI NATIONAL INDUSTRIAL ZONE RAWAT ISLAMABAD **(000744)**
	Application Form Dy. No / Tracking ID & date of submission	(VL4-41Y-W4DR, 2026-01-16)
	Detail of Fee Submitted	38700, 2026-01-13,
	The proposed proprietary name / brand name	**KETOSON 10% liquid Injection**
	Label Claim	Each ml contains (BP Spec.) Ketoprofen BP 100mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 30c°
	For generic drugs (me-too Status)	KETOJET INJECTION (102085) Breeze Pharma
	Pharmacotherapeutic Group of (API)	NSAID
	Name, address of Manufacturing site:	--
	GMP status of the firm	Panel Issue the GMP certificate and suggest for further Production
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
630	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	(1WL-1P5-W9G2, 2025-10-11)
	Detail of Fee Submitted	38700, 2025-09-30,
	The proposed proprietary name / brand name	**Augmaxtin Water soluble Powder**
	Label Claim	Each 100gm. contains Amoxicillin Trihydrate 20gm eq. to Amoxicillin Base (B.P) .....17.392 gm Colistin Sulphate(B.P) .....4gm Clavulanic acid(B.P) ..... 4gm (As Per Innovator’s Spec)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 KG-De-Controlled,10 KG-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,2.5 KG-De-Controlled,20gm-De-Controlled,25 KG-De-Controlled,250gm-De-Controlled,5 KG-De-Controlled,500gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from

		direct sun light and heat.
	For generic drugs (me-too Status)	Moxilav-C Powder (Reg. No 082791) 12. Name of company manufacturing in Pakistan. Leads Pharma (Pvt) Ltd. Islamabad
	Pharmacotherapeutic Group of (API)	PENICILLIN 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	
631	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	(3DT-1SJ-P9XN, 2025-12-31)
	Detail of Fee Submitted	38700, 2025-10-14,
	The proposed proprietary name / brand name	**WormNil Super Oral Suspension**
	Label Claim	Each 100ml. contains • Oxyclozanide .....3.0gm • Levamisole HCl..... 1.5gm • Cobalt Sulphate ... .0.380gm • Sodium Selenite.....0.035gm
	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,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store at cool and dry place. • Store at room temperature (25□C - 30□C) • Protect from direct sun light and heat.
	For generic drugs (me-too Status)	Levacol Plus Oral Suspension (Reg. # 048262)
	Pharmacotherapeutic Group of (API)	ANTHELMENTIC/ MINERALS
	Name, address of Manufacturing site:	--
	GMP status of the firm	Inspection was conducted on 23rd of December 2025 (Report copy Attached) Remarks of the Panels are as follows:- Based on the documentation reveiwed, technical/management people met, material/processes flow and detailed inspection of the stores, section
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	

	Approved Approved upto 1 Litre.	
632	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	(3UD-QG9-BZVS, 2025-10-11)
	Detail of Fee Submitted	38700, 2025-09-30,
	The proposed proprietary name / brand name	**Benzo Flush Powder**
	Label Claim	Each 1000gm. contains:- Sodium Benzoate.....500gm Ethanol Beta Amino phosphoric Acid..... 100gm Vitamin A.....10MIU Vitamin E.....2.5gm Vitamin K3.....01gm Vitamin C.....2.5gm (Manufacturer's Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10 KG-De-Controlled,1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,20gm-De-Controlled,25 KG-De-Controlled,5 KG-De-Controlled,500gm-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)	BETATOX Powder (Reg. No. 046660) company manufacturing in Pakistan. Selmore Pharmaceuticals (Pvt.) Ltd.
	Pharmacotherapeutic Group of (API)	Hepato-renal tonic
	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	
633	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	(P6R-A7D-SADZ, 2025-10-11)
	Detail of Fee Submitted	38700, 2025-09-30,
	The proposed proprietary name / brand name	**Aspergonil / Brootin /Broodinox Oral Solution**

	Label Claim	Each 100ml contains: Nystatin..... 10 MIU (As Per Manufacturer's Specs)
	Reference to Finished product specifications	United States Pharmacopeia
	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)	NYSTATIN BP AQUEOUS SOLUTION (Reg. # 058894) Attabak Pharmaceutical Industries Islamabad
	Pharmacotherapeutic Group of (API)	Antifungal
	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	
	For change of specs applicant have submitted pre registration variation fee.	
	Decision	
	Approved Approved up to 1 Litre.	
634	Case Category	Routine (Sabahat Zehra)
	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	(1EZ-RTD-AMBP, 2026-01-26)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**O-Scour Liquid**
	Label Claim	Each ml Contains: Sulphadimidine ..... 35mg Sulphadiazine ..... 36mg Streptomycin Sulphate ..... 7.6mg Neomycin Sulphate ..... 1.8mg Sodium Chloride ..... 11.33mg Calcium Gluconate ..... 2.2mg Magnesium Sulphate ..... 0.6mg Potassium Chloride ..... 3.6mg Kaolin ..... 103.33mg Pectin ..... 7.1mg Glycine 20.9mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 ml-De-Controlled,100ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	N0-Scour Oral Suspension

	Pharmacotherapeutic Group of (API)	Antibacterial
	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	Present
	Evaluation Remarks	
	The applied formulation contains four antibiotics, under review of sub-committee on veterinary drugs.	
	Decision	
	Deferred For submission of valid international references in support of their product, if available.	
635	Case Category	Routine (Sabahat Zehra)
	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	(3QX-92B-GJZS, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**G-Diges Powder**
	Label Claim	Each 1kg Contains: propianic Acid Calcium USP.....250gm Propianic Acid Sodium USP.....400gm Acetanilide USP.....150gm Magnesium Oxide USP.....125gm Iron Sulphate USP.....400mg Zinc Sulphate USP.....100mg Magnesium Sulphate USP...200mg Copper Sulphate USP.....450mg Cobalt Sulphate USP.....400mg Sodium Molybdate USP.....100mg Sodium Chloride USP..... 20gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-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)	Alvegest Powder
	Pharmacotherapeutic Group of (API)	Nutritional Supplement
	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	PRESENT
	Evaluation Remarks	
	Decision	

	Approved	
636	Case Category	Routine (Sabahat Zehra)
	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	(49S-G7N-GEWM, 2026-01-26)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**Zero Scour Liquid**
	Label Claim	Each ml Contains: Sulphadiazine USP.....35.500mg Sulphadimidine USP .....28.400mg Neomycin Sulphate USP.....1.800mg Hyoscine N-butylbromide USP.....0.040mg Pectin USP.....7.100mg Kaolin USP.....103.300mg Vitamin B1 USP.....0.150mg Vitamin B2 USP.....0.220mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 ml-De-Controlled,100ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Scour-X Oral Suspension
	Pharmacotherapeutic Group of (API)	Antibiotics
	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	Present
	Evaluation Remarks	
	Decision	
	Approved	
637	Case Category	Routine (Sabahat Zehra)
	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	(5ZN-GMY-2R43, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**Aldazole Powder**

	Label Claim	each gram Contains Albendazole.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,10 Gm-De-Controlled,100 Gm-De-Controlled,5 gm-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Zoben 20 Granules
	Pharmacotherapeutic Group of (API)	Anthelmintic
	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	Present
	Evaluation Remarks	
	Decision	
	Approved	
638	Case Category	Routine (Sabahat Zehra)
	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	(6XS-HV1-EJYU, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**Ectonil Powder**
	Label Claim	Each Gram contains Trichlorfon..... 960mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Gm-De-Controlled,100 Gm-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)	Ectofon water soluble Powder
	Pharmacotherapeutic Group of (API)	Anthelmintic
	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	Present
	Evaluation Remarks	
	Decision	

	Approved	
639	Case Category	Routine (Sabahat Zehra)
	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	(B1X-HVT-LNZJ, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**G-Diarrho Powder**
	Label Claim	Each 12gram Contains: Neomycin Sulphate.....400mg Streptomycin Sulphate.....400mg Sulphaguanidine.....4gm Kaolin.....4gm Pectin.....400mg Bismuth Subnitrate.....2gm Vitamin A Acetate.....80000 IU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,100 Gm-De-Controlled,12 Gm-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)	Diarroban Powder
	Pharmacotherapeutic Group of (API)	
	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	Present
	Evaluation Remarks	
	Decision	
	Approved	
640	Case Category	Routine (Sabahat Zehra)
	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	(Y9A-74P-S32Q, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**G-Gold Powder**
	Label Claim	Each 1kg Contains: Vitamin A (USP) ... 0.8 gm Vitamin D3 (USP) ... 0.16 gm Vitamin E (USP) ...

		0.38 gm Vitamin B1 (USP) ... 1.0 gm Vitamin B2(USP) ... 1.25 gm Vitamin B12 (USP) ... 0.001 gm Vitamin B3 (USP) ... 6.25 gm Vitamin B6 (USP) ... 4.0gm Copper Sulphate (USP) ... 0.25 gm Magnesium Sulphate (USP).....25gm Calcium Chloride (USP) ... 0.023 gm Zinc Sulphate (USP) ... 2.17 gm Manganese Sulphate(USP) ... 10 gm Potassium iodide (USP) ... 0.50 gm Sodium Selenite (USP) ... 0.01 gm DCP (Phosphorous) (USP) ... 150 gm Sodium Chloride (USP) ... 120 gm
	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 below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Vetz-Vita Oral Powder
	Pharmacotherapeutic Group of (API)	Nutritional Supplement
	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	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
641	Case Category	Routine (Sabahat Zehra)
	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	(SYJ-3NA-14J6, 2026-01-24)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**G-Trichlo Oral Powder**
	Label Claim	Each Gram Contains: Trichlorfon 980mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Gm-De-Controlled,100 Gm-De-Controlled,500 Gm-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	TrichloVetz 98%
	Pharmacotherapeutic Group of (API)	
	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	
	Decision	
	Approved	
642	Case Category	Routine (Sabahat Zehra)
	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	(JYE-XZB-5VJ2, 2026-01-26)
	Detail of Fee Submitted	38700, 2026-01-16,
	The proposed proprietary name / brand name	**G-Delta Liquid**
	Label Claim	Each ml Contains: Deltamethrin BP.....25mg
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	10 ml-De-Controlled,100ml-De-Controlled,20 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from light & moisture.
	For generic drugs (me-too Status)	Delta-25 Solution
	Pharmacotherapeutic Group of (API)	Synthetic pyrethroids
	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	
	Deltamethrin is a synthetic pyrethroid intended for topical veterinary formulations. However, the firm's manufacturing authorization is limited to the following sections: (i) Veterinary Oral Powder (General) (ii) Veterinary Oral Liquid (General) The firm does not have a dedicated topical manufacturing section for products containing deltamethrin.	
	Decision	
	Rejected Because requisite facilities for the manufacture of the topical formulation are not available.	
643	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Grand Pharma Pvt Ltd** Plot no 5-A , Street No N-5 , National Industrial Zone Rawat Islamabad **(000680)**
	Application Form Dy. No / Tracking ID & date of submission	(RMV-NZU-E2LL, 2025-08-20)

	Detail of Fee Submitted	38700.0, 2025-08-07,
	The proposed proprietary name / brand name	**Oxy Fm injection 100ml**
	Label Claim	Each ml. contains Oxytetracycline dihydrate ..... 300mg. Flunixine Meglumin.....20 mg. (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)15oC - 25oC
	For generic drugs (me-too Status)	Foxyvet injection Reg # 122158
	Pharmacotherapeutic Group of (API)	Antibiotic, Anti Inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the above stated facts, the Panel unanimously agreed to recommend renewal of DML No.000680 (Formulation} for further period of five years as per under mentioned sections In the light of Tracking ID TN9-LVX-GDZI dated 16th May 2025 by Direc
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
644	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Grand Pharma Pvt Ltd** Plot no 5-A , Street No N-5 , National Industrial Zone Rawat Islamabad **(000680)**
	Application Form Dy. No / Tracking ID & date of submission	(TZY-65R-N4W1, 2025-08-30)
	Detail of Fee Submitted	38700.0, 2025-08-30,
	The proposed proprietary name / brand name	**Melo Grand 10 Injection**
	Label Claim	Each ml. contains: - Meloxicam ..... 10mg.
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)15oC - 25oC
	For generic drugs (me-too Status)	Mcloxibar-10 Injection (Reg.# 087109)
	Pharmacotherapeutic Group of (API)	Analgesics Nonstcroidal Pain Killers Anti-inflammatory
	Name, address of Manufacturing site:	--
	GMP status of the firm	Keeping in view the above stated facts, the Panel unanimously agreed to recommend renewal of DML No.000680 (Formulation} for further period of five years as per under mentioned sections In the light of Tracking ID TN9-LVX-GDZI dated 16th May 2025 by Direc
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	

	Approved	
645	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**GHAZALI BROTHERS** 1ST FLOOR AZZAINAB COURT CAMPBELL STREET **(629)**
	Application Form Dy. No / Tracking ID & date of submission	(SLQ-DHQ-QL4M, 2026-03-14)
	Detail of Fee Submitted	313500, 2026-01-16,
	The proposed proprietary name / brand name	**OXYTET-VET 5% INJECTION 50ML**
	Label Claim	EACH ML CONTAINS: OXYTETRACYCLINE....50MG
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	1 VIAL (50ML) / BOX-De-Controlled
	Shelf Life (Unit)	3 Year(s)STORE BELOW 30C. PROTECT FROM LIGHT
	For generic drugs (me-too Status)	OXYTETRACYCLINE INJECTION
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	HEBEI LIHUA PHARMACEUTICAL CO., LTD-NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, CHINA-China
	Name, address of Marketing Authorization Holder:	HEBEI LIHUA PHARMACEUTICAL CO., LTD, NO.3, XINGHUA STREET, ECONOMIC DEVELOPMENT ZONE, XINLE CITY, HEBEI PROVINCE, CHINA, China
	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 Approved subject to submission of the original legalized CoPP/GMP and FSC, and in accordance with the current import policy.	
646	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, **(000449)**
	Application Form Dy. No / Tracking ID & date of submission	(TSP-3Q7-JSLX, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**HIRRA CTC PLUS WATER SOLUBLE POWDER**
	Label Claim	Each KG contains: CHLORTETRACYCLINE HCL.....250GM

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 kg-De-Controlled,100 gm-De-Controlled,2.5 KG-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)	HICHLOR-250 WATER SOLUBLE POWDER, M/S SUAVE PHARMACEUTICAL(PVT)LTD Suave,2-C VALUE ADDITION CITY, INDUSTRIAL ESTATE
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	This certificate is valid for 2 years from the date of inspection. Responsibilities to maintain quality of Good manufacturing standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drug act 1976 and the r
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1kg pack size.	
647	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, **(000449)**
	Application Form Dy. No / Tracking ID & date of submission	(AEH-4UL-8T6P, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**HIRRA ULTRA-ZOLE 3 DRENCH**
	Label Claim	Each 100 mL contains: Triclabendazole----------12gm Ivermectin----------0.2 gm Albendazole----------10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 Litre-De-Controlled,100ml-De-Controlled,2.5 Litre-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 degree
	For generic drugs (me-too Status)	THUNDER DRENCH, M/S Star Laboratories (Pvt) Ltd
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	This certificate is valid for 2 years from the date of inspection. Responsibilities to maintain quality of Good manufacturing standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drug act 1976 and the r
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved Approved upto 1 litre pack size.	
648	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, **(000449)**
	Application Form Dy. No / Tracking ID & date of submission	(99G-GBA-DT8U, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**HIRRA VETAL ORAL POWDER**
	Label Claim	EACH 100GM CONTAINS PARACETAMOL----------20gm VITAMIN-C----------05gm POTASSIUM CARBONATE---12.5gm SODIUM BICARBONATE-----12.5gm VITAMIN-E----------1.25gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 KG-De-Controlled,100 gm-De-Controlled,2.5 KG-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)	PARA-CE ORAL POWDER, M/S BIOGEN PHARMA
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	This certificate is valid for 2 years from the date of inspection. Responsibilities to maintain quality of Good manufacturing standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drug act 1976 and the r
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
649	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, **(000449)**
	Application Form Dy. No / Tracking ID & date of submission	(2M7-W7S-29GY, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**HIRRA FOSFO GOLD ORAL POWDER**
	Label Claim	EACH KG CONTAINS Fosfomycin Calcium----------200g Tylosin Tartrate----------100g Fructose----------180g

		Sodium Phosphate----------150g Magnesium Sulphate---------- 100g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 KG-De-Controlled,100 gm-De-Controlled,2.5 KG-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)	FOSFO-20 ORAL Powder, M/S Evergreen Pharmaceuticals (Pvt) Ltd. 69-70/B, Main Glaxo Town Industrial Estate, 20 km Ferozpur Road, Lahore
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	This certificate is valid for 2 years from the date of inspection. Responsibilities to maintain quality of Good manufacturing standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drug act 1976 and the r
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1kg pack size.	
650	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, **(000449)**
	Application Form Dy. No / Tracking ID & date of submission	(8YS-RUZ-HBBX, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**HIRRA FENRA PLUS ORAL DRENCH**
	Label Claim	Each ml contain FENBENDAZOLE---------- -10mg RAFOXANIDE----------10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0Litre-De-Controlled,100 ml-De-Controlled,2.5Litre-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 degree
	For generic drugs (me-too Status)	Curafluke 10% Oral drench, M/S Univet Pharmaceuticals Pakistan 14 KM, Adyala Road, P.O Dahgal, Rawalpindi-Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	This certificate is valid for 2 years from the date of inspection. Responsibilities to maintain quality of Good manufacturing standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drug act 1976 and the r
	Evidence of approval of manufacturing facility	

	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 litre pack size.	
651	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, **(000449)**
	Application Form Dy. No / Tracking ID & date of submission	(6DT-NPU-31RH, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**HIRRA ENDOKILL SUSPENSION**
	Label Claim	Each ml contain Oxfendazole---------- -22.65mg Triclabendazole----------85mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 Litre-De-Controlled,100ml-De-Controlled,2.5 Litre-De-Controlled,250ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Below 25 degree
	For generic drugs (me-too Status)	VORCID SUSPENSION, M/S Lucky Core Industries Limited Head Office - 5 West Wharf, Karachi 74000, Pakistan
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	This certificate is valid for 2 years from the date of inspection. Responsibilities to maintain quality of Good manufacturing standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drug act 1976 and the r
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 litre pack size.	
652	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Hirra Pharmaceutical Laboratories (Pvt) Ltd** 3A, 2nd floor, Queen's Center, Queen's Road, **(000449)**
	Application Form Dy. No / Tracking ID & date of submission	(WE9-WB8-4W9U, 2026-02-09)
	Detail of Fee Submitted	38700, 2026-02-04,
	The proposed proprietary name / brand name	**HIRRA AMOXISOL 50 POWDER**
	Label Claim	Each gram Contains: Amoxicillin as Trihydrate...500mg
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	1.0 kg-De-Controlled,100 gm-De-Controlled,2.5 kg-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)	AMOVET 50% POWDER (AMOXICILLIN), Nawan Laboratories, Plot No.136-138,sector-15,korangi Industrial Area Karachi
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	This certificate is valid for 2 years from the date of inspection. Responsibilities to maintain quality of Good manufacturing standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drug act 1976 and the r
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
653	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	(45E-QBP-1A8S, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-03-11,
	The proposed proprietary name / brand name	**Benamine 100 Injection**
	Label Claim	Each ml contains: Flunixin as 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°C in a cool and dry place. Protect form light
	For generic drugs (me-too Status)	Product Name:: Tricure Injection Registration No: 109893, By: Lucky Core Industries Limited Company Address: 45-Km, Off Multan Road, Lahore
	Pharmacotherapeutic Group of (API)	NSAIDs
	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	

654	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	(UXS-3ZH-MRGE, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-03-11,
	The proposed proprietary name / brand name	**Oxy Shell 10% Injection**
	Label Claim	Each ml contains: Oxytetracycline as HCl .....100mg (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°C in a cool and dry place. Protect form light
	For generic drugs (me-too Status)	Product Name:: Rasomycin-10 injection Registration No: 003792, by: Star Laboratories Pvt. Ltd. Company Address: 45-Km, Off Multan Road, Lahore
	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	
655	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	(WA6-YXM-8W78, 2026-03-13)
	Detail of Fee Submitted	38700, 2026-03-11,
	The proposed proprietary name / brand name	**AED Vet 50 Injection**
	Label Claim	Each ml contains: Vitamin A.....100000 IU Vitamin E.....40mg Vitamin D3.....40000 IU (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 25°C in a cool and dry place. Protect form light
	For generic drugs (me-too Status)	Product Name:: ADE-FAR Injection Registration No: 074746 By: Izfaar Pharmaceuticals Pvt Ltd.

		Company Address: 542 A&B Sundar Industrial Estate, Lahore.
	Pharmacotherapeutic Group of (API)	Multivitamin
	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	
656	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	(SME-148-B5M8, 2026-01-23)
	Detail of Fee Submitted	38700, 2026-01-14,
	The proposed proprietary name / brand name	**Calsi-Fos Powder**
	Label Claim	Each 100 gram contains: Fosfomycin Calcium .....20gm Tylosin as Tartrate .....10gm Fructose .....18gm Sodium Phosphate.....15gm Magnesium Sulphate.....10gm (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)	Product Name:: Fosfotyl Powder Registration No: 078240, by: Leads Pharma (Pvt) Ltd. Plot#81-A, Street#6, I-10/3, Industrial Area, Islamabad
	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	

	Approved upto 1 kg pack size.	
657	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(A6L-DUV-V7Q2, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**ENROFAS-BC LIQUID**
	Label Claim	Each 100ml Contains: Enrofloxacine (BP Vet) 10gm. Colistin Sulphate (BP) 5MIU. Bromhexine (BP) ..0.50%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	ENROCOLI LIQUID (Reg No. 059167) Symans Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 litre pack size	
658	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(DVM-L4G-5LY8, 2025-10-10)
	Detail of Fee Submitted	38700, 2025-10-09,
	The proposed proprietary name / brand name	**NORSOL-C LIQUID**
	Label Claim	Each 100ml Contains: Norfloxacin (BP Vet) ..... 20gm Colistin Sulphate (BP) .....60 MIU.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled

	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	Coli-Nor Liquid (Reg no. 049501) Leads Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 litre pack size.	
659	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(H81-EHD-UQB8, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**LEVAFAS-500 WATER SOLUBLE POWDER**
	Label Claim	Each 1000gm Contains: Levamisole HCI 500.00 gm.
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10Kg-De-Controlled,200gm-De-Controlled,250gm-De-Controlled,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	LEVAZOC-50 WSP (Reg No. 090661) Zoic International Pharma
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

	Approved upto 1 kg pack size.	
660	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(NSD-EPM-3LB7, 2026-02-13)
	Detail of Fee Submitted	38700, 2026-02-13,
	The proposed proprietary name / brand name	**VIROFAS-TD POWDER**
	Label Claim	Each 1000gm Contains: Doxycycline HCI (M.S) 200gm Tylosin Tartrate (B.P) 100gm Amantadine HCI 40gm Colistin Sulphate 500MIU Bromhexine HCI 5gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000gm-De-Controlled,100gm-De-Controlled,10gm-De-Controlled,2.5Kg-De-Controlled,20gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Do not store above 30° C. Protect from direct sunlight
	For generic drugs (me-too Status)	VIROX-TD POWDER (Reg no. 075777) Leads Pharma Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	The formulation contains amantadine as an active ingredient in combination with other antimicrobial agents and is intended for use in poultry species.	
	Decision	
	Rejected 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.	
661	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(YD2-5SY-3E5D, 2025-10-08)
	Detail of Fee Submitted	38700, 2025-10-06,
	The proposed proprietary name / brand name	**AMCLAVE-B ORAL POWDER**
	Label Claim	Each 100gm Contains: Amoxicillin as Trihydrate..... 16 gm. Clavulanic Acid as Potassium Clavulanate 4 gm. Bromhexine Hydrochloride. 0.5gm

	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100gm-De-Controlled,10gm-De-Controlled,1Kg-De-Controlled,2.5Kg-De-Controlled,200gm-De-Controlled,250gm-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	Grand ABC Water Soluble Powder (Reg no. 113502) Grand Pharma Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
662	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(1QW-9R2-S42E, 2025-09-23)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Novomin Water Soluble Powder**
	Label Claim	Each Kg contains : Amoxicillin as trihydrate..... 100g Colistin sulphate ..... 50g Neomycin Sulphate 200g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100g-De-Controlled,2.5 Kg-De-Controlled,250g-De-Controlled,5 Kg-De-Controlled,500g-De-Controlled,50g-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C
	For generic drugs (me-too Status)	NEO AC Water Soluble Powder by Decent Pharma Islamabad
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

	Approved upto 1kg pack size.	
663	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(DX2-1JE-ZBLS, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**INTERMOX-G FORTE INJECTION 100ML**
	Label Claim	Each ml Contains: Amoxicillin Trihydrate (BP) 150 mg Gentamicin Sulphate eq. to Gentamicin (BP)..... 40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	AMOXYGENT FORTE INJECTION 100ML (Reg No. 097946) Slemore Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
664	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(57N-NE5-9MVQ, 2025-12-19)
	Detail of Fee Submitted	38700, 2025-12-19,
	The proposed proprietary name / brand name	**KETOFAS INJECTION**
	Label Claim	Each ml Contains: KETOPROFEN (BP).. .100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) 30 degree centigrade
	For generic drugs (me-too Status)	Vetpro 100 Injection Reg no. 093605 Bio-Labs(Pvt) Ltd
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated

		for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
665	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(PQY-MQ1-RZUZ, 2025-11-11)
	Detail of Fee Submitted	38700, 2025-11-11,
	The proposed proprietary name / brand name	**INTERMOX-G FORTE INJECTION 50ML**
	Label Claim	Each ml Contains: Amoxicillin Trihydrate (BP) 150 mg Gentamicin Sulphate eq. to Gentamicin (BP)..... 40 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	AMOXYGENT FORTE INJECTION 50ML (Reg No. 097945) Slemore Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
666	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(NR6-5UX-YEXN, 2025-11-12)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**FLUXIFAS-L INJECTION**

	Label Claim	Each ml Contains: FLUNIXIN AS MEGLUMINE (USP).....50mg LIDOCAINE HCI. 10mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	MEGAFLUX INJECTION (Reg No. 063794) ETERNA PHARMA PVT. LTD.
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
667	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(9EX-TJ8-TET9, 2025-09-23)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Iskocas Oral Powder**
	Label Claim	Each 100g contains : Acetylsalicylic acid ..... 20g Ascorbic Acid ..... 20g Vitamin K3 ..... 2.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100g-De-Controlled,2.5 Kg-De-Controlled,250g-De-Controlled,5 Kg-De-Controlled,500g-De-Controlled,50g-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C
	For generic drugs (me-too Status)	Intervit C Oral Powder by International Pharma Lahore
	Pharmacotherapeutic Group of (API)	Analgesic, Antioxidant, Provitamin
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	

	Approved upto 1kg pack size.	
668	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(HDE-GTP-LVGL, 2025-09-23)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Isfotyl Powder**
	Label Claim	Each 100g contains : Fosfomycin calcium ..... 20g Tylosin tartrate ..... 10g Fructose ..... 18g Sodium Phosphate ..... 15g Magnesium Sulphate 10g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100g-De-Controlled,2.5 Kg-De-Controlled,250g-De-Controlled,5 Kg-De-Controlled,500g-De-Controlled,50g-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C
	For generic drugs (me-too Status)	Fosfotyl Oral Powder by Leads Pharma Lahore
	Pharmacotherapeutic Group of (API)	Antibacterial/Electrolytes
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
669	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(M8J-ESX-TR12, 2025-09-23)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Kanacet Water Soluble Powder**
	Label Claim	Each 100g contains : Paracetamol ..... 20g Vitamin C ..... 5g Potassium Carbonate ..... 12.5g Sodium Bicarbonate ..... 12.5g Vitamin E 12.5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100g-De-Controlled,2.5 Kg-De-Controlled,250g-De-Controlled,5 Kg-De-Controlled,500g-De-Controlled,50g-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C

	For generic drugs (me-too Status)	Cemol Oral Powder by Selmore Pharmaceuticals Lahore
	Pharmacotherapeutic Group of (API)	Pain, fever, and inflammation
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
670	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(UTH-TL1-V9MQ, 2025-09-22)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Ischlocin Water Soluble Powder**
	Label Claim	Each 1000g contains : Neomycin Sulphate ..... 70g Colistin sulphate ..... 4g Chlortetracycline HCl ..... 80g Bromhexine 5g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 Kg-De-Controlled,10 kg-De-Controlled,100g-De-Controlled,2.5 Kg-De-Controlled,250g-De-Controlled,5 Kg-De-Controlled,500g-De-Controlled,50g-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C
	For generic drugs (me-too Status)	Z-CNC Plus Water Soluble Powder by Zoic International Lahore
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
671	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(WY9-ZJL-JB48, 2025-09-23)
	Detail of Fee Submitted	38700, 2025-09-15,

	The proposed proprietary name / brand name	**Neomycin 70% Powder**
	Label Claim	Each 100g contains : Neomycin Sulphate 70g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1 Kg-De-Controlled,10 Kg-De-Controlled,100g-De-Controlled,2.5 Kg-De-Controlled,250g-De-Controlled,5 Kg-De-Controlled,500g-De-Controlled,50g-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C
	For generic drugs (me-too Status)	Neomycin 70% Powder by Attabak Pharmaceuticals Islamabad
	Pharmacotherapeutic Group of (API)	Aminoglycosides
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
672	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(HN5-GSD-NP7W, 2025-09-23)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Isflostin oral Liquid**
	Label Claim	Each 1000ml contains : Florfenicol ..... 230gm Colistin Sulphate ..... 500 MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Litre -De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,25 Litre -De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5 Litre -De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C
	For generic drugs (me-too Status)	SAFLOR-Plus by Sanna Laboratories Faisalabad
	Pharmacotherapeutic Group of (API)	Antimicrobial drug
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre.	

673	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**ISIS Pharmaceuticals & Chemical Works** 25/1-3, Sector 12-C, North Karachi Industrial Area **(000126)**
	Application Form Dy. No / Tracking ID & date of submission	(WEJ-PYL-XZ7H, 2025-09-22)
	Detail of Fee Submitted	38700, 2025-09-15,
	The proposed proprietary name / brand name	**Enrocin oral Liquid**
	Label Claim	Each 100ml contains : Enrofloxacin ..... 10gm Aminophylline ..... 4gm Guaiphenesin 10gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10 Litre-De-Controlled,1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,25 Litre -De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5 Litre-De-Controlled,500ml-De-Controlled,50ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 30 C
	For generic drugs (me-too Status)	Bromogel Oral Solution by Evergreen Pharmaceuticals Lahore
	Pharmacotherapeutic Group of (API)	Fluoroquinolone
	Name, address of Manufacturing site:	--
	GMP status of the firm	Good
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
674	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	(E37-S78-NU8G, 2025-12-01)
	Detail of Fee Submitted	38700, 9400 2025-11-24, 2026-07-06
	The proposed proprietary name / brand name	**Lectibol**
	Label Claim	Each 100ml contains: Cyanocobalamin (Vitamin B12) ..... 50mg Sodium Selenite..... 100mg Adenosin Triphosphate Tetra Sodium Dihydrate Salt..... 100mg Potassium Aspartate Semi Hydrate.....1mg Magnesium Aspartate Tetra Hydrate.....1.5mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)25-30 C

	For generic drugs (me-too Status)	Actibol injection, 117323, Selmore Pharmaceutical (PVT) Ltd.
	Pharmacotherapeutic Group of (API)	Vitamins & 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	
675	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	(RHH-78Y-73EN, 2025-12-01)
	Detail of Fee Submitted	38700, 9400 2025-11-24, 2026-07-06
	The proposed proprietary name / brand name	**Le Butin**
	Label Claim	Each ml contains: Butaphosphan..... 100mg Cyanocobalamin ..... 50mg Taurine..... 37.3mg Nicotinamide..... 23mg DL Methionine.....1mg
	Reference to Finished product specifications	Manufacturer Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)25-30 C
	For generic drugs (me-too Status)	Brutin injection, 101480, Star Laboratories (PVT) Ltd. Lahore
	Pharmacotherapeutic Group of (API)	Vitamins & amino acids
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Applicant has submitted pre registration variation fee.	
	Decision	
	Approved	
676	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	(LG7-4Q5-MRJ1, 2025-12-01)
	Detail of Fee Submitted	38700, 9400 2025-11-20, 2026-07-06
	The proposed proprietary name / brand name	**Ledovit-3**
	Label Claim	Each 3ml contains: Thiamine HCl (Vitamin B1).....100mg Pyridoxine HCl (Vitamin

		B6).....100mg Cyanocobalamin (Vitamin B12)....500mcg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)25-30 C
	For generic drugs (me-too Status)	Neurofos injection, Reg# 063582, Zakfas Pharmaceutical (PVT) Ltd.
	Pharmacotherapeutic Group of (API)	Vitamins & 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	
677	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	(V6R-ST1-9PR6, 2025-12-01)
	Detail of Fee Submitted	38700, 9400 2025-11-20, 2026-07-06
	The proposed proprietary name / brand name	**Ledorin**
	Label Claim	Each Kg contains: Sodium Benzoate.....500gm Ethanol Beta Amino Phosphoric Acid.....100gm Vitamin A..... 10,000,000IU Vitamin E.....2500mg Vitamin K3.....1000mg Vitamin C.....2500mg
	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,25Kg-De-Controlled,500gm-De-Controlled,5Kg-De-Controlled
	Shelf Life (Unit)	24 Year(s)25-30 C
	For generic drugs (me-too Status)	Diurizone powder, 073908, Mylab Pharmaceuticals (PVT) Ltd.
	Pharmacotherapeutic Group of (API)	Vitamins & 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 Approved upto 1 kg pack size.	

678	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	(5SL-R4T-WL1H, 2025-09-24)
	Detail of Fee Submitted	38700, 2025-09-23,
	The proposed proprietary name / brand name	**Strep Strep**
	Label Claim	Each ml contains: ocaine Penicillin G.....2, 00,000 IU Streptomycin Sulphate.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	30ml-De-Controlled
	Shelf Life (Unit)	24 Year(s)25-30 C
	For generic drugs (me-too Status)	Di strep injection, Reg# 112335, Eterna Pharmaceutical (PVT) Ltd.
	Pharmacotherapeutic Group of (API)	Antibiotic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML Renewal
	Evidence of approval of manufacturing facility	presenr
	Evaluation Remarks	
	Decision	
	Approved	
679	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**NeoTech Pharmaceuticals Pvt Ltd** 28-km Gujranwala to Lahore chak hinda kamoke ,Gujranwala **(000929)**
	Application Form Dy. No / Tracking ID & date of submission	(ER6-Q2A-BTZA, 2026-03-03)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**Enro NAC Oral Solution**
	Label Claim	Each ml contains: Enrofloxacin.....100mg N-Acetyl L-Cysteine ..186mg Benzyl Alcohol .....20mg Propylene Glycol 100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1.0 Liter-De-Controlled,5.0 Liter-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Yearcool and dry places
	For generic drugs (me-too Status)	ENPROZYLE Solution Reg.#125929 Faisons Meilleur Pharmaceuticals.Each ml contains: Enrofloxacin..……100mg N-Acetyl L-Cysteine ..186mg Benzyl Alcohol ……20mg Propylene Glycol ……100mg
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The certificate is valid for three years from the date of inspection. Responsibility to maintain

		quality of Good Manufacturing Standard throughout the period of validity of this certificate will lie on the manufacturer itself as per drugs act, 1976 and th
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	DML has been expired however, renewalapplication has been submitted.	
	Decision	
	Approved	
680	Case Category	Routine (Sabahat Zehra)
	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	(ADM-R88-TMMH, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**ADE-Vet Injection 50ml**
	Label Claim	Each ml contains: Vitamin A .....80, 000 IU Vitamin D3 .....40,000 IU Vitamin E..... 20 mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25
	For generic drugs (me-too Status)	Vital-3 Injection (Reg No. 049635)
	Pharmacotherapeutic Group of (API)	itamins, (Multivitamins
	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	Present
	Evaluation Remarks	
	DML has been expired however, renewal application has been submitted.	
	Decision	
	Approved	
681	Case Category	Routine (Sabahat Zehra)
	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	(D47-SGJ-NLLH, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Amovet-20% Injection 50ml**
	Label Claim	Each ml contains: Amoxicillin as Trihydrate.....200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)below 25

	For generic drugs (me-too Status)	Primox-20 LA 50ml Injection (Reg No. 102126)
	Pharmacotherapeutic Group of (API)	Antibiotics
	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	Present
	Evaluation Remarks	
	DMl has been expired however the renewal application has been submitted.	
	Decision	
	Approved	
682	Case Category	Routine (Sabahat Zehra)
	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	(GHQ-646-7G4U, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Megapen-Strep Injection 50ml**
	Label Claim	Each ml Contains: Procaine Penicillin G....200mg Dihydrostreptomycin Sulphate eq. to Dihydrostreptomycin....200mg
	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 heat and light.
	For generic drugs (me-too Status)	Streplin Injection (Reg. No.: 083244), M/s. Selmore Pharmaceutical (Pvt.) Ltd.,
	Pharmacotherapeutic Group of (API)	Antibacterial
	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	Present
	Evaluation Remarks	
	DML has been expired however the renewal application has been submitted.	
	Decision	
	Approved	
683	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	(XNE-ZUU-2HR7, 2025-08-30)
	Detail of Fee Submitted	37000.0, 2025-06-26,
	The proposed proprietary name / brand name	**AN-CIN - C..A Oral Solution**

	Label Claim	Each 100ml Contains : Enrofloxacin.....10mg Colistin Sulphate .....3.5gm , Amantadine 4gm
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1 liter -De-Controlled,2.5 Liter -De-Controlled,250ml -De-Controlled,5 Liter -De-Controlled,500ML -De-Controlled
	Shelf Life (Unit)	2 Year(s)20 -25 *C
	For generic drugs (me-too Status)	Encodine Oral Solutions / Diversified Marketing Group
	Pharmacotherapeutic Group of (API)	Antibiotics
	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	Present
	Evaluation Remarks	
	The formulation contains amantadine as an active pharmaceutical ingredient (API) in combination with other antimicrobial agents. The product is intended for use in poultry species.	
	Decision	
	Rejected 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.	
684	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**S.J & G. Fazul Ellahie (pvt) limited.** E-46, S.I.T.E., Karachi **(000083)**
	Application Form Dy. No / Tracking ID & date of submission	(EG1-SHB-4662, 2026-03-12)
	Detail of Fee Submitted	38700, 2026-03-11,
	The proposed proprietary name / brand name	**Ketto Injection 20mL**
	Label Claim	Each mL contains: Ketoprofen.....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20 mL-De-Controlled
	Shelf Life (Unit)	2 YearStore below 30 Degree Celsius
	For generic drugs (me-too Status)	Ketovet Injection by Vetz Pharmaceuticals
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	The Facility of M/s. S.J&G Fazul Ellahie, Karachi was found to be operating in compliance with the requirement of GMP.
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	

685	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(HSN-7YU-V31E, 2026-02-10)
	Detail of Fee Submitted	38700, 2025-11-12,
	The proposed proprietary name / brand name	**Hepatostar Powder**
	Label Claim	Each kg contains: Sodium Benzoate (B.P) .....500gm Ethanol Beta Amino Phosphoric Acid (MS).....100gm Vitamin A (B.P) .....10,000,000IU Vitamin E (B.P)..... .....2500mg Vitamin K3 (B.P).....1000mg Vitamin C (B.P)..... 2500mg (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 YearStore below 30°C.
	For generic drugs (me-too Status)	Diurizone Powder Reg. # 073908
	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	
686	Case Category	Routine (Sabahat Zehra)
	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	(MMD-ZEG-Z8A2, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-02-26,
	The proposed proprietary name / brand name	**Fosfovet-T PLus Oral Powder**
	Label Claim	Each 100gm contains: Fosfomycin Calcium ...20g Tylosin as Tartrate.....5g Fructose 1,6 Diphosphate.....18g Sodium Phosphate.....15g Magnesium Phosphate....10g (as per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 20kg,25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30°C and Protect from light and moisture.
	For generic drugs (me-too Status)	Fosfo Powder
	Pharmacotherapeutic Group of (API)	Antibiotics / Electrolytes
	Name, address of Manufacturing site:	--
	GMP status of the firm	Satisfactory
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
687	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**
	Application Form Dy. No / Tracking ID & date of submission	(775-1ZP-YMPX, 2025-12-26)
	Detail of Fee Submitted	38700, 2025-12-10,
	The proposed proprietary name / brand name	**Oxyway-30 LA Injection 100ml**
	Label Claim	Each ml contains:-Oxytetracycline HCl eq.to 300mg Oxytetracycline Base
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15C ---30C
	For generic drugs (me-too Status)	Bio-Oxyne 30% Injection Reg.# 088833 Mfg.by Bio Lab Islamabad
	Pharmacotherapeutic Group of (API)	Tetracycline.
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
688	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**
	Application Form Dy. No / Tracking ID & date of submission	(7S2-419-AP3Y, 2025-12-27)
	Detail of Fee Submitted	38700, 2025-12-10,

	The proposed proprietary name / brand name	**PRI-TYLODOX FORTE WSP(VET)**
	Label Claim	Each 1000g Pri-Tylodox Forte wsp(Vet) contains: Tylosin Tartrate =200 g Colistine Sulphate =100 g Doxycycline HCl =400 g Bromhexine HCl = 20 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 g, 5Kg in HDPE Jars/bags-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15C ---30C
	For generic drugs (me-too Status)	Dox-Tyl Powder Reg. No: 092186 Lucky Core Industries Limited 45-Km, Off Multan Road, Lahore
	Pharmacotherapeutic Group of (API)	Macrolide, Tetracycline and Polymixns antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
689	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**
	Application Form Dy. No / Tracking ID & date of submission	(BQ2-SUY-LUSA, 2025-12-27)
	Detail of Fee Submitted	38700, 2025-12-10,
	The proposed proprietary name / brand name	**Cap 980 water soluble powder**
	Label Claim	Each 1000g Cap 980 wsp contains: Amprolium Hydrochloride (BP) ----------980 g
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	1000 g, 5Kg in HDPE Jars/bags-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15C ---30C
	For generic drugs (me-too Status)	Cap 600 wsp Reg.# 041294
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
690	Case Category	Routine (Sabahat Zehra)

	Name, address of Applicant.	**PRIX PHARMACEUTICA (PRIVATE) LIMITED** PLOT NO.5 PHARMACITY, 30-KM MULTAN ROAD, LAHORE **(000587)**
	Application Form Dy. No / Tracking ID & date of submission	(T61-6S9-TUPB, 2025-12-27)
	Detail of Fee Submitted	38700, 2025-12-10,
	The proposed proprietary name / brand name	**PRI-TYLODOX wsp (Vet)**
	Label Claim	Each 1000g Pri-Tylodox wsp(Vet) contains: Doxycycline Hyclate---------400 g Tylosin Tartrate---------- 200 g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000 g, 5Kg in HDPE Jars/bags-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store between 15C ---30C
	For generic drugs (me-too Status)	Doxityl Water Soluble Powder. Doxytil-60 oral powder Reg No: 096834 RAS Pharmaceuticals PVT LTD. 25-Km, Lahore Road, MultanReg. No: 059115 Lucky Core Industries Limited, 45-Km, Off Multan Road, Lahor
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Authorization of production of medicine in all approved sections
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
691	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	(VR6-AY3-BJG3, 2025-08-18)
	Detail of Fee Submitted	313500.0, 2025-08-11,
	The proposed proprietary name / brand name	**Genta-HP (Injectable Solution)**
	Label Claim	Each ml Contains: Gentamicin (as Gentamicin sulfate) 200mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	100 ml-De-Controlled,250 ml-De-Controlled,50 ml-De-Controlled,500 ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Room Temperature
	For generic drugs (me-too Status)	1-Gentabar-20 Injection (BAARIQ PHARMACEUTICALS) , 2-GENTA-RUS 20% Injection (Supreme Pharma) , 3- Gentam 20% Injection (Rg.No. 57149) (Ghazi Brothers Importer)
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	Hebei Hope Harmony Pharmaceutica Co., LTD.- Industry Development Area, Yuanshi County,

		Shijiazhuang City, Hebei Province , China -China
	Name, address of Marketing Authorization Holder:	Hebei Hope Harmony Pharmaceutica Co., LTD., Industry Development Area, Yuanshi County, Shijiazhuang City, Hebei Province , 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	
692	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(78B-YQG-PUL3, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Albelim-KS Oral Powder**
	Label Claim	"{Each 100gm contains:- Albendazole BP.....10gm Levamisole HCl BP.....2gm Potassium Chloride USP.....8gm,Sodium chloride BP.....25g}(As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 10gm,50gm,100gm,250gm,500gm, 1000g ,5kg,10kg,20kg,25kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	albaweal oral powder by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
693	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(D8V-8U4-5M7B, 2026-03-31)
	Detail of Fee Submitted	38700, 2026-03-18,

	The proposed proprietary name / brand name	**Olaquintal Powder**
	Label Claim	Each Kg Powder Contains: Olaquindox..... 100g (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10g,50g,100g, 250g,500g,1Kg,5kg,10kg,20kg,25kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	olandox powder by nawan pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1kg pack size.	
694	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(X55-224-248U, 2026-03-31)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Tylotal Powder**
	Label Claim	Each Kg Contains: Tylosin Tartrate BP..... 100g (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 10g,50g,100g, 250g,500g,1Kg,5kg,10kg,20kg,25kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	vety tylomix s powder by leads pharma pvt ltd
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
695	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi

		(001006)
	Application Form Dy. No / Tracking ID & date of submission	(NGB-PMG-DP2T, 2026-03-31)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Colikill Powder**
	Label Claim	"Each gm Contains: Flumequine BP..... 100mg, Colistin Sulphate BP.....500000IU} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 10g,50g,100g, 250g,500g,1Kg,5kg,10kg,20kg,25kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	farmecol oral powder by farm aid group
	Pharmacotherapeutic Group of (API)	Antibacterial
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 kg pack size.	
696	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(PNX-1WP-D15W, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Absest Oral Liquid**
	Label Claim	"Each ml contains:- Albendazole BP.....170mg Cobalt Sulphate .....1.67mg Sodium selenite BP.....0.50mg Zinc USP.....2.6mg (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml ,1000ml,2.5L,5 L,25L.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	albo 17% liquid Reg# 063785 by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	

	Decision	
	Approved Approved up to 1 litre pack size.	
697	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(RLD-ELQ-1NVT, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Fenzol Oral Liquid**
	Label Claim	Each ml contains:-Rafoxanide .....50mg, Fenbendazole.....50mg} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml ,1000ml,2.5L,5 L,25L.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	FEN fox oral liquid Reg#062170 by attabak pharmaceutical industries
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
698	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(SME-MBD-S7BX, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Albezinc Oral Liquid**
	Label Claim	Each ml contains:- Albendazole BP....25mg Zinc USP.....6mg} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml ,1000ml,2.5L,5 L,25L.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	ji zole liquidReg# 075637 by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics

	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
699	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(Z6Q-GYL-925T, 2026-03-29)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**ClosanVet Oral Suspension**
	Label Claim	Each 100ml Contain: Closantel EP.....5%W/V ,Levamisole Hcl BP..... 1.5%W/V } (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	zentol plus suspension by nobel pharma
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
700	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(N3J-2QQ-134Y, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Albezole Oral Liquid**
	Label Claim	Each ml contains:- Albendazole BP....125mg Zinc USP.....2.0mg} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification

	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml ,1000ml,2.5L,5 L,25L.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	alvex 12.5% liquid by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
701	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(LZM-DTE-W6YN, 2026-03-29)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Rafonil Liquid**
	Label Claim	Each liter Contains:- Rafoxanide .....15gm, Oxibendazole.....10gm } (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	Rafoxamall plus liquid by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
702	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(HLN-UEP-R3DD, 2026-03-29)

	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Oxazole suspension**
	Label Claim	Each 100ml contains: Oxfendazole BP..... 2.265gm, Vitamin K USP..... 0.5gm} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	oxfa k suspension by attabak pharmaceutical industries
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
703	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(GT4-RA9-Z4US, 2026-03-29)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Ricoliv Oral Suspension**
	Label Claim	“Each mL contains: Albendazole.....25mg, Ricobendazole ....40mg} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	ricoben-s suspension by intervec pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	

704	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(9AW-JV9-SLW3, 2026-03-29)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Triclaforte plus Oral Suspension**
	Label Claim	Each mL contains: Triclabendazole USP.....50mg Fenbendazole BP .....25 mg} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	trifen act liquid by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
705	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(8T1-WPL-MNN3, 2026-03-29)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Triclaforte Oral Suspension**
	Label Claim	Each mL contains: Triclabendazole USP.....50mg, Fenbendazole BP .....25mg, Cobalt Sulphate..... 1.67mg, Sodium Selenite BP..... 0.5mg} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	tribenzole plus suspension by zakfas pharmaceuticals
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present

	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 liitre pack size.	
706	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(7GN-BEG-LYP1, 2026-03-29)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**FenzoCare Liquid**
	Label Claim	Each 100mL contains: Fenbendazole BP .....12.5g, Cobalt Sulphate..... 1.6gm, Zinc Carbonate USP..... 0.6 gm, Sodium Selenite BP..... 3gm} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	fenmall liquid by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
707	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(7WG-ALW-TRZW, 2026-03-29)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Niclocare Drench**
	Label Claim	“Each Liter Contains: Niclosamide BP..... 250gm Oxfendazole BP..... 10gm} (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml,1000ml,2.5 De-Controlled

	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	niczole drench by syamns pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
708	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(1AP-L4W-JV6S, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Levtricob Oral Liquid**
	Label Claim	Each ml contains:- Triclabendazole USP.....50mg, Levamisole HCl BP.....37.5mg, Cobalt Sulphate .....1.67mg, Sodium selenite BP.....0.35mg (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	30ml,50ml,100ml,120ml,250ml,500ml ,1000ml,2.5L,5 L,25L.-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 30 degree
	For generic drugs (me-too Status)	ENDOMALL PLUS ORAL LIQUID by mallard pharmaceuticals pvt ltd
	Pharmacotherapeutic Group of (API)	Anthelmintics
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
709	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	(S51-9JR-JLYY, 2026-03-27)
	Detail of Fee Submitted	38700, 2026-03-27,

	The proposed proprietary name / brand name	**CETO RATE ORAL POWDER**
	Label Claim	Each gm powder contains (As Per Innovator Spec.) Acetyl Isovaleryl Tylosin Tartrate 50mg
	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)	TYLVOTART 50 POWDER (106755) GRAND PHARMA RAWAT
	Pharmacotherapeutic Group of (API)	Antibacterial
	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 Approved up to 1kg pack size.	
710	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	(DXQ-MWL-D3BJ, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-14,
	The proposed proprietary name / brand name	**NOGA ORAL LIQUID**
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin BP..... 20% Guaifenesin USP..... 20% Aminophylline USP..... 8%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	NOR+AG SOLUTION (058968) BIOGEN PHARMA
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	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	

	Approved up to 1litre pack size.	
711	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	(7RP-HPA-2Z5Q, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-14,
	The proposed proprietary name / brand name	**NOFLOX ORAL LIQUID**
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin HCl 25g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	NORMAK ORAL LIQUID (058943) A&K PHARMA FAISLABAD
	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	Present
	Evaluation Remarks	
	Decision	
	Approved Approved upto 1 litre pack size.	
712	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	(N1N-UDT-E68U, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-14,
	The proposed proprietary name / brand name	**TRIZINE ORAL LIQUID**
	Label Claim	Each ml contains (As Per Innovator Spec.) Norfloxacin BP..... 50mg Sulphamethoxypyridazine ..... 50mg Trimethoprim ..... 10mg Phenylbutazone ..... 12mg Bromhexine 2mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C

	For generic drugs (me-too Status)	MEGA BIOTIC SOLUTION (057006) SELMORE PHARMA LAHORE
	Pharmacotherapeutic Group of (API)	Antibiotics, Expectorant, Bronchodilator
	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 Approved up to 1 litre pack size.	
713	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	(16X-D83-ZL2R, 2026-01-14)
	Detail of Fee Submitted	38700, 2026-01-14,
	The proposed proprietary name / brand name	**NORSTIN ORAL LIQUID**
	Label Claim	Each 100ml contains (As Per Innovator Spec.) Norfloxacin BP..... 20g Colistin sulphate BP..... 60MIU
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled,1Lit-De-Controlled,250ml-De-Controlled,500ml-De-Controlled,5Lit-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store Below 30°C
	For generic drugs (me-too Status)	COLI-NOR ORAL LIQUID (049051) LEADS PHARMA ISLAMABAD
	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	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
714	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	(6XS-TJV-MEUS, 2026-01-13)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Mexulon DS Injection 10mL**

	Label Claim	Each ml contains: - Ivermectin 20mg & Clorsulon 100mg (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)	Actimec DS Injection by M/S M/S Selmore Pharmaceuticals Lahore (Reg No. 101524)
	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	
	DML has been expired however renewal application has been submitted.	
	Decision	
	Approved	
715	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	(477-72Q-W4JD, 2026-01-13)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**Mexulon DS Injection 50mL**
	Label Claim	Each ml contains: - Ivermectin 20mg & Clorsulon 100mg (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)	Actimec DS Injection by M/S M/S Selmore Pharmaceuticals Lahore (Reg No. 101524)
	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	
	DML has been expired however renewal application has been submitted.	
	Decision	
	Approved	
716	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	(XNJ-614-R5GM, 2026-01-13)

	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**LIVERMECTIN-1.2% INJECTION 100ML**
	Label Claim	Each ml contains: - Ivermectin 12mg (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)	MECTOGEN-1.2% INJECTION by M/S. BIOGEN PHARMA (Reg No. 075623)
	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	
	DML has been expired however renewal application has been submitted.	
	Decision	
	Approved	
717	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	(T18-1EU-6QB4, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Zurivit-K Oral Liquid**
	Label Claim	EACH 1000ML CONTAINS:- TOLTRAZURIL.....25GM VITAMIN K3.....3GM
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1L,500mL,100mL,2.5L,5L, 150ml,250ml, 450mL, 30mL, 50mL-De-Controlled
	Shelf Life (Unit)	2 YearStore in a cool and dry place, below 30c.
	For generic drugs (me-too Status)	TOLTRA-K ORAL LIQUID by M/S. ATTABAK PHARMACEUTICALS, ISLAMABAD (Reg. No. 062165)
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	DML has been expired however renewal application has been submitted.	
	Decision	
	Approved Approved up to 1 litre pack size.	

718	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	(VNJ-DV9-TV48, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Bioxin-5% Oral Liquid**
	Label Claim	EACH ML CONTAINS:- BROMHEXINE HCI.....50MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1L,500mL,100mL,2.5L,5L, 150ml,200ml, 250ml, 450mL, 30ml, 50mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place, below 30c.
	For generic drugs (me-too Status)	BROMO-5% ORAL LIQUID by M/S. M/S.CHERISHED PHARMACEUTICALS, LAHORE (REG NO. 069631)
	Pharmacotherapeutic Group of (API)	Mucolytic agent
	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	
	DML has been expired however renewal application has been submitted.	
	Decision	
	Approved Approved up to 1 litre pack size.	
719	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	(281-M9S-2AWQ, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Pvimal-P Water Soluble Powder**
	Label Claim	Each 100 gm contains: Paracetamol...2gm. Vitamin C (Ascorbic Acid).....20gm. Calcium carbonate....4.5gm. Megnesium sulphate.....3.5gm. Potassium chloride.....4gm. (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg,500g,100g,250g,10g,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)	Spin-C Powder by M/S Leads Pharma, Islamabad (Reg No. 078239)
	Pharmacotherapeutic Group of (API)	Antipyretic and anti-inflammatory and analgesi
	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 Approved up to 1 kg pack size.	
720	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	(1ZG-D3M-GGG5, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Doxylis-50 Powder**
	Label Claim	Each 100gm contains: - Doxycycline Hyclate.....50gm (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1Kg,100g,500g,10g,250g,2.5Kg,5Kg, 25Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place, below 30c.
	For generic drugs (me-too Status)	XEDO-50 POWDER by M/S. A & K PHARMACEUTICAL, FAISALABAD (Reg No. 080141)
	Pharmacotherapeutic Group of (API)	antibiotic
	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	
	DML has been expired however renewal application has been submitted.	
	Decision	
	Approved Approved up to 1 kg pack size.	
721	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	(2AS-Q62-BASN, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Motilix Powder**
	Label Claim	Each 1000gm contains: - Amantadine HCl.....10gm (Innovator's Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1Kg, 100 g, 250 g, 500 g, 10g, 2.5Kg, 5Kg. 10Kg And 25Kg-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place, below 30c.
	For generic drugs (me-too Status)	AMANTABAK 10% POWDER by M/S. ATTABAK PHARMACEUTICALS, ISLAMABAD (Reg. No. 075697)

	Pharmacotherapeutic Group of (API)	Antiviral
	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	
	The formulation is intended for use in POULTRY	
	Decision	
	Rejected 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.	
722	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	(5D5-QPQ-M372, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Enrise-10% Injection**
	Label Claim	Each ml contains:- Enrofloxacin.....100mg (Innovator's Specifications)
	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)	Dr-Flox-10 INJECTION by M/S. INTERNATIONAL PHARMA, LAHORE (Reg No. 053980)
	Pharmacotherapeutic Group of (API)	Antibiotic
	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	
	Submit pre registration variation fee for change of specs from innovator to BP. As per letter No. F. 1-12/2014-Lic dated 8th June, 2021. firm has been granted approval of Liquid Injection Vial Section (General) vet, firm has applied pack size of 500ml. The said letter suggest that the firm has approval only for SVP. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant section (LVP) through Licensing Division before the approval of applied formulation. Submitted for consideration of Board,please.	
	Decision	
	Deferred Deferred for the clarification of section approval from Licensing Division.	
723	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	(DV6-MRS-ZBD1, 2026-01-13)

	Detail of Fee Submitted	38700, 2025-12-09,
	The proposed proprietary name / brand name	**Acetapred Injection 50mL**
	Label Claim	Each ml contains: Prednisolone Acetate 25mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore in a cool and dry place, below 25c.
	For generic drugs (me-too Status)	Solopred Injection by M/S M/S Selmore Pharmaceuticals Lahore (Reg No. 043142)
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	The firm holds approval only for the following veterinary sections. (i) Oral Powder Section (General) Veterinary. (ii) Oral Liquid Section (General) Veterinary. (iii) Liquid Injection Vial Section (General) Veterinary. The firm does not hold approval for the Steroidal section therefore, the manufacture of steroidal products is not covered under the firm's approved sections.	
	Decision	
	Rejected The instant case was rejected on the grounds that adequate facilities for the manufacture of the steriodal formulation were not available.	
724	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	(RJE-UD5-Y4HA, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**Florimax-23% Oral Liquid**
	Label Claim	EACH 100ML CONTAINS:- FLROFENICOL 23g
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1L, 500mL, 100mL, 250mL, 2.5L, 5L, 25L, 150mL, 450mL,50ml, 30ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store in a cool and dry place, below 30c.
	For generic drugs (me-too Status)	NEFLOX SOLUTION by M/S. SELMORE PHARMACEUTICALS, LAHORE (Reg. No. 049647)
	Pharmacotherapeutic Group of (API)	antibiotic
	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	
	DML has been expired however, the application for renewal has been submitted by the applicant.	
	Decision	
	Approved	

	Approved upto 1litre pack size.	
725	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	(YQT-6U5-V49R, 2026-01-13)
	Detail of Fee Submitted	38700, 2025-11-26,
	The proposed proprietary name / brand name	**SUPERTAD-MG POWDER**
	Label Claim	Each 1000 gm contains: Choline chloride...100gm. L-Lysine...25gm. DL-Methionine...50gm. Vitamin D3...2gm. Vitamin E...9gm. Virginiamycin.....12gm. (Innovator's Specs)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1kg,500g,100g,250g,10g,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)	Supercine TM Powder by M/S Leads Pharma, Islamabad (Reg No. 019946)
	Pharmacotherapeutic Group of (API)	Combination of nutrients, Amino acids and vitamins
	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	
	DML has been expired however, the application for renewal has been submitted by applicant.	
	Decision	
	Approved Approved upto 1 kg pack size.	
726	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(B5A-34R-EZEQ, 2025-12-19)
	Detail of Fee Submitted	38700, 38700 2025-12-19, 2026-08-10
	The proposed proprietary name / brand name	**KETOFAS INJECTION**
	Label Claim	Each ml Contains: KETOPROFEN (BP).....100mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 Year(s) 30 degree centigrade
	For generic drugs (me-too Status)	Vetpro 100 Injection Reg no. 093606 Bio-Labs(Pvt) Ltd
	Pharmacotherapeutic Group of (API)	NSAIDS
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated

		for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved	
727	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(L22-UZL-P6YX, 2025-10-08)
	Detail of Fee Submitted	38700, 38700 2025-10-06, 2026-08-10
	The proposed proprietary name / brand name	**NORFAS-AG ORAL SOLUTION**
	Label Claim	Each 100ml Contains: Norfloxacin (BP Vet).....20% Aminophyllin.....8% Guaifenesin.....20%
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	1000ml-De-Controlled,100ml-De-Controlled,200ml-De-Controlled,2500ml-De-Controlled,250ml-De-Controlled,5000ml-De-Controlled,500ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	NOR +AG Solution (Reg no. 058968) Biogen Pharma
	Pharmacotherapeutic Group of (API)	antibiotics
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 litre pack size.	
728	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**STAR LABORATORIES PVT. LTD.** 23KM MULTAN ROAD LAHORE **(000130)**
	Application Form Dy. No / Tracking ID & date of submission	(TMM-H9Z-MPWQ, 2026-02-10)

	Detail of Fee Submitted	38700, 2025-12-11,
	The proposed proprietary name / brand name	**Star-Tim 45 Powder**
	Label Claim	Each gm contains: Tiamulin Hydrogen Fumarate.....450mg (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 30°C.
	For generic drugs (me-too Status)	Bio-Tim 45 Powder Reg. # 103969
	Pharmacotherapeutic Group of (API)	Antibiotics
	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	Present
	Evaluation Remarks	
	Decision	
	Approved Approved up to 1 kg pack size.	
729	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**INTERVAC (PVT) LTD** 18KM SHEIKHUPURA ROAD **(000623)**
	Application Form Dy. No / Tracking ID & date of submission	(G8B-7Q2-YAQM, 2025-10-10)
	Detail of Fee Submitted	38700, 38700 2025-10-09, 2026-08-10
	The proposed proprietary name / brand name	**NOVAFAS INJECTION**
	Label Claim	Each ml Contains: Novaminsulfon.....40 mg Etilefrin.....0.2mg Calcium gluconate.....110 mg Magnesium gluconate.....10 mg Sodium salicylate.....7 mg Nicotinamide.....0.3mg Caffeine.....10 mg Boric acid.....10 mg
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	250ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)30C degree centigrade
	For generic drugs (me-too Status)	Novasul Injection (Reg no. 062056) Symans Pharmaceuticals Pvt. Ltd.
	Pharmacotherapeutic Group of (API)	Minerals, Supplements
	Name, address of Manufacturing site:	--
	GMP status of the firm	The firm M/s Intervac (Pvt.) Ltd. 18 Km, Lahore Sheikhupura Road, Sheikhupura was evaluated for facilities like building, flow, HVAC, Water treatment, personnel, Quality Control / Quality Assurance, production operations and facilities, Keeping in view th

	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	As per letter No. F. 1-37/2004-Lic-(Vol-11) dated 10th July, 2017.. firm has been granted approval of Injectable (Veterinary), firm has applied pack size of 250ml. The said letter suggest that the firm has approval only for SVP. Therefore, firm may be advised to regularize/ obtain requisite approval for the relevant section (LVP) through Licensing Division before the approval of applied formulation. Submitted for consideration of Board, please.	
	Decision	
	Deferred Deferred for the clarification of section approval from Licensing Division.	
730	Case Category	Contract Manufacturing (Sabahat Zehra)
	Name, address of Applicant.	**Citi pharma ltd** 3-km head balloki, Bhai Phero, Kasur. **(000512)**
	Application Form Dy. No / Tracking ID & date of submission	(V8Q-9Q9-9X89, 2026-02-26)
	Detail of Fee Submitted	97200, 2026-02-24,
	The proposed proprietary name / brand name	**Citi Linco-4.4% Water Soluble Powder**
	Label Claim	Each 100 gm contains: Lincomycin HCl .....4.4 gm USP Specifications
	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)	2 Year(s)Store at or below 25°C.
	For generic drugs (me-too Status)	LincoPri 44 Oral Powder by PRIX PHARMACEUTICA (PVT) LTD
	Pharmacotherapeutic Group of (API)	Penicillin Antibiotic
	Name, address of Manufacturing site:	M/S Oxford Health Care -Plot No. 12 & 13 , Street No. SS-1, RCCI Industrial Estate ,Rawat.-
	GMP status of the firm	GMP is valid till 18-01-2029
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	The applicant firm did not possess approval from the CLB for the manufacture of veterinary products.	
	Decision	
	Deferred According to S.R.O 1347(I)/2021 dated 15 October, 2021 contract manufacturing shall be allowed between human to human and veterinary to veterinary drugs only.	
731	Case Category	Routine (Sabahat Zehra)
	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	(5J7-6TD-3RR1, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Cefur-Duo Injection 10ml**

	Label Claim	Each ml Contains: Ceftiofur (as HCl).....50mg Ketoprofen.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 Year(s)Store below 25°C. Protect from heat and light.
	For generic drugs (me-too Status)	Not Available (NA)
	Pharmacotherapeutic Group of (API)	Antibacterial
	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	Present
	Evaluation Remarks	
	Decision	
	Approved	
732	Case Category	Routine (Sabahat Zehra)
	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	(M3P-4QV-358H, 2026-02-24)
	Detail of Fee Submitted	38700, 2026-02-23,
	The proposed proprietary name / brand name	**Cefur-Duo Injection 50ml**
	Label Claim	Each ml Contains: Ceftiofur (as HCl).....50mg Ketoprofen.....150mg
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	2 YearStore below 25°C. Protect from heat and light.
	For generic drugs (me-too Status)	Not Available (NA)
	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	
733	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	(9GY-BXM-GJUJ, 2026-01-13)

	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**LIVERMECTIN-1.2% INJECTION 10ML**
	Label Claim	Each ml contains: - Ivermectin 12mg (USP Specifications)
	Reference to Finished product specifications	United States Pharmacopeia
	Proposed Pack Size	10ml-De-Controlled
	Shelf Life (Unit)	2 YearStore in a cool and dry place, below 25c.
	For generic drugs (me-too Status)	Actimec DS Injection by M/S M/S Selmore Pharmaceuticals Lahore (Reg No. 101524)
	Pharmacotherapeutic Group of (API)	
	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	
	Evaluation Remarks	
	DML has been expired however, application has been submitted.	
	Decision	
	Approved	
734	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	(39L-853-PYW2, 2026-01-16)
	Detail of Fee Submitted	38700, 2026-01-05,
	The proposed proprietary name / brand name	**HYPOPHYSIN LA INJECTABLE SOLUTION**
	Label Claim	Each mL Contains Carbetocin 0.07 MG
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50mL-De-Controlled
	Shelf Life (Unit)	2 Year(s)2 - 8 C
	For generic drugs (me-too Status)	Manufactured by; Veyx-Pharma b.v. Netherlands IMPORTED BY Mustafa Brothers. Reg.NO. 096796
	Pharmacotherapeutic Group of (API)	Hormone
	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	
	Decision	
	Approved	

735	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Al-Habib Agencies** Office No. 11, Kala Khan Shopping Center, Shamsabad, Murree Road. **(01-374-0177-032506D)**
	Application Form Dy. No / Tracking ID & date of submission	(WW5-AJ6-NEJ8, 2025-10-17)
	Detail of Fee Submitted	313500, 2025-10-08,
	The proposed proprietary name / brand name	**TROXIL-34% INJECTION**
	Label Claim	Each ml contains: Nitroxinil ... 340mg B.P Vet Specifications
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 25ºC
	For generic drugs (me-too Status)	Troxy-34% Inj. (100ml) of M/s. Selmore Pharma (Reg. No. 034596)
	Pharmacotherapeutic Group of (API)	Anthelmintic
	Name, address of Manufacturing site:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI-No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, China.-China
	Name, address of Marketing Authorization Holder:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI, No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, 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 Approved subject to submission of the original legalized CoPP/GMP and FSC and in accordance with the current import policy.	
736	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Al-Habib Agencies** Office No. 11, Kala Khan Shopping Center, Shamsabad, Murree Road. **(01-374-0177-032506D)**
	Application Form Dy. No / Tracking ID & date of submission	(NU9-JQZ-3AU6, 2025-10-17)
	Detail of Fee Submitted	313500, 2025-10-08,
	The proposed proprietary name / brand name	**OXYSOL INJECTION**
	Label Claim	Each ml contains: Oxytetracycline as HCl ... 300mg Flunixin as Meglumine ... 20mg As per innovator’s specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	50ml-De-Controlled
	Shelf Life (Unit)	3 YearBelow 25ºC

	For generic drugs (me-too Status)	Xenox Injection (50ml) of M/s D-Haans Pharmaceuticals, Azad Kashmir (Reg. No. 114810)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI-No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, China.-China
	Name, address of Marketing Authorization Holder:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI, No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, 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 Approved subject to submission of the original legalized CoPP/GMP and FSC and in accordance with the current import policy.	
737	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Al-Habib Agencies** Office No. 11, Kala Khan Shopping Center, Shamsabad, Murree Road. **(01-374-0177-032506D)**
	Application Form Dy. No / Tracking ID & date of submission	(6AN-1VV-SRGU, 2025-10-17)
	Detail of Fee Submitted	313500, 2025-10-08,
	The proposed proprietary name / brand name	**OXYSOL INJECTION**
	Label Claim	Each ml contains: Oxytetracycline as HCl ... 300mg Flunixin as Meglumine ... 20mg As per innovator’s specifications
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 25ºC
	For generic drugs (me-too Status)	Oxymore-F Inj. (100ml) of M/s Moreno Iglisias Research Laboratories (Reg. No. 120803)
	Pharmacotherapeutic Group of (API)	Antibiotic + Analgesic
	Name, address of Manufacturing site:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI-No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, China.-China
	Name, address of Marketing Authorization Holder:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI, No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, 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 Approved subject to submission of the original legalized CoPP/GMP and FSC and in accordance with the current import policy.	
738	Case Category	Import (Sabahat Zehra)
	Name, address of Applicant.	**Al-Habib Agencies** Office No. 11, Kala Khan Shopping Center, Shamsabad, Murree Road. **(01-374-0177-032506D)**
	Application Form Dy. No / Tracking ID & date of submission	(2BQ-8X1-DT3U, 2025-10-17)
	Detail of Fee Submitted	313500, 2025-10-08,
	The proposed proprietary name / brand name	**BUPRA 50 INJECTION**
	Label Claim	Each ml contains: Buparvaquone ... 50mg (As per Innovator's specifications)*
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	20ml-De-Controlled
	Shelf Life (Unit)	3 Year(s)Below 25ºC
	For generic drugs (me-too Status)	Parvon Injection (20ml) of M/s. Selmore Pharma (Reg. No. 034580)
	Pharmacotherapeutic Group of (API)	Antiprotozoal
	Name, address of Manufacturing site:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI-No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, China.-China
	Name, address of Marketing Authorization Holder:	M/s. BAODING SUNLIGHT HERB MEDICAMENT Co. Ltd CHI, No. 3881, Great Wall South Street, Qingyuan District, Baoding City, Hebei Province, 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 Approved subject to submission of the original legalized CoPP/GMP and FSC and in accordance with the current import policy.	
739	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Pivotal pharmaceuticals (Pvt) Ltd.** Plot No. 255, Haraka Mor, Chak Beli Road, Rawalpindi **(001006)**
	Application Form Dy. No / Tracking ID & date of submission	(5WZ-HB2-MH96, 2026-03-31)

	Detail of Fee Submitted	38700, 2026-03-18,
	The proposed proprietary name / brand name	**Fucosin Powder**
	Label Claim	Each Kg Contains: Tylosin tartrate ..... 200gm ,Furaltadone Hcl.....200gm, Colistin Sulphate .....10MIU (As per Innovator Specifications)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	Jar of 10g,50g,100g, 250g,500g,1Kg,5kg,10kg,20kg,25kg.-De-Controlled
	Shelf Life (Unit)	2 Year(s)store below 30 degree
	For generic drugs (me-too Status)	tycofura powder Reg #029635 by farm aid group
	Pharmacotherapeutic Group of (API)	bactericidal
	Name, address of Manufacturing site:	--
	GMP status of the firm	Recommended for DML
	Evidence of approval of manufacturing facility	Present
	Evaluation Remarks	
	The formulation contains FURALTADONE as an ingredient and target species are POULTRY, CALVES, GOATS, LAMBS.	
	Decision	
	Rejected The Sub-committee on Veterinary Drugs didn't recommended the use of furaltadone in food-producing animals, in view of international regulatory practices and associated public health risks.	
740	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(5PB-GRP-DRTN, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX-750 INJECTION**
	Label Claim	Each ml contains Meloxicam BP..... 7.5mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 7.5 LIQUID INJECTION (108992)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved	
741	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(GVB-B49-R967, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX-500 INJECTION**
	Label Claim	Each ml contains Meloxicam ..... 5mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 5 LIQUID INJECTION (108991)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
742	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(QYL-6VE-63H8, 2026-02-25)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX-500 INJECTION**
	Label Claim	Each ml contains Meloxicam ..... 5mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 5 LIQUID INJECTION (108992)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--

	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
743	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(XNS-A5M-2DJP, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**MELOX-750 INJECTION**
	Label Claim	: Each ml contains Meloxicam BP..... 7.5mg (BP Specification)
	Reference to Finished product specifications	British Pharmacopeia
	Proposed Pack Size	50 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	CAMROLD 7.5 LIQUID INJECTION (108994)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
744	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(Y6S-VQS-1MX2, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,

	The proposed proprietary name / brand name	**PRONEX-4 INJECTION**
	Label Claim	Each ml contains: 2 Phenoxy-2 Methyl-2 Propionic acid ..... 100mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100 ML-De-Controlled
	Shelf Life (Unit)	2 YearROOM TEMPERATURE
	For generic drugs (me-too Status)	HEPAFOS INJECTION (063574)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	Based on the current inspection and documentation review, the premises and equipment setup are technically acceptable for the applied manufacturing section. The facility demonstrates readiness for initiation of operations subject to regulatory approval of
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
745	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(W2N-M8V-9VH4, 2026-02-22)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VALBAZEN 12% ORAL SUSPENSION**
	Label Claim	Each 100ml contains: Albendazole..... 12.5 g (AS per innovators specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml, 150ml, 250ml,450ml, 500ml, 1Litre, -De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	HANZOLE 12.5 % ORAL SUSLPENSION (REG NO. 113393)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	

	Decision	
	Approved Approved upto 1 litre pack size.	
746	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(WX4-8MD-DRW2, 2026-03-01)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**VITOFIT INJECTION**
	Label Claim	Each ml contains Vitamin B1HCl .....5mg Vitamin B2 Sodium Phosphate.....2.5mg Vitamin B6 (HCl)..... 2.5mg Nicotinamide.....37.5mg (As Per Innovator's Specification)
	Reference to Finished product specifications	As per Innovators Specification
	Proposed Pack Size	100ml-De-Controlled
	Shelf Life (Unit)	2 Yearat Room Temperature
	For generic drugs (me-too Status)	Thiaprin Injection. (022185)
	Pharmacotherapeutic Group of (API)	
	Name, address of Manufacturing site:	--
	GMP status of the firm	SUMMARY The facility has been constructed in accordance with approved layout plan, ensuring compliance with Good Manufacturing Practices (GMP) structural and spatial requirements. The Manufacturing and testing areas are appropriately demarcated and equipp
	Evidence of approval of manufacturing facility	
	Evaluation Remarks	
	Decision	
	Approved	
747	Case Category	Routine (Sabahat Zehra)
	Name, address of Applicant.	**Archard Pharmaceuticals Pvt Ltd** Plot No 27-28/B Small Industrial Estate Bhimber AJK **(000991)**
	Application Form Dy. No / Tracking ID & date of submission	(B3X-Z6L-27H3, 2026-02-26)
	Detail of Fee Submitted	38700, 2026-02-17,
	The proposed proprietary name / brand name	**PRONEX-4 INJECTION**
	Label Claim	Each ml contains: 2 Phenoxy-2 Methyl-2 Propionic acid ..... 100mg (As Per Innovator Spec.)
	Reference to Finished product specifications	As per Innovators Specification