**Minutes of 288th Meeting of Registration Board held on 14th-15th February, 2019**

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Drug Regulatory Authority of Pakistan
T.F. Complex, Mauve Area, G-9/4
Islamabad.

288th meeting of Registration Board was held on 14–15th February, 2019 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was chaired by Dr.Obaidullah, Director, Pharmaceutical Evaluation & Registration Division, DRAP. The meeting started with recitation of the Holy Verses and was attended by following:-

| | | |
|---|---|---|
| 1. | Dr. Rafeeq Alam Khan,<br>Meritorious Professor/Chairman, Faculty of Pharmacy,<br>Univeristy of Karachi. | Member |
| 2. | Maj.Gen. Dr.Tahir Mukhtar Sayed,<br>Director General Medicine, Pak Army, Rawalpindi | Member |
| 3. | Prof.Dr.Ghulam Sarwar,<br>Dean, Faculty of Pharmacy, Jinnah University for Women, Karachi | Member |
| 4. | Dr.Aslam Shah, Senior Manager,<br>Indus Hospital, Karachi | Member |
| 5. | Dr. Amanullah Khan,<br>Director, Drugs Testing Laboratory, Quetta.<br>Government of Balochistan | Member |
| 6. | Dr. Shafiq ur Rehman,<br>Director, Drugs Testing Laboratory, Lahore.<br>Government of Punjab | Member |
| 7. | Syed Adnan Rizvi,<br>Director, Drugs Testing Laboratory, Karachi.<br>Government of Sindh | Member |
| 8. | Dr. Muhammad Khalid Jawed,<br>Director, Drugs Testing Laboratory, Peshawar<br>Government of Khyber Pakhtunkhwa | Member |
| 9. | Mr. Muhammad Aslam, Assistant Draftsman-II,<br>Representative of Ministry of Law & Justice, Islamabad | Member |
| 10. | Dr. Noor-us-Saba,<br>Director, Biological Evaluation & Research Division, DRAP | Member |
| 11. | Dr. Hafsa Karam Ellahi, Additional Director,<br>Representative of QA&LT Division, DRAP | Member |
| 12. | Mr. Abdullah,<br>Additional Director (PE&R), DRAP. | Member / Secretary |
| 13. | Dr.Muhammad Akram, Represntative of Animal Husbandry Commissioner, M/o National Food Security & Research, Islamabad. | Co-opted Member |

Ms.Tahreem Sara (Dy.Director,RRR), Mr. Asif Jalil, Incharge PEC and respective Assistant Directors, presented the agenda of PE&R Division. Director, BE&R assisted by respective Assistant Directors, presented the agenda of Biological Evaluation & Research Division. Mr. Abdul Sattar Suhrani (Additional Director, QA&LT) assisted by respective Assistant Director, presented the agenda of QA & LT Division.

Syed Farooq Bukhari, Mr. Arshad Mehmood & Mr. Iftikhar (PPMA), Ms. Anila Sikandar and Nadeem Alamgir (Pharma Bureau) and Mr.M.Asad Malik (PCDA) attended the meeting as observers.

**Item No. I: Confirmation of Minutes of 287th Meeting of Registration Board.**

287th meeting of Registration Board was held on 03–04th January 2019. The draft minutes of 287th meeting of Registration Board were circulated among the members of the meeting on 31st January 2019 for perusal/ comments (if any) within five days. In continuation of previous minutes, an updated version of minutes was shared via email with the members of the meeting on 04th February 2019 for their comments/perusal/approval by 06th February 2019. In later minutes, one case of Division of Biological Evaluation & Research (Case No.01 of Additional Agenda) was updated and shared. Whereas, rest of minutes were same.

None of the members disagreed the draft minutes. Accordingly, fair minutes were approved by the Chairman Registration Board and circulated to all concerned.

**Decision: Registration Board confirmed minutes of 287th meeting.**

**Item No. II: Discussion points of Director DTL Lahore.**

Since the Registration Board has done a good job for dealing with outstanding registration cases over the last couple of years, now we need to focus on the following matters using science and risk-based approach;

1. We need to establish some criteria for granting maximum number of registrations at least for critical drug products i.e. Antimicrobial, Anti-tuberculosis, Anti-malarial, Oncology and HIV drug products especially when DRB is granting registration of these drug products without any pre-registration test/ analysis and Bioequivalence studies, to ensure availability of safe and effective drug products required for protection of public health/ patient.
2. Start gathering data for licensed drug product manufacturers and their registered drug products. Currently provisional list is available but data is not sufficient for reference. Drug Registration Board shall provide following lists to begin with;
    a. Official list of licensed drugs manufacturers along with the following details;
        - Name of manufacturer
        - Manufacturing License number,
        - Scanned copy of license,
        - Complete address
        - List of manufacturing facilities approved i.e. OSD, Sterile etc.
    b. Official list of registered drug products with detailed information like
        - Name of drug,
        - Generic name,
        - Registration number,
        - Strength,
        - Dosage form,
        - Product specifications,
        - Scanned method of analysis
        - Name of manufacturer,
        - Year of registration,
        - Scanned copy of registration letter etc.
3. Panel Inspection report for the verification of stability study data shall include the Make, Model, Software Description/ Version (i.e. software validation report for 21 CFR Part 11 Compliance part by part for each clause e.g. data integrity, audit trail, password protection, date & time lock and user authorizations etc.) for analytical equipments i.e. HPLC (equipped with specific accessories e.g. Amphoteric ECD detector with dual glassy carbon electrodes for azithromycin Capsule & Oral Suspension), Raman Spectrum for Lincomycin Hydrochloride Capsule and Dissolution Apparatus for Slow Release & Extended Release OSDs etc. and Number and utilized/ available capacity of stability chambers used for stability studies program to facilitate the review/ disposition by the members of the Registration Board. Members of the inspection panel shall be adequately trained to verify the same during their site inspection. Current stability data verifications/ inspection checklist can be revised in the light of above-mentioned points.
4. Outcome of regulatory panel inspection e.g. DML renewal, GMP inspections, stability data review or Product Specific Inspections (PSI) shall be available on DRAP website and it shall have a follow-up for the compliance/ surveillance of manufacturing/ supply of deregistered products/ un-approved areas.

5. Develop and delegate ISO/ IEC 17025 Accredited 3rd party drug testing laboratory(ies) and Bioequivalence Centers for the pre-registration test/ analysis for registering safe, effective & quality drug products.

6. **Directions for Manufacturer by DRAP:** All Pharmaceutical Manufacturers must mention the "Procut Specifications" clearly on the packaging material along with the API Specifications as per the requirements of Packaging & Labeling Rule 1986 clause 11 and respective SROs. Punjab Drugs Testing Laboratories have been directed by PQCB-Punjab that all drug product mentioning the "Procut Specifications as "Manufacturer Specifications (MS)" even the product is available in any of the Pharmacopoeia then such products will be reported as Mis-branded with immediate effect. Manufacturer must provide current updated Complete Validated Method of Analysis provided for all products labelled as "Manufacturer Specifications (MS)" and not available in any Pharmacopoeia.

7. Drugs that are not included in any of the previous three editions of British Pharmacopoeia (BP), United States Pharmacopoeia (USP), European Pharmacopoeia (EP), International Pharmacopoeia (IP), or British Pharmaceutical Codex (BPC) or not been included in the list of International Non-proprietary Names (INN) published by World Health Organization (WHO), should not be approved for manufacture, unless desperately required by the country.

**Discussion of 287th meeting of Registration Board**

Discussion: Registration Board appreciated the efforts of Director DTL Lahore, Government of Punjab for his valuable input. It was apprised that Registration Board has already taken various steps for further enhancing quality parameters like adaptation of CTD as registration dossier, investigation / root cause analysis for Out of Specifications (OOS) results, amendment in Drug Specification Rules, 1976, etc. However, above points will be deliberated is detail in forthcoming meeting.

**Decision:** **Registration Board appreciated Director DTL Lahore, Government of Punjab for his valuable input. The Board decided to incorporate the following two queries with Question no. 30 & 35 respectively in the questionnaire for the onsite for the verification of stability study**

- **Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations.**
- **Number and utilized/available capacity of stability chambers.**

**Item No. III Division of Pharmaceutical Evaluation & Registration**

**Pharmaceutical Evaluation Cell**

| S.No. | Detail |
|---|---|
| Case No. 01 | **Review of Formulation.** |
| Case No. 02 | **Registration Applications for Local Manufacturing of (Human) Drugs.** |
| | a. New cases |
| | b. Deferred cases |
| Case No. 03 | **Registration Applications of Newly Granted DML or New Section (Human)** |
| | a. New DML |
| | b. New/Additional section (s) |
| | c. Remaining products of new section |
| | d. Deferred cases |
| Case No. 04 | **Registration Applications for Local Manufacturing of (Veterinary) Drugs.** |
| | a. New Cases |
| | b. Deferred Cases |
| Case No. 05 | **Registration Applications of Newly Granted DML or New Section (Veterinary)** |
| | a. New DML /section |
| Case No. 06 | **Registration Applications of Categories to be Considered on Priority.** |
| | a. Export Facilitation |
| | b. Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting |
| | c. Applications submitted on CTD format |
| | d. Import applications of priority categories defined by Registration Board in its 257th meeting |
| Case No. 07 | **Registration Applications of Import Cases.** |
| | a. New Cases (Human) |
| | b. New Cases (Veterinary) |
| | c. Deferred cases |
| | i. Human |
| | ii. Veterinary |
| Case No. 08 | **Registration Applications of Drugs for which Stability Study Data is Submitted.** |
| | a. New cases |
| | b. Deferred cases |
| | c. Onsite Verification of stability study data |
| | d. Exemption from onsite verification of stability data |
| Case No. 09 | **Miscellaneous Cases.** |
| | a. Case Referred by Appellate Board |
| | |

**Case No. 01: Review of Formulation.**

**a) Review of Quinolone- and Fluoroquinolone-Containing Medicinal Products.**

The case was deferred by Registration Board for further deliberation in 287th meeting. In May 2016, the FDA conducted a review of disabling and potentially permanent serious side effects of systemically applied fluoroquinolones resulting in a restriction of use in less severe infections such as acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections, particularly in patients who have other treatment options. A similar approach was recently followed by Health Canada.

In view of the above, Germany decided to refer the matter to the Pharmacovigilance Risk Assessment Committee (PRAC) on 1st February 2017 that it gives its recommendation as to whether marketing authorizations of these products should be maintained, varied, suspended, or revoked. The referral included following drugs in all strengths, and pharmaceutical forms for systemic and inhalational use: (Accessed from https://www.ema.europa.eu/documents/referral/quinolone-fluoroquinolone-article-31-referral-notification_en.pdf dated: 31-12-2018)

1. Nalidixic acid
2. Pipemidic acid
3. Cinoxacin
4. Enoxacin
5. Pefloxacin
6. Lomefloxacin
7. Ciprofloxacin
8. Levofloxacin
9. Ofloxacin
10. Moxifloxacin
11. Norfloxacin
12. Prulifloxacin
13. Rufloxacin
14. Flumequin

PRAC on 5th October 2018 completed its review and issued recommendations (Accessed from: https://www.ema.europa.eu/documents/referral/quinolone-fluoroquinolone-article-31-referral-prac-recommends-restrictions-use_en.pdf dated 31-12-2018) which were forwarded to Committee for Medicinal Products for Human Use (CHMP) for its opinions. The final opinion of CHMP was published on 16th November 2018 (Accessed from: https://www.ema.europa.eu/documents/referral/quinolone-fluoroquinolone-article-31-referral-disabling-potentially-permanent-side-effects-lead_en.pdf dated 31-12-2018). The recommendations will be forwarded to European Commission for final decision. The overall recommendations are as follows:

Disabling and potentially permanent side effects lead to suspension or restrictions of quinolone and fluoroquinolone antibiotics, EMA has reviewed serious, disabling and potentially permanent side effects with quinolone and fluoroquinolone antibiotics given by mouth, injection or inhalation. The review incorporated the views of patients, healthcare professionals and academics presented at EMA's public hearing on fluoroquinolone and quinolone antibiotics in June 2018.

EMA's human medicines committee (CHMP) has endorsed the recommendations of EMA's safety committee (PRAC) and concluded that the marketing authorization of following medicines should be SUSPENDED.

1. Cinoxacin
2. Flumequine
3. Nalidixic acid and
4. Pipemidic acid

The CHMP confirmed that the use of the remaining fluoroquinolone antibiotics which included following should be RESTRICTED.

1. Enoxacin
2. Pefloxacin
3. Lomefloxacin
4. Ciprofloxacin
5. Levofloxacin
6. Ofloxacin
7. Moxifloxacin
8. Norfloxacin
9. Prulifloxacin
10. Rufloxacin

In addition, the prescribing information for healthcare professionals and information for patients will describe the disabling and potentially permanent side effects and advice patients to stop treatment with a fluoroquinolone antibiotic at the first sign of a side effect involving muscles, tendons or joints and the nervous system.

Restrictions on the use of fluoroquinolone antibiotics will mean that they should NOT be used:

- to treat infections that might get better without treatment or are not severe (such as throat infections);
- to treat non-bacterial infections, e.g. non-bacterial (chronic) prostatitis;
- for preventing traveller's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
- to treat mild or moderate bacterial infections unless other antibacterial medicines commonly recommended for these infections cannot be used.

Importantly, fluoroquinolones should generally be AVOIDED in patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic. They should be used With Special Caution in the elderly, patients with kidney disease and those who have had an organ transplantation because these patients are at a higher risk of tendon injury. Since the use of a corticosteroid with a fluoroquinolone also increases this risk, combined use of these medicines should be avoided.

*The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU countries.* National authorities will enforce this decision for the fluoroquinolone and quinolone medicines authorised in their countries and they will also take other appropriate measures to promote the correct use of these antibiotics.


**Information for Healthcare Professionals:**

- Fluoroquinolones are associated with prolonged (up to months or years), serious, disabling and potentially irreversible drug reactions affecting several, sometimes multiple, systems, organ classes and senses.

- The serious side effects include tendonitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia, depression, fatigue, memory impairment, sleep disorders, and impaired hearing, vision, taste and smell.
- Tendon damage (especially to Achilles tendon but also other tendons) can occur within 48 hours of starting fluoroquinolone treatment but the damage may be delayed several months after stopping treatment.
- Patients who are older, have renal impairment or have had solid organ transplantation and those being treated with a corticosteroid are at higher risk of tendon damage. Concomitant treatment with a fluoroquinolone and a corticosteroid should be avoided.
- Fluoroquinolone treatment should be discontinued at the first sign of tendon pain or inflammation and patients should be advised to stop treatment with a fluoroquinolone and speak with the doctor in case of symptoms of neuropathy such as pain, burning, tingling, numbness or weakness so as to prevent development of potentially irreversible condition.
- Fluoroquinolones should generally not be used in patients who have had serious adverse reactions associated with the use of quinolone or fluoroquinolone medicines.
- Up-to-date summary of product characteristics should be consulted for authorized indications when considering treatment with a fluoroquinolone medicine. This is because the indications for these medicines have been restricted.
- The benefits and risks of fluoroquinolones will be monitored continuously and a drug utilization study will evaluate the effectiveness of the new measures to reduce inappropriate use of fluoroquinolones by investigating changes in prescribing behavior.

**Information for Patients:**

- Fluoroquinolone medicines (which contain ciprofloxacin, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin and rufloxacin) can cause long-lasting, disabling and potentially permanent side effects involving tendons, muscles, joints and the nervous system.
- These serious side effects include inflamed or torn tendon, muscle pain or weakness, and joint pain or swelling, walking difficulty, feeling pins and needles, burning pain, tiredness, depression, problems with memory, sleeping, vision and hearing, and altered taste and smell.
- Tendon swelling and injury may occur within 2 days of starting treatment with a fluoroquinolone but may even occur several months after stopping treatment.
- Stop taking a fluoroquinolone medicine and contact your doctor at once in the following cases:
    - at the first sign of tendon injury, such as tendon pain or swelling–rest the painful area;
    - if you get pain, feel pins and needles, tingling, tickling, numbness or burning, or weakness especially in the legs or arms;
    - if you get swelling in the shoulder, arms or legs, have walking difficulty, feel tired or depressed or have problems with your memory or with sleeping or you notice changes with your vision, taste, smell or hearing. You and your doctor will decide if you can continue treatment or if you need to take another type of antibiotic.
- You may be more prone to joint pain or swelling or tendon damage if you are aged over 60 years, your kidneys do not work well or you have received organ transplantation.
- Speak with your doctor if you are taking a corticosteroid (medicines such as hydrocortisone and prednisolone) or need to have treatment with a corticosteroid. You may be especially prone to tendon damage if you are taking a corticosteroid and a fluoroquinolone medicine at the same time.
- You should not take a fluoroquinolone medicine if you have ever had a serious side effect with a fluoroquinolone or a quinolone medicine and you should speak with your doctor immediately.
- If you have any questions or concerns about your medicines, speak to your doctor or pharmacist.

**FDA Review of Quinolones.**

FDA has started reviewing quinolones due to safety issues in 2016 and recently issued warning and suggested changes in safety information in 2018. As per safety announcement of 20-12-2018 "*A U.S. Food and Drug Administration (FDA) review found that fluoroquinolone antibiotics can increase the occurrence of rare but* ***serious events of ruptures or tears in the main artery*** *of the body, called the aorta. These tears, called aortic dissections, or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death. They can occur with fluoroquinolones for systemic use given by mouth or through an injection.*

*Fluoroquinolones should not be used in patients at increased risk unless there are no other treatment options available. People at increased risk include those with a history of blockages or aneurysms (abnormal bulges) of the aorta or other blood vessels, high blood pressure, certain genetic disorders that involve blood vessel changes, and the elderly. We are requiring that a new warning about this risk be added to the prescribing information and patient Medication Guide for all fluoroquinolones.*

FDA has only approved following qunilones and there review is also limited to these approved quinolones only.

**List of FDA-Approved Fluoroquinolones for Systemic Use**

| Brand Name | Active Ingredient |
|---|---|
| Avelox | moxifloxacin[+] |
| Baxdela | delafloxacin |
| Cipro | ciprofloxacin[+] |
| Cipro extended-release[±] | ciprofloxacin extended-release |
| Factive | gemifloxacin[+] |
| Levaquin | levofloxacin[+] |
| Ofloxacin (Generic brand)[±] | ofloxacin |

[+] available as brand and generic
[±] available only as generic

**Decision: Keeping in view above status, Registration Board decided to re-consider the case after decision of EMA and other reference regulatory authorities.**

**Evaluator PEC-II**

**b) Registration of Linagliptin and Other Cases of Similar Nature.**

The registration of "Linaglitpin" and other cases of similar nature, including registration of "Ferric carboxymaltose" containing products, are pending before the Drug Registration Board for it sconsideration since long. In this regard, the IPO of Pakistan furnished its opinion vide letter No. 2/AD-patent/2006 dated 11th November, 2015. The said case was placed before Registration Board in its 278th meeting held on 29th to 31st January, 2018 along with following opinion of Legal Affair Division, DRAP,

"This Division is of the concerted opinion that the approach of IPO-Pakistan would create a system of "patent linkage" i.e. practice of linking drug marketing approval to the status of the patent of the originator's product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term, unless consented to by the patent owner. The concept of patent linkage requires the generic manufacturer to prove that the drug, for which he seeks approval, is not covered by a valid patent.

1. The assertion that drug approval cannot be granted for any drug that is likely to violate any existing patent right is highly misleading on following grounds:-

(i) The grant of drug regulatory approval cannot, by itself amount to a patent infringement.

(ii) The existence of patent infringement cannot be assumed merely because the patentee states so, but has to be clearly established before a court of law in accordance with the infringement provisions mentioned under the Patents Ordinance, 2000. Such an

assessment is beyond the statutory powers of the Drug Registration Board, which may not be able to deal with complex issues of patent scope, validity and infringement.

2. The mere grant of a drug regulatory approval, would not, ipso facto, entail a contravention of the Patent Ordinance or any other law. Section 30 of the Patents Ordinance, 2000 spells out the various exclusive rights of a patentee and includes the acts of "making, using, offering for sale, selling or importing" the patented product or process as the case may be. The grant of a drug regulatory approval on the basis that drug is safe and effective does not amount to an act of "making, using, offering for sale, selling or importing" the patented product.

3. Section 30(5)(e) of the Patents Ordinance, 2000 clearly stipulates that the rights under the patent shall not extend to acts, including tests, necessary for the approval of a product. It is highly illogical to argue that when all acts leading up to the stage of drug approval are exempt from patent infringement, the very act of approval itself amounts to an infringement. The aforesaid section permits any drug manufacturer to experiment with any patented drug with a view to generating data that could then be submitted to a drug control authority. The aim of this section is to ensure that generic drugs are introduced into the market as soon as the patent expires or is invalidated, so that consumers may benefit from this early entry of affordably priced drugs. On the contrary, if generis manufacturers are not allowed to start with their proceedings for regulatory approval during validity of a patent, it would indirectly amount to an extension of the term for exclusive patent rights to the rights holder.

4. More importantly, neither is the Drug Registration Board authorized by the DRAP Act, 2012 or the Drugs Act, 1976 and rules made thereunder to make assessment of patent infringement nor does it possess the institutional competence to make such an assessment. Under section 18 of the IPO Act, 2012, it is only the IP Tribunal that can make such an assessment in an infringement suit filed under the Patents Ordinance, 2000.

5. The countries that follow a system of patent linkage have a specific statutory or other legal provision enabling such linkage. In fact, even developed countries such as the EU have, for several policy reasons, avoided creating a patent linkage mechanism.

6. Patent linkage falls under the umbrella of 'TRIPS Plus' concept, i.e. higher intellectual property standards negotiated among WTO members subsequent to TRIPS agreement. This concept covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions.

7. The system of patent linkage is against public health interests as the time gap between expiration of patent protection period of a drug and the introduction of its generic equivalent in the market can prove disadvantageous. Grant of marketing approval does not in any manner infringe the patent holder's rights. The approval sought is only addressing the drug as safe and bestowing upon it the right to carry on clinical trials, so that as soon as a valid patent expires, it is ready to enter the market without any further delay.

8. Therefore, keeping in view the exceptions provided in law and public health interest, it is proposed that the drug marketing approval should not be linked to the patent status of the originator's product by the Drug Registration Board."

The Board in 278th meeting decided as under:

**"Legal Affair Division, DRAP furnished their opinion vide letter No.F.11-1/2013 /DD(LA) dated 31.01.2018, thus Registration Board decided to forward forementioned opinion to IPO Pakistan for their comments. Moreover, Deputy Director, Legal Affair Division, DRAP was advised to follow up the matter with IPO Pakistan for their response."**

Accordingly, IPO-Pakistan was requested by Deputy Director (Legal Affairs Division) to furnish its comments vide letter No. F.11-1/2013/DD (LA) dated 14-03-2018. IPO-Pakistan forwarded its views/comments vide letter No. 02/AD-I (Patents)/2008 dated 2nd October, 2018 which are reproduced as under:

"With reference to DRAP's letter No. F.11-1/2013/DD (LA) DATED MARCH 14, 2018, on the above noted subject, the comments are as under:

2. The matter of use of rights by third parties, for patented products against Patent No.141311. 141044, and 141068, has already been decided by Sindh High Court, Karachi. The decision was made after detailed arguments between the parties and in light of the Patent Ordinance, 2000. The same is reproduced as:

"…. till the validity of Plaintiff's Patent No. 141311, 141044, 141068, Defendants are restrained from selling, 'Linagliptin' containing products or manufacturing or making formulating supplying, stocking, importing, exporting, offering for sale, passing off, advertising or otherwise enabling others to infringe or pass off, offer for sale or use in any form in any manner which is in infringement of the claims of the petitioners patent, Resultantly, pending application(s) is also disposed of…."

3. The referred Section 30(5) e of the Patent Ordinance, 2000, in the DRAP letter, is an exception to the Patent rights established under this Ordinance with certain limitation. Accordingly to Section 30(5) E, the rights under patent shall not extend to acts, including tests, necessary for approval of a product for its commercialization after the expiration of the patent.

4. DPAP's Drug Registration Board has a purview with regard to the approval of a product that also includes its commercialization, however the said exception of the Patents law shall be applied with limitation to commercialization after the expiration of the patents.

5. The concept of Patent linkage falls under the umbrella of 'TRIPS plus'. The developing countries including Pakistan do not support the concept of Patent linkage.

6. Three products (Drugs) containing Linagliptin are valid patents granted to a German firm (the applicant), BOEHRINGER INGELHEIM INTERNATIONAL GMBH by the patent Office, Karachi as per following details:

| SN | Patent No. | Filing date/Novelty date | Patent Expiry date | Next renewal date | Current patent validity status |
|---|---|---|---|---|---|
| 1 | 141311 | 21/08/2002 | 20/08/2022 | 21/08/2019 | Valid |
| 2 | 141044 | 05/11/2004 | 04/11/2024 | 05/11/2018 | Valid |
| 3 | 141068 | 14/05/2009 | 13/05/2029 | 14/05/2019 | Valid |

7. In view of the above legal references and the decision of Singh High Court, Karachi, it is concluded the rights of commercialization of Linagliptin and similar products, patented in Pakistan, Only confer to the patentee(s) till the validity of their respective granted patent(s). However, third parties have rights for acts, including tests, necessary for approval of Linagliptin etc., for its commercialization after of the patent(s), under Section 30(5) e of patents Ordinance, 2000."

**Discussion & Decision:**

1. The matter for registration of *Linagliptin* containing products and other cases of similar nature were considered by Registration Board.

2. Mr. Aamar Latif, Deputy Director (Legal Affairs), DRAP briefed the members about the issue of "patent linkage" i.e. practice of linking drug marketing approval to the status of the patent of the originator's product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term, unless consented to by the patent owner. The Board was informed that the concept of patent linkage requires the generic manufacturer to prove that the drug, for which he seeks approval, is not covered by a valid patent.

3. The assertion that drug approval cannot be granted for any drug that is likely to violate any existing patent right is highly misleading on following grounds:-

(i) The mere grant of a drug regulatory approval, would not, ipso facto, entail a contravention of the Patents Ordinance, 2000 or any other law. Section 30 of the Patents Ordinance, 2000 spells out the various exclusive rights of a patentee and includes the acts of "making, using, offering for sale, selling or importing" the patented product or process as the case may be. The grant of a drug regulatory approval on the basis that

drug is safe and effective does not amount to an act of "making, using, offering for sale, selling or importing" the patented product.

(ii) The Drug Registration Board is solely concerned with scientific quality, safety and efficacy of drugs as mandated under the Drugs Act, 1976 and Drugs (Licensing, Registering and Advertising) Rules, 1976. The Board has no expertise in patent rights policing.

(iii) The existence of patent infringement cannot be assumed merely because the patentee states so, but has to be clearly established before a court of law in accordance with the infringement provisions of the Patents Ordinance, 2000. Such an assessment is beyond the statutory powers of the Drug Registration Board, which may not be able to deal with complex issues of patent scope, validity and infringement.

(iv) Patent rights are private rights. Section 60 of the Patents Ordinance, 2000 read with section 18 of the Intellectual Property Organization of Pakistan Act, 2012 sets out the jurisdiction of Intellectual Property Tribunals in respect of infringement suits. Therefore, the State–the Drug Registration Board in this instance – cannot enforce the private rights of a patentee. More importantly, neither is the Drug Registration Board authorized by the Drugs Act, 1976 and rules made there under to make assessment of patent infringement nor does it possess the institutional competence to make such an assessment. Under section 18 of the IPO Act, 2012, it is only the Intellectual Property Tribunal that can make such an assessment in an infringement suit filed under section 60 of the Patents Ordinance, 2000.

(v) Patent linkage potentially undermines the "Bolar/Early Working" exception that encourages quick access to the post patent markets for generic medicines. Section 30(5)(e) of the Patents Ordinance, 2000 clearly stipulates that the rights under the patent shall not extend to acts, including tests, necessary for the approval of a product. It is illogical to argue that when all acts leading up to the stage of drug approval are exempt from patent infringement, the very act of approval itself amounts to an infringement.

(vi) Section 60 of the Patents Ordinance, 2000 sets out the defenses available in suits for infringement. It states that every ground on which a patent may be revoked under the provisions of this Ordinance shall be available by way of defense to a suit for infringement. The conditions under which a patent is granted are also available as a defense. The Patents Ordinance actually contemplates that a person can take the risk of facing an infringement proceeding and seek revocation in its counterclaim. This remedy to challenge a patent by way of counterclaim cannot be closed off, by preventing a party other than the patentee from selling a patented product, before the other party has actually infringed the patent.

(vii) In the present scheme of law, the concept of patent linkage would make various provisions of the Patent Ordinance, 2000 useless. Those particularly relate to patent policing, such as enforcement of patent standards, in the context of infringement complaints, such as post grant oppositions, challenges before the Controller of Patents and suits in the Intellectual Property Tribunal / High Court. Before each such body, the patentee has to establish and prove infringement, wherever alleged, and may, in some cases, face challenges to the grant of its patent. Such crucial provisions, conceived in public interest, would be rendered a dead letter, if the Drug Registration Board, on a representation of the patentee were to refuse drug marketing approval, to applicants who otherwise satisfy the requirement of the Drugs Act, 1976 and Drugs (Licensing, Registering and Advertising) Rules, 1976, or even be precluded from examining such applications, on assumed infringement.

(viii) The countries that follow a system of patent linkage have a specific statutory or other legal provision enabling such linkage. In fact, even developed countries such as the EU have, for several policy reasons, avoided creating a patent linkage mechanism. Patent linkage falls under the umbrella of 'TRIPS Plus' concept, i.e. higher intellectual

property standards negotiated among WTO members subsequent to TRIPS agreement. This concept covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions.

4. During the discussion, the observer representing Pharma Bureau argued that a combined reading of the Drugs Act, 1976 and the Patents Ordinance 2000 lead to the conclusion that no marketing approval can be granted to applicants for drugs or formulations, of which others are patent owners, by reason of section 2 of the Drugs Act, 1976 read with sections 30 of the Patents Ordinance, 2000. He was informed that the grant of the patent does not guarantee its validity. Section 16(5) of the Patents Ordinance, 2000 stipulates that the investigation required under this section shall not be held in any way to guarantee the validity of any patent, and no liability shall be incurred by the Federal Government or any officer by reason of, or in connection with, any such investigation or any proceeding consequent thereon. In another words, a patent granted to an applicant can be challenged on various grounds in accordance with the Patents Ordinance, 2000. When a suit for infringement is filed by the patent holder, the defendant can always raise, as part of its defense, a challenge to the validity of the patent, under section 60 of the Patents Ordinance, 2000.

5. Section 30 of the Patents Ordinance, 2000, subject to the other provisions of the Ordinance, confers on the patentee, both where the subject matter of the patent is a product or a process, the exclusive right to prevent third parties, without prior permission of the patent holder, from making, using, offering for sale, selling or importing for those purposes in Pakistan the patented product or a product obtained by the patented process. This is a negative right which is enforceable at the instance of the patent holder and only subject to other provisions which permit challenge to the validity of the patent to be raised as a defense in a suit for infringement of the patent. This is evident from sections 46 and 60 of the Patents Ordinance, 2000. Therefore, in relation to any steps that a patent holder might wish to take to protect the patent from being infringed, resort should be had only to the provisions of the Patents Ordinance.

6. Further, section 102 of the Patents Ordinance, 2000 (omitted by the Patents Amendment Ordinance, 2002) stipulated that "subject to the other provisions of this Ordinance, a patent shall have to all intents the like effect as against the Government as it has against any person". Even if this provision was not omitted, it would not mean that the Drug Registration Board has to enforce and protect the patent for the product, in respect of which marketing approval is sought, from being infringed. It was a negative obligation on the government not to infringe. It created no duty or positive obligation on the Federal Government, or any department thereof, to protect a patent from infringement.

7. Keeping in view the above discussion and public health interest, the Board decided that the drug marketing approval / grant of registration should not be linked to the patent status of the originator's product.

**c) Tranexamic acid Capsule 500mg**

The formulation of tranexamic acid 500mg capsule was deferred by Registration Board from various meetings, now the reference has been verified from The Italian Medicine Agency (AIFA).

The formulation is available in Italy and registered by AIFA Italy in the following strength and dosage form. The details of product registration are as follows

- **Brand Name:** TRANEX 500 mg capsules
- **Market Authorization number:** AIC n. 022019020
- **Composition**

  **Active ingredient:**

  Each capsule contains Tranexamic acid……500mg
- **Marketing Authorization holder:** MALESCI INSTITUTE FARMACOBIOLOGICO SpA, Italy.
- **Link for reference:** https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/farmaco?farmaco=022019 (Accessed on 31-01-2019)

The following previously deferred cases of the same formulation are hereby presented before the Board:

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| 1. | Name and address of manufacturer / Applicant | M/s StandPharm (Pvt.) limited, 20 Km Ferozepur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Tramic capsule 500mg |
| | Composition | Each capsule contains:<br>Tranexamic acid……..500mg |
| | Diary No. Date of R& I & fee | Dy.No.17184; 05-10-2017; Rs.20,000/- (04-10-2017) |
| | Pharmacological Group | Anti- fibrinolytic agent |
| | Type of Form | Form-5 |
| | Finished Product Specification | Not provided |
| | Pack size & Demanded Price | 2x 10's & Rs. 16.5/- per cap |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Maxna 500mg capsule of M/s AGP Ltd (Reg.#032378) |
| | GMP status | Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | • The official monograph of the applied formulation is not available in USP and BP.<br>• The evidence of approval in reference regulatory authorities could not be confirmed. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting (M-285) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• The GMP inspection report stated in this case falls within period of last 3 years |
| | **Decision: Approved with JP specification.** | |
| 2. | Name and address of manufacturer / Applicant | M/s Islam Pharmaceuticals,7 km, Pasrur Road, Sialkot |
| | Brand Name +Dosage Form + Strength | Tramic Capsule 500mg |
| | Composition | Each Capsule Contains:<br>Tranexamic Acid…500mg |
| | Diary No. Date of R& I & fee | DyNo.29174;31-08-2018; Rs. 20,000/- |
| | Pharmacological Group | Antifibrinolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 20's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Traxic 500mg Capsules of Fassgen Pharmaceuticals, |
| | GMP status | New License (letter issuance date: 29th August 2018) |
| | Remarks of the Evaluator. | Evidence of approval status of applied formulation in reference agencies is required as provided evidence has not been verified. |
| | Decision of previous meeting of RB | Deferred for evidence of approval status of applied formulation i.e. "Tranexamic Acid 500mg Capsule" in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting (M-285) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• The GMP inspection report stated in this case falls within period of last 3 years |
| | **Decision: Approved with JP specification.** | |
| 3. | Name and address of manufacturer / Applicant | Cunnigham Pharmaceuticals (Pvt) Ltd. Plot No. 81 Sundar Industrial Estate Raiwind Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Tranmic 500mg Capsule |

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| | Composition | Each Capsule contains:<br>Tranexamic acid…. 500mg |
| | Diary No. Date of R& I & fee | Dy No.18687; 22-05-2018; Rs.20,000/- |
| | Pharmacological Group | Anti-fibrinolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Specifications |
| | Pack size & Demanded Price | 2×10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Traxic 500mg Capsules of Fassgen Pharmaceuticals, |
| | GMP status | New License (letter Issuance Date: ) |
| | Remarks of the Evaluator. | Applicant has added 5 % overage in master formulation. Evidence of approval status of applied formulation in reference agencies is required. |
| | Decision of previous meeting of RB | Deferred for the following:<br>• Justification on scientific basis for addition of 5% overage in master formulation.<br>• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. (M-284) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 31-1-2018 concludes as "It was a new unit constructed purposefully for the production of pharmaceuticals and granted license by way of formulation in march 2016. On the basis of finding of the panel it was concluded that the firm was operating under good compliance of cGMP on the day of inspection. |
| | **Decision: Deferred for Justification on scientific basis for addition of 5% overage in master formulation.** | |
| 4. | Name and address of manufacturer / Applicant | M/s Nabi Qasim Industries Pvt Ltd, Karachi |
| | Brand Name +Dosage Form + Strength | Transic capsule 500mg |
| | Composition | Each capsule contains:<br>Tranexamic acid…….500mg |
| | Diary No. Date of R& I & fee | Dy. No.1461; 29-8-2017; Rs.20,000/- (22-8-2017) |
| | Pharmacological Group | Haemostatic/Fibrinolytic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's Specification |
| | Pack size & Demanded Price | 20's, 30's, 100's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | HAEMIC-500mg by GENIX |
| | GMP status | GMP status Last inspection conducted on 03-8-2017 and 02-11-2017 reports conclude that firm is found GMP compliant. |
| | Remarks of the Evaluator. | Approval status in RRA could not be confirmed. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in 275th meeting (M-283) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 02-08-2018 concludes as "Based on the area inspected, people met, and documents reviewed and considering the finding of the inspection, M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of cGMP requirements at the time of inspection" |
| | **Decision: Approved with JP specification.** | |

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| 5. | Name and address of manufacturer / Applicant | M/s Danas Pharmaceuticals, Islamabad |
| | Brand Name +Dosage Form + Strength | Danim 500mg capsules |
| | Composition | Each capsule contains:<br>Tranexamic acid….500mg |
| | Diary No. Date of R& I & fee | Dy. No.4160; 30-05-2017; Rs.20,000/- (29-5-2017) |
| | Pharmacological Group | Anti-fibrinolytic |
| | Type of Form | Form-5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | 2x10's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | HAEMIC-500mg by M/s GENIX, Karachi |
| | GMP status | The firm was granted GMP certificate based on inspection conducted on 03-10-2017. |
| | Remarks of the Evaluator. | Approval status in RRA could not be confirmed. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. (M-282) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• The GMP inspection report stated in this case falls within period of last 3 years |
| | **Decision: Approved.** | |
| 6. | Name and address of manufacturer / Applicant | M/S Epharm Laboratories, A-40, Road No.1, S.I.T.E, Super Highway, Industrial Area, North Karachi, Pakistan. |
| | Brand Name +Dosage Form + Strength | Ephamic-500mg Capsules |
| | Composition | Each capsule contains:<br>Tranexamic Acid----500mg |
| | Diary No. Date of R& I & fee | Dy.No.1180, 11-01-2017, Rs.20,000/- |
| | Pharmacological Group | Haemostatic/Fibrinolytic |
| | Type of Form | Form-5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | 10's,20's,30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | HAEMIC-500mg by GENIX |
| | GMP status | Last Inspection report conducted on 27-04-2017 and panel is of the view to grant GMP certificate |
| | Remarks of the Evaluator. | •Approval status of product in Reference Regulatory Authorities not confirmed. Provided reference of Amchafibrin-500mg Capsules by Rottapharm Spain could not be confirm in capsule.<br>On asking about the clarification regarding submission of accelerated stability studies data before production starts the firm reply that submitted study is for small scale trail batch however the long term accelerated and real time stability will be submitted after production starts. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting (M-279) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report 01-03-2018 concludes as "Based on above observations and keeping in view the attitude of the management towards the continuous |

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| | | improvements their current level of compliance was noted as satisfactory." |
| | **Decision: Approved.** | |
| 7. | Name and address of manufacturer / Applicant | M/s NOA HEMIS Pharmaceuticals, Plot No. 154 Sector 23 Korangi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Extam-D Capsule 500mg |
| | Composition | Each capsule contains:<br>Tranexamic acid… 500mg |
| | Diary No. Date of R& I & fee | Dy No.1159; 15-12-2015; Rs.20,000/- |
| | Pharmacological Group | Hemostatics /Antifibrinolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | 10's, 20's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Maxna 500mg capsules by Novartis. |
| | GMP status | Last GMP Inspection dated 14-6-17 with conclusive remarks of cGMP compliance. |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation in Reference Regulatory Authorities. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-278) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 09-08-2018 confirms good compliance to GMP |
| | **Decision: Approved.** | |
| 8. | Name and address of manufacturer / Applicant | M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Inxamic Capsules 500mg |
| | Composition | Diary No: 24118 , 13-12-2017 , Rs: 20,000/- |
| | Diary No. Date of R& I & fee | Each capsule contains:-<br>Tranexamic Acid....500mg |
| | Pharmacological Group | Antifibrinolytic |
| | Type of Form | Form-5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | 20's, 100's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Trasamin 500mg Capsule by M/s Hilton Pharma (Reg#009730) |
| | GMP status | 13-07-2017; Grant of new DML,<br>Panel recommends grant of new DML. |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-278) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• The GMP inspection report stated in this case falls within period of last 3 years, no latest inspection report could be confirmed |
| | **Decision: Approved.** | |
| 9. | Name and address of manufacturer / Applicant | M/s Treat Pharmaceutical Industry(Pvt.) Ltd. A-37, Small Industrial Estate Township Kohat Road Bannu. |
| | Brand Name +Dosage Form + Strength | TRANXAM 500mg CAPSULES |

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| | Composition | Each capsule contains:-<br>Tranexamic acid…500mg |
| | Diary No. Date of R& I & fee | Diary No: 26574, 29/12/2017, Rs: 20,000/- |
| | Pharmacological Group | Antifibrinolytics (Amino acids) |
| | Type of Form | Form-5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | 2x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Caprilon (Finland)/Hexatron (Japan) not confirmed. |
| | Me-too status | Trasamin 500mg Capsule by M/s Hilton Pharma (Reg#009730) |
| | GMP status | Routine GMP inspection dated 06-11-2018 concluded, the firm may be considered to be operating at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | Approved by AIFA of Italy |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board (M-278) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• The GMP inspection report stated in this case falls within period of last 3 years, no latest inspection report could be confirmed |
| | **Decision: Approved.** | |
| 10. | Name and address of manufacturer / Applicant | M/s N.S Pharma, Plot no. 576, 577 Sunder Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | Tramic 500mg Capsule |
| | Composition | Diary No. 16186, 26/09/2017, Rs: 20,000/- |
| | Diary No. Date of R& I & fee | Each capsule contains:-<br>Tranexamic Acid.....500mg |
| | Pharmacological Group | Plasminogen activation inhibitor |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's |
| | Pack size & Demanded Price | 20's/As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Transamin of Daiichi Sanko (Japan) (Not confirmed) |
| | Me-too status | Trasamin 500mg Capsule by M/s Hilton Pharma (Reg#009730) |
| | GMP status | 08-06-2017<br>Grant of new DML<br>Panel recommends grant of new DML. |
| | Remarks of the Evaluator. | Approved by AIFA of Italy |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation in Reference Regulatory Authorities (M-275) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• The GMP inspection report stated in this case falls within period of last 3 years, no latest inspection report could be confirmed |
| | **Decision: Approved with JP specification.** | |
| 11. | Name and address of manufacturer / Applicant | M/s. Lisko Pakistan,L-10-D, Block No 21, Shaheed Rashid Minhas Road, Federal B, Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Tranxic Capsule 500 mg |
| | Composition | Each capsule contains:<br>Tranexamic acid….500 mg |
| | Diary No. Date of R& I & fee | 665, 25-04-2016, Rs. 20,000/- (25-04-2016) |
| | Pharmacological Group | Fibrinolytic /Haemostatic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Not provided |

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| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Transamin of Hilton Pharmaceuticals |
| | GMP status | 23-01-2017, Good |
| | Remarks of the Evaluator. | M/s. Lisko Pakistan,L-10-D, Block No 21, Shaheed Rashid Minhas Road, Federal B, Industrial Area, Karachi |
| | Decision of previous meeting of RB | Deferred for the submission of evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting. (M-274) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 24-4-2018 concludes "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance.<br>• (Show cause notice revoked on 27-04-2018)" |
| | **Decision: Approved with JP specification.** | |
| 12. | Name and address of manufacturer / Applicant | M/s. Wellborne PharmaChem and Biologicals, Plot No. 51/1,52/2, Phase I-II, Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Transec Capsule 500mg |
| | Composition | Each capsule contain:<br>Tranexamic acid….500mg |
| | Diary No. Date of R& I & fee | Dy. No. 153, 16-06-2015 , Rs.20,000/- (16-06-2015) |
| | Pharmacological Group | Anti-fibrinolytic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Transamin of Hilton Pharmaceuticals |
| | GMP status | Last inspection conducted on 27-02-2017"Strictly following the GMP compliance." |
| | Remarks of the Evaluator. | • Firm have not applied on prescribed application format as per Schedule-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976. |
| | Decision of previous meeting of RB | Deferred for the following reasons:<br>□ Submission of evidence of approval of applied formulation in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 249th meeting.<br>□Submission of applied formulation on prescribed application format as per Schedule-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976. (M-274) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 27-6-2018 concludes "The firm was inspected to ascertain and assess the manufacturing testing facilities and to evaluate the GMP compliance. During the inspection, certain suggestions/improvements were made regarding the production, quality control and other facilities. The management of the firm agreed to comply with these suggestions at their earliest and look committed to bring the necessary improvements. The firm was also in the process of installation a 2D bar code printer to comply with DRAP guidelines. As per available production, quality control facilities and technical/qualified personnel |

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| | | employed, it is concluded the firm M/s Wellborn Pharmachem and Biologiclas Industrial Estate Hattar is operating under good level of cGMP."<br>• Firm has submitted new Form-5 |
| | **Decision: Approved with JP specification.** | |
| 13. | Name and address of manufacturer / Applicant | M/s Inventor Pharma, Plot No. K/196, S.I.T.E, (SHW) Phase-II, Karachi |
| | Brand Name +Dosage Form + Strength | Tranza 500mg Capsule |
| | Composition | Diary No: 13026, 22/08/2017, Rs: 20,000/- |
| | Diary No. Date of R& I & fee | Each capsule contains:-<br>Tranexamic Acid.....500mg |
| | Pharmacological Group | Plasminogen activation inhibitor |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Trasamin 500mg Capsule by M/s Hilton Pharma (Reg#009730) |
| | GMP status | New License (Inspection Date: 10th June 2017) |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation by reference regulatory authorities. (M-274) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 5-7-2018 concludes as "Keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD" |
| | **Decision: Approved.** | |
| 14. | Name and address of manufacturer / Applicant | PALPEX PHARMACEUTICALS (Pvt) Ltd.<br>Plot # FD-46-A8 Korangi Creek Industrial Park Karachi. |
| | Brand Name +Dosage Form + Strength | TRANSPAL Capsule 500 mg |
| | Composition | Each capsule contains<br>Tranexamic Acid ....500 mg |
| | Diary No. Date of R& I & fee | Dy. No. 5706, Dated 12/06/2017,<br>Rs 20,000/= Dated 12/06/2017, |
| | Pharmacological Group | Anti – Fibrinolytic |
| | Type of Form | Form – 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | Pack Size: 1×10's Price: As per S.R.O |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Trasamin 500mg Capsule by M/s Hilton Pharma (Reg#009730) |
| | GMP status | New License |
| | Remarks of the Evaluator. | • The firm has claimed USP specifications and the product is not present in USP/BP. However, the product is present in JP.<br>• Approval status of the product in reference regulatory authorities cannot be confirmed. |
| | Decision of previous meeting of RB | Deferred for evidence of approval in reference regulatory authorities. (M-272). |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• GMP certificate issued dated 8-5-2018 |
| | **Decision: Approved with JP specification.** | |

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| 15. | Name and address of manufacturer / Applicant | M/s Astellas Pharmaceutical (Pvt) Ltd.<br>Industrial Estate, Hayatabad, Peshawar. |
| | Brand Name +Dosage Form + Strength | Asmic 500mg capsules |
| | Composition | Diary No: 4378, 30/05/2017, Rs: 20,000/- |
| | Diary No. Date of R& I & fee | Each capsule contains:<br>Tranexamic acid…500mg |
| | Pharmacological Group | Antifibrinolytic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer‘s Specifications |
| | Pack size & Demanded Price | 20’s/ As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Trasamin 500mg Capsule by M/s Hilton Pharma (Reg#009730) |
| | GMP status | 31-03-17; Inspection of Additional Sections.<br>Panel recommends grant of additional sections |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed. |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied formulation by reference regulatory authorities. (M-272) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 2-10-2017 concludes as over all the firm was operating under satisfactory level of GMP." |
| | **Decision: Approved with JP specification.** | |
| 16. | Name and address of manufacturer / Applicant | Wimits Pharmaceuticals, Lahore |
| | Brand Name +Dosage Form + Strength | Xamic 500mg capsules |
| | Composition | Dy No:51; 23-12-2013; Rs.20,000/- |
| | Diary No. Date of R& I & fee | Each capsule contains<br>Tranexamic acid….500mg |
| | Pharmacological Group | Antifibrinolytics/Antiplasmenic agent |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer’s Specification |
| | Pack size & Demanded Price | 20’s As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Transamin by Himont |
| | GMP status | Last Inspection report 10-10-2016 firm had maintained conformance to GMP compliance in the manufacturing and quality control operations. |
| | Remarks of the Evaluator. | ➢ Fee challan photocopy is attached<br>➢ International availability in reference regulatory authorities is not confirmed.<br>➢ Firm has claimed Mfg Specs while the product is present in Japanese Pharmacopeia. |
| | Decision of previous meeting of RB | Deferred for evidence of approval status of formulation in the reference regulatory authorities. (M-271) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 3-11-2017 concludes as *“The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection.”GMP Certificate issued on 10-12-2018..*" |
| | **Decision: Approved with JP specification.** | |

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| 17. | Name and address of manufacturer / Applicant | M/s Rotex pharma, Islamabad |
| | Brand Name +Dosage Form + Strength | Voxin 500mg Capsule |
| | Composition | 34, 7-2-2011, Rs 8000, Rs 12000 |
| | Diary No. Date of R& I & fee | Each capsule contains:<br>Tranexamic acid……500mg |
| | Pharmacological Group | Antifibrinolytic hemostatic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 20's. 30's As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Maxna capsules 500mg by AGP |
| | GMP status | Last Inspection report 17-3-2017<br>The panel concluded that the company is following GMP guidelines. |
| | Remarks of the Evaluator. | ➢ Fee challan photocopy is attached.<br>➢ International availability in RRA cannot be confirmed.<br>➢ The firm has claimed manufacturer's specs and has not submitted the data as per requirement of the decision made in 267th meeting of DRB. |
| | Decision of previous meeting of RB | Deferred for evidence of approval in Reference Regulatory Authorities. (M-270) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• The GMP inspection report stated in this case falls within period of last 3 years, no latest inspection report could be confirmed |
| | **Decision: Approved with JP specification.** | |
| 18. | Name and address of manufacturer / Applicant | M/s. Martin Dow Limited, Plot No. 37 Sector 19, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Tivita 500mg Capsule |
| | Composition | Dy No. 1068, 30-06-2014, Rs.20000/- |
| | Diary No. Date of R& I & fee | Each capsule contains:<br>Tranexamic acid(USP) …500mg |
| | Pharmacological Group | Hemostatics, (Amino acid antifibrinolytics)( B02AA02) |
| | Type of Form | Form-5 |
| | Finished Product Specification | Mfg Specs |
| | Pack size & Demanded Price | 20's, 30's, 30's (alu/alu blister); As per brand leader's price. |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Maxna 500mg capsules by Novartis. |
| | GMP status | Last GMP Inspection of M/s Martin Dow conducted on 18-03-2016 with conclusive remarks of satisfactory level of cGMP compliance & overall it is rated as good.<br>Certificate of cGMP issued to the firm based on inspection conducted on 18-03-16 & is valid for a period of one year from the date of issue. |
| | Remarks of the Evaluator. | i. Firm has claimed Mfg Specs but has not submitted the data as required by decision taken in 267th R.B meeting, & the applied formulation does not exist in available USP & B.P.<br>ii. Firm has capsule general section. |
| | Decision of previous meeting of RB | Deferred for:<br>I. Evidence of approval, of applied formulation, by reference regulatory authorities as decided in 249th meeting of Registration Board as stated reference is incorrect |

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| | | II. Submission of GMP inspection report conducted within the period of last one year. (M-269) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 29-1-2018 concludes as *"After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personnel capacity the current GMP are rated as GOOD."* |
| | **Decision: Approved with JP specification.** | |
| 19. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals Rawat. |
| | Brand Name +Dosage Form + Strength | Exacyl-500 Capsules |
| | Composition | Each capsule contains:-<br>Tranexamic Acid……500mg |
| | Diary No. Date of R& I & fee | 11-07-2012 Rs.8000/= (Photocopy attached) 30-10-2014 Rs.12,000/= Dy.No.6945 |
| | Pharmacological Group | (Haemostatic) |
| | Type of Form | Form 5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | 2x10's As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Transamin of Hilton pharma |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | RRA not provided □<br>Firm claims manufacturer's specs |
| | Decision of previous meeting of RB | Deferred for evidence of approval by reference regulatory authorities. (M-268) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy |
| | **Decision: Approved with JP Specifications.** | |
| 20. | Name and address of manufacturer / Applicant | M/s Bio Labs (Pvt) Ltd, Islamabad |
| | Brand Name +Dosage Form + Strength | Tranex 500mg Capsules |
| | Composition | Each capsule contains:-<br>Tranexamic Acid ……..500mg |
| | Diary No. Date of R& I & fee | Dy.No.2695 Rs.8000/= 31-05-2012<br>Rs.12,000/= 28-07-2014 |
| | Pharmacological Group | (Antihaemorrhagics/ Antihaemophillic Preparations) |
| | Type of Form | Form 5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | 1x10's, 2x10's, 10x10's: As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Aneptil by Alina |
| | GMP status | Last inspection report of 16-8-2016 submitted with compliance remarks. |
| | Remarks of the Evaluator. | |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied dosage form & strength (formulation) by reference regulatory authorities (M-267) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• GMP certificate issued on the basis of inspection dated 5th and 6th December 2017. |
| | **Decision: Approved with JP specification.** | |

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| 21. | Name and address of manufacturer / Applicant | M/s Swiss PharmaceuticalKarachi |
| | Brand Name +Dosage Form + Strength | Utramax 500mg Capsule |
| | Composition | Each capsule contains:<br>Tranexamic Acid…..500 mg |
| | Diary No. Date of R& I & fee | Duplicate 28-7-2010, Dy.No.1449<br>Rs.8000/- (Photocopy) + Rs.12,000/-12-11-2014 |
| | Pharmacological Group | (Anti hemorrhagic) |
| | Type of Form | Form-5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | 20's Rs.250/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by AIFA of Italy |
| | Me-too status | Transamin by Hilton Pharma |
| | GMP status | Last inspection report 19-04-2016 Shows acceptable level of GMP compliance. |
| | Remarks of the Evaluator. | Reference Authority status could not be confirmed<br>□ Firm has claimed Mfg. Specs while the product is present in Japanese Pharmacopeia |
| | Decision of previous meeting of RB | Deferred for evidence of approval by reference regulatory authorities (M-266) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 18-10-2018 concludes as *GMP compliance level is rated as GOOD."* |
| | **Decision: Approved with JP specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 22. | Name and address of manufacturer / Applicant | M/s. Tayyab Laboratories, Islamabad |
| | Brand Name +Dosage Form + Strength | TRANEX 500 MG CAPSULE |
| | Composition | Each Capsule Contains<br>Tranexamic Acid BP……500 MG |
| | Diary No. Date of R& I & fee | 16-12-2016 Dy. No 2976 Rs. 20000/- |
| | Pharmacological Group | (Fibrinolytic) |
| | Type of Form | Form5 |
| | Finished Product Specification | (Manufacturing Specs) |
| | Pack size & Demanded Price | As per SRO: 100s |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | *Transamire by hiton pharma* |
| | GMP status | Routine GMP inspection conducted on 23-10-2017 concluded that overall GMP compliance is good. |
| | Remarks of the Evaluator. | |
| | Decision of previous meeting of RB | Deferred for evidence of approval by reference regulatory authorities (M-264) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy |
| | **Decision: Deferred for submission of revised Form 5 with fee due to change in title of the firm.** | |
| 23. | Name and address of manufacturer / Applicant | M/s. Weather Folds Pharmaceuticals, Hattar |
| | Brand Name +Dosage Form + Strength | Tranxam 500mg Capsule |
| | Composition | Each capsule contains:-<br>Tranexamic acid.. 500mg |
| | Diary No. Date of R& I & fee | 29-12-2010 Dy No. 41 Rs.8000/ Rs.12000/ 17-11-2014 |
| | Pharmacological Group | (Antifibrinolytic) |
| | Type of Form | Form 5 |
| | Finished Product Specification | Mfg Specs |
| | Pack size & Demanded Price | as per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | RANEX-Ambrosia pharmaceuticals |
| | GMP status | Inspection report dated 04-08-2016<br>Grant Renewal of DML |
| | Remarks of the Evaluator. | Evidence of approval status in reference regulatory authorities in capsule dosage form is required. |
| | Decision of previous meeting of RB | Deferred for evidence of approval status in reference regulatory authorities in capsule dosage form. (M-263) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy.<br>• Last GMP inspection report dated 15-9-2017 concludes as *Overall the firm was GMP Compliant as per DRAP Guidelines* |
| | **Decision: Approved with JP specification.** | |
| 24. | Name and address of manufacturer / Applicant | M/s Jaens Pharmaceutical Industries (Pvt) Ltd., Sheikhupura |
| | Brand Name +Dosage Form + Strength | Xamic Capsule |
| | Composition | Each Capsule Contains:<br>Tranexamic Acid : 500mg. |
| | Diary No. Date of R& I & fee | Dy No. 633 fee Rs.20,000/ |
| | Pharmacological Group | Haemostatic / Fibrinolytic |
| | Type of Form | Form 5 |
| | Finished Product Specification | MFG Specs |
| | Pack size & Demanded Price | Rs.20,000/ 1x20‘s blister As fixed by Govt. |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Transamin Capsule By M/s Hilton |
| | GMP status | Inspection Date 28-09-2016<br>GMP status: Submit compliance within 15 days time period, so that follow up inspection could be carried out. |
| | Remarks of the Evaluator. | |
| | Decision of previous meeting of RB | Deferred for evidence of approval of applied dosage form & strength in reference regulatory authorities (M-263) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Italy<br>• Last GMP inspection report dated 20-12-2017 concludes as Based on the areas inspected, the people met and considering the findings of inspection M/s Jaens Pharmaceuticals (Pvt.) Ltd., is operating satisfactory. Overall hygienic condition of the firm was satisfactory at the time of inspection however, they were advised to continue improvements in production and quality control, they agreed.” |
| | **Decision: Approved with JP specification.** | |

**d) Propyphenazone 175 mg / Caffeine Anhydrous 25 mg sugar coated tablet**

The formulation of Propyphenazone 175 mg / Caffeine Anhydrous 25 mg sugar coated tablet was deferred by Registration Board from various meetings, now the reference has been verified from Spanish Agency for Medicines and Health Products Spain.

The formulation is available in Spain and registered by **Spanish Agency for Medicines and Health Products** in the following strength and dosage form. The details of product registration are as follows

- **Brand Name:** OPTALIDON DRAGEES*
- **Market Authorization number:** 3941

- **Composition** (This formulation is sugar coated)
  **Active ingredient:**
  Propyphenazone ……175mg
  Caffeine anhydrous…….25mg
- **Marketing Authorization holder:** PERRIGO SPAIN SA.
- **Link for reference:**
  https://cima.aemps.es/cima/pdfs/ft/3941/FT_3941.pdf (Accessed on 08-02-2019)

*. DRAGEES is a dosage form previously used to describe coated tablets in Europe. Now this term has been re-mapped by EMA (https://www.ema.europa.eu/documents/other/eudravigilance-extended-medicinal-product-dictionary-xevmpd-pharmaceutical-dose-forms_en.xls Accessed on 08-02-2019)

The following previously deferred cases of the same formulation are hereby presented before the Board:

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| 25. | Name and address of manufacturer / Applicant | M/s MBL Pharma, B-77-A, H.I.T.E., Hub Baluchistan |
| | Brand Name +Dosage Form + Strength | Andinole Tablet |
| | Composition | Each sugar coated tablet contains:<br>Propyphenazone …..175 mg<br>Caffeine anhydrous…25mg |
| | Diary No. Date of R& I & fee | Dy No. 1030: 18-5-2016PKR 20,000/-: 18-5-2016 |
| | Pharmacological Group | (Analgesics) |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & Demanded Price | 200‘s: Rs. 160/- |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Romtolido tablets by Regent Pharma |
| | GMP status | Last inspection report dated 22-5-2017 confirms good compliance to GMP |
| | Remarks of the Evaluator. | Evidence of approval in reference regulatory authorities could not be confirmed |
| | Decision of previous meeting of RB | Deferred for evidence of approval by reference regulatory authorities (M-274) |
| | Evaluation by PEC | • The evidence of approval status of this formulation has now been verified from Spain |
| | **Decision: Approved with innovator’s specification.** | |

**Case No. 02: Registration Applications for Local Manufacturing of (Human) Drugs.**

**a. New Cases.**

**Evaluator PEC-II**

| | | |
|---|---|---|
| 26. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi. |
| | Brand Name +Dosage Form + Strength | Linzomed tablet 600mg<br>Other proposed brand names:<br>Linozid<br>Lizomed<br>Zizolid |
| | Composition | Each film coated tablet contains:<br>Linezolid…….……600mg |
| | Diary No. Date of R& I & fee | Dy. No.4830; 05-06-2017; Rs.20,000/- (05-06-2017) |
| | Pharmacological Group | Oxazolidinone anti-infective |
| | Type of Form | Form-5 |
| | Finished product Specifications | Manufacturer’s specifications |
| | Pack size & Demanded Price | 1x10’s; As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox 600mg tablet(USFDA approved) |

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| | Me-too status (with strength & dosage form) | Linzol tablet 600mg of M/s Regal Pharmaceuticals |
| | GMP status | Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| 27. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi. |
| | Brand Name +Dosage Form + Strength | Welfenac tablet 100mg<br>Other proposed brand names:<br>Aceclofenac<br>Welfin |
| | Composition | Each film coated tablet contains:<br>Aceclofenac…. ……100mg |
| | Diary No. Date of R& I & fee | Dy. No.4835; 05-06-2017; Rs.20,000/- (05-06-2017) |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Preservex 100mg tablets (MHRA approved) |
| | Me-too status (with strength and dosage form) | Anac tablet 100mg of M/s Ankaz Pharmaceuticals |
| | GMP status | Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| 28. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi. |
| | Brand Name +Dosage Form + Strength | Montimed tablet 10mg<br>Other proposed brand names:<br>Montimedwin<br>Telukast |
| | Composition | Each film coated tablet contains:<br>Montelukast as sodium…. ……10mg |
| | Diary No. Date of R& I & fee | Dy. No.4828; 05-06-2017; Rs.20,000/- (05-06-2017) |
| | Pharmacological Group | Leukotriene receptor antagonist |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1x10's; As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | Singulair (USFDA approved) |
| | Me-too status (with strength and dosage form) | Montewns tablet 10mg of M/s Wnsfeild Pharmaceutical |
| | GMP status | Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. |

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| | | The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| 29. | Name and address of manufacturer / Applicant | "M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad" |
| | Brand Name +Dosage Form + Strength | Xalfin 200mg Tablets |
| | Composition | "Each Film Coated Tablet Contains:<br>Rifaximin ……200mg" |
| | Diary No. Date of R& I & fee | Dy. No 1622 dated 11-01-2018 Rs. 20,000 Dated 11-01-2018 |
| | Pharmacological Group | Intestinal anti-infective |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10's As recommended by PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Nixaf 200mg Tablet of M/s Sami Karachi (Reg.#076310) |
| | GMP status | Copy of GMP certificate submitted issue on the basis of inspection conducted on 05 & 06-12-2017 |
| | Remarks of the Evaluator[2] | |
| | **Decision: Approved with innovator's specification.** | |
| 30. | Name and address of manufacturer / Applicant | "M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad" |
| | Brand Name +Dosage Form + Strength | Xalfin 550mg Tablets |
| | Composition | "Each Film Coated Tablet Contains:<br>Rifaximin…550mg" |
| | Diary No. Date of R& I & fee | Dy. No 1623 dated 11-01-2018 Rs. 20,000 Dated 11-01-2018 |
| | Pharmacological Group | Intestinal anti-infective |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10's As recommended by PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Rixago 550mg Tablet by M/s OBS Pharma Karachi (Reg#081073). |
| | GMP status | Copy of GMP certificate submitted issue don the basis of inspection conducted on 05 & 06-12-2017 |
| | Remarks of the Evaluator[2] | |
| | **Decision: Approved with innovator's specification.** | |
| 31. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Valpine tablet |
| | Composition | Each film coated tablet contains:<br>Amlodipine (as besylate) …… 10mg<br>Valsartan (as potassium)…….. 60mg |
| | Diary No. Date of R& I & fee | Dy. No. 2259; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 7's; Rs.140/-, 14's; Rs. 250/-, 28's; Rs. 500/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Amlodine Tablet 10/160 of M/s Jupiter Pharma (Reg.#081933) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were |

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| | | discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | • Master formulation includes "Valsartan as Potassium" whereas reference product approved by USFDA & MHRA contains Valsartan in pure form only. Clarification is required in this regard.<br>• Upon communication of above observations firm has submitted revised master formulation containing Valsartan as base form only. |
| | **Decision: Deferred for submission of fee for revision of formulation and for updated status of GMP of the firm from QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 32. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Valpine 5/80 tablet |
| | Composition | Each film coated tablet contains:<br>Amlodipine (as besylate) …… 5mg<br>Valsartan (as potassium)…….. 80mg |
| | Diary No. Date of R& I & fee | Dy. No. 2261; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 7's; Rs.98/-, 14's; Rs. 180/-, 28's; Rs. 340/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | • Master formulation includes "Valsartan as Potassium" whereas reference product approved by USFDA & MHRA contains Valsartan in pure form only. Clarification is required in this regard.<br>• Upon communication of above observations firm has submitted revised master formulation containing Valsartan as base form only. |
| | **Decision: Deferred for submission of fee for revision of formulation and for updated status of GMP of the firm from QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 33. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Valpine 5/160 tablet |
| | Composition | Each film coated tablet contains:<br>Amlodipine (as besylate) …… 5mg<br>Valsartan (as potassium)…….. 160mg |
| | Diary No. Date of R& I & fee | Dy. No. 2265; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 7's; Rs.126/-, 14's; Rs. 240/-, 28's; Rs. 450/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Amlodine Tablet 5/160 of M/s Jupiter Pharma (Reg.#081932) |

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| | GMP status | Copy of cGMP panel inspection, dated 07-8-2018, 04-9-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | • Master formulation includes "Valsartan as Potassium" whereas reference product approved by USFDA & MHRA contains Valsartan in pure form only. Clarification is required in this regard.<br>• Upon communication of above observations firm has submitted revised master formulation containing Valsartan as base form only. |
| | **Decision: Deferred for submission of fee for revision of formulation and for updated status of GMP of the firm from QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 34. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Stevia tablet 100mg |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate) …… 100mg |
| | Diary No. Date of R& I & fee | Dy. No. 2258; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; Rs.300/-, 20's; Rs. 600/-, 14's; Rs. 420/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Duvel 100mg Tablet of M/s Martin Dow Ltd. (Reg.#079616) |
| | GMP status | Copy of cGMP panel inspection dated 07-8-2018, 04-9-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 35. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Stevia-M tablet 50/500mg |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate) …… 50mg<br>Metformin hydrochloride …… 500mg |
| | Diary No. Date of R& I & fee | Dy. No. 2257; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | 10's; Rs.150/-, 20's; Rs. 300/-, 14's; Rs. 210/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Treviamet 50mg/500mg Tablets by M/s GETZ Pharma Pakistan (Reg# 055443) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |

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| | Remarks of the Evaluator. | • In contrary to approved by reference agencies/ authorities wherein the applied formulation is contains Metformin hydrochloride equal to 500mg, while you have applied for Metformin as hydrochloride equal to 500mg of Metformin. Clarification is required in this regard.<br>• Upon communication of above observations firm has submitted revised master formulation containing Metformin hydrochloride equal to 500mg. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 36. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Stevia tablet 25mg |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate) …… 25mg |
| | Diary No. Date of R& I & fee | Dy. No. 2263; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; Rs.150/-, 20's; Rs. 300/-, 14's; Rs. 210/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Duvel 25mg Tablet by M/s Martin Dow Ltd. Karachi (Reg# 079614) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 37. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Stevia-M tablet 25/500mg |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate) …… 25mg<br>Metformin hydrochloride …… 500mg |
| | Diary No. Date of R& I & fee | Dy. No. 2256; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | 10's; Rs.100/-, 20's; Rs. 200/-, 14's; Rs. 140/- |
| | Approval status of product in Reference Regulatory Authorities. | Not verifiable |
| | Me-too status | Tagipmet 25/500 Tablet by M/s.Highnoon Lab. (Reg# 071231) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board shall be submitted. |

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| | **Decision: Deferred for following:**<br>• **Updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting** | |
| 38. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Stevia-M tablet 50/1000mg |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate) …… 50mg<br>Metformin hydrochloride …… 1000mg |
| | Diary No. Date of R& I & fee | Dy. No. 2262; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | 10's; Rs.180/-, 20's; Rs. 350/-, 14's; Rs. 240/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Tagipmet 50/1000 Tablets by M//s. Highnoon Laboratories, (Reg.# 059787) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | • In contrary to approved by the reference agencies/authorities wherein the applied formulation is contains Metformin hydrochloride equal to 1000mg, while you have applied for Metformin as hydrochloride equal to 1000mg of Metformin. Clarification is required in this regard.<br>• Upon communication of above observations firm has submitted revised master formulation containing Metformin hydrochloride equal to 1000mg. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 39. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Stevia tablet 50mg |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate) …… 50mg |
| | Diary No. Date of R& I & fee | Dy. No. 2260; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; Rs.180/-, 20's; Rs. 360/-, 14's; Rs. 252/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Duvel 50mg Tablet by M/s Martin Dow Ltd. (Reg#079615) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |

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| 40. | Name and address of manufacturer / Applicant | M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore. |
| | Brand Name +Dosage Form + Strength | Moflox tablet 400mg |
| | Composition | Each film coated tablet contains:<br>Moxifloxacin (as hydrochloride) …… 400mg |
| | Diary No. Date of R& I & fee | Dy. No. 2264; 08-12-2016; Rs.20,000/- (08-12-2016) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specification |
| | Pack size & Demanded Price | 1 x 5's; Rs. 475/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Navelox Tablets 400mg by M/s Navegal Laboratories (R#068237) |
| | GMP status | Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:<br>"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report." |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |

**Evaluator PEC-III**

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| 41. | Name and address of manufacturer / Applicant | M/s Nortech Pharmaceuticals, Plot No. 203, Sihala Industrial Triangle, Kahuta Road, Islamabad`<br>***Contract Manufactured by:*** M/s Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22 - 23, Industrial Estate, Kahuta road, Model Town, Islamabad. |
| | Brand Name +Dosage Form + Strength | Essonor 40mg Injection |
| | Composition | Each vial Contains:<br>Esomeprazole (as sodium)…40mg |
| | Diary No. Date of R& I & fee | Dy.No 21383 dated 17-11-2017<br>Rs. 50,000/- Dated 17-11-2017 |
| | Pharmacological Group | PPI |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Nexium I.V. 40 mg Powder for solution for injection/infusion by Astrazaneca (MHRA Approved) |
| | Me-too status | Nexum Injection by Getz |
| | GMP status | Vision Pharmaceuticals was issued GMP certificate based on inspection dated 26-01-2018 |
| | Remarks of the Evaluator[3]. | • Firm has initially applied for contract manufacturing from Bio-labs, but later firm has requested to change the manufacturer from M/s Bio-labs to M/s Vision Pharma<br>• M/s Nortech pharma has 6 approved sections and have no product already approved for contract manufacturing. |
| | **Decision: Approved with innovator's specification.** | |
| 42. | Name and address of manufacturer / Applicant | M/s Nortech Pharmaceuticals, Plot No. 203, Sihala Industrial Triangle, Kahuta Road, Islamabad<br>***Contract Manufactured by:*** M/s Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22 - 23, Industrial Estate, Kahuta road, Model Town, Islamabad. |
| | Brand Name +Dosage Form + Strength | Omepranor 40mg Injection |
| | Composition | Each vial Contains:<br>Omeprazole (as sodium)…40mg |
| | Diary No. Date of R& I & fee | Dy.No 21382 (17-11-2017) Rs. 50,000/- Dated 17-11-2017 |

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| | Pharmacological Group | PPI |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Omeprazole 40 mg Powder for Solution for Infusion by Sandoz (MHRA Approved) |
| | Me-too status | Risek Injection by Getz |
| | GMP status | Vision Pharmaceuticals was issued GMP certificate based on inspection dated 26-01-2018 |
| | Remarks of the Evaluator[3]. | • Firm has initially applied for contract manufacturing from Bio-labs, but later firm has requested to change the manufacturer from M/s Bio-labs to M/s Vision Pharma<br>• M/s Nortech pharma has 6 approved sections and have no product already approved for contract manufacturing. |
| | **Decision: Approved with innovator's specification.** | |
| 43. | Name and address of manufacturer / Applicant | M/s Caraway Pharmaceuticals, Plot No. 12, Street # N-3, Rawat Industrial Zone (RCCI), Rawat, Islamabad.<br>***Contract Manufactured by:*** M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Ompro 40mg Injection |
| | Composition | Each vial Contains:<br>Omeprazole (as sodium)…..40mg |
| | Diary No. Date of R& I & fee | Dy.No 1239 (12-11-2017) Rs. 50,000/- Dated 12-11-2017 |
| | Pharmacological Group | PPI |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Omeprazole 40 mg Powder for Solution for Infusion by Sandoz (MHRA Approved) |
| | Me-too status | Risek Injection by Getz |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Caraway pharma has 9 approved sections.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Deferred as Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement".** | |
| 44. | Name and address of manufacturer / Applicant | M/s Caraway Pharmaceuticals, Plot No. 12, Street # N-3, Rawat Industrial Zone (RCCI), Rawat, Islamabad.<br>***Contract Manufactured by:*** M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Vogue 40mg Injection |
| | Composition | Each vial Contains:<br>Esomeprazole (as sodium)…40mg |
| | Diary No. Date of R& I & fee | Dy.No 1238 dated 12-11-2017<br>Rs. 50,000/- Dated 12-11-2017 |
| | Pharmacological Group | PPI |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | Nexium I.V. 40 mg Powder for solution for injection/infusion by Astrazaneca (MHRA Approved) |
| | Me-too status | Nexum Injection by Getz |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Caraway pharma has 9 approved sections.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Decision: Deferred as Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement".** | |
| 45. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>***Contract Manufactured by:*** M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Julac Injection |
| | Composition | Each 1ml ampoule contains:<br>Ketorolac Tromethamine …….30mg |
| | Diary No. Date of R& I & fee | Dy.No 1675 dated 17-11-2017 Rs. 50,000/- |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & demanded price | 5's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ketorolac Injection by Hospira<br>(USFDA Approved) |
| | Me-too status | Toradol Injection |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Approved.** | |
| 46. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>***Contract Manufactured by:*** M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Jumep Injection |
| | Composition | Each vial contain:<br>Omeprazole sodium eq. to Omeprazole ……..40mg |
| | Diary No. Date of R& I & fee | Dy.No 1671 dated 17-11-2017 Rs. 50,000/- |
| | Pharmacological Group | PPI |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |
| | Approval status of product in | Omeprazole 40 mg Powder for Solution for Infusion by |

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| | Reference Regulatory Authorities. | Sandoz (MHRA Approved) |
| | Me-too status | Risek Injection by Getz |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) & Ampoule (General) section. |
| | **Decision: Deferred as Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement"** | |
| 47. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>***Contract Manufactured by:*** M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Esojup Injection |
| | Composition | Each vial contain:<br>Esomeprazole (as sodium)…….40mg |
| | Diary No. Date of R& I & fee | Dy.No 1668 dated 17-11-2017<br>Rs. 50,000/- Dated 17-11-2017 |
| | Pharmacological Group | PPI |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Nexium I.V. 40 mg Powder for solution for injection/infusion by Astrazaneca (MHRA Approved) |
| | Me-too status | Nexum Injection by Getz |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Deferred as Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement"** | |
| 48. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>***Contract Manufactured by:***M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Julevo Infusion 500mg /100ml |
| | Composition | Each 100 ml contains:<br>Levofloxacin Hemihydrate equivalent to levofloxacin……..500mg |
| | Diary No. Date of R& I & fee | Dy.No 1669 dated 17-11-2017 Rs. 50,000/- 17-11-2017 |

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| | Pharmacological Group | Antibiotic |
| | 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. | Levofloxacin 5 mg/ml Solution for Infusion by Hospira (MHRA Approved) |
| | Me-too status | Livaquin Injection by Barret Hodgson |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Approved with JP specifications.** | |
| 49. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>***Contract Manufactured by:*** M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Ostoblock Ampoule |
| | Composition | Each 1ml contains:<br>Cholecalciferol ……5mg |
| | Diary No. Date of R& I & fee | Dy.No 1670 dated 17-11-2017<br>Rs. 50,000/- Dated 17-11-2017 |
| | Pharmacological Group | Vitamin D3 analogue |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Vitamin D3 Good 200,000 IU / 1 ml, oral solution in ampoule and Vitamin D3 Good 200,000 IU / 1 ml, solution for injection IM in ampoule by Bouchara-Recordati. ANSM Approved |
| | Me-too status | ORA-D3 Injection by Ameer & Adnan Pharmaceuticals |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Approved with innovator's specification and change of brand name.** | |
| 50. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>Contract Manufactured by:<br>M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Jucip Infusion |
| | Composition | Each 100ml contains:<br>Ciprofloxacin lactate eq.to Ciprofloxacin……200mg |

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| | Diary No. Date of R& I & fee | Dy.No 1672 dated 17-11-2017 Rs. 50,000/- 17-11-2017 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ciprofloxacin 2 mg/ml solution for infusion by Hospira (MHRA Approved) |
| | Me-too status | Novidat Injection by Sami |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Approved with USP specification.** | |
| 51. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>***Contract Manufactured by:*** M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Neurojup Injection |
| | Composition | Each ampoule (1ml) contains:<br>Mecobalamin……..500mcg |
| | Diary No. Date of R& I & fee | Dy.No 1673 dated 17-11-2017 Rs. 50,000/- 17-11-2017 |
| | Pharmacological Group | Vitamin B12 |
| | 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. | PMDA Japan Approved |
| | Me-too status | Flench inj. By Tabros Pharma |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Approved with innovator's specification.** | |
| 52. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Islamabad.<br>Contract Manufactured by:<br>M/s Bio-Labs (Pvt.) Ltd., Plot No. 145, Industrial Triangle, Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Jurose Injection |
| | Composition | Each 5ml ampoule contains:<br>Iron sucrose eq. to elemental iron …….100mg |
| | Diary No. Date of R& I & fee | Dy.No 1674 (17-11-2017) Rs. 50,000/- Dated 17-11-2017 |
| | Pharmacological Group | Anti- anaemic |

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| | Type of Form | Form 5 |
| | Finished Product Specification | BP Specs |
| | Pack size & demanded price | 5ml x 5's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Venofer Injection<br>(TGA Australia Approved) |
| | Me-too status | Irofit Injection by Zafa |
| | GMP status | Bio-labs pharma was issued GMP certificate based on inspection dated 5th and 6th December 2017 |
| | Remarks of the Evaluator[3]. | • M/s Jupiter Pharma has 3 approved sections and have no product already registered for contract manufacturing.<br>• Registration Board in its 286th meeting on the basis of panel inspection report for capacity assessment decided NOT to allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (nonantibiotic and antibiotic) and Ampoule (General) section. |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-IV**

| | | |
|---|---|---|
| 53. | Name and address of manufacturer / Applicant | M/s Brookes Pharma Pvt Ltd.<br>58 & 59, Sector 15, Korangi Industrial Area, Karach |
| | Brand Name +Dosage Form + Strength | Gen-Zithro 250mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Azithromycin……250mg |
| | Diary No. Date of R& I & fee | Dy.No;24930 18-12-2017 Rs. 20,000-(18-12-2017) |
| | Pharmacological Group | Antibiotic (Macrolide) |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 6's, ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Azithromycin tablet of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Azic 250mg Tablet by M/s NabiQasim |
| | GMP status | Last GMP inspection conducted 11-10-2017 & 16-10-2017and the report concludes that firm was considered to be operating at Satisfactory level of compliance with GMPguidelines |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 54. | Name and address of manufacturer / Applicant | M/s Brookes Pharma Pvt Ltd.<br>58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Gen-Zithro 500mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Azithromycin……500mg |
| | Diary No. Date of R& I & fee | Dy.No;24929 18-12-2017 Rs. 20,000-(18-12-2017) |
| | Pharmacological Group | Antibiotic (Macrolide) |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 6's, ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Azithromycin tablet of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Azic 500mg Tablet by M/s NabiQasim |
| | GMP status | Last GMP inspection conducted 11-10-2017 & 16-10-2017 and the report concludes that firm was considered to be operating at Satisfactory level of compliance with GMPguidelines |

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| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 55. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Toward 25mg Tablet |
| | Composition | Each film coated tablet contains:<br>Topiramate…25mg |
| | Diary No. Date of R& I & fee | Dy.No 5337 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Pharmacological Group | Anti Psychotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | TOPAMAX tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Neutop 25mg Tablet M/s Nabiqasim |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 56. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Toward 50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Topiramate…50mg |
| | Diary No. Date of R& I & fee | Dy.No 5338 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Anti Psychotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | TOPAMAX tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Neutop 50mg Tablet M/s Nabiqasim |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 57. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Nebiwrd 2.5mg Tablet |
| | Composition | Each uncoated tablet contains:<br>Nebivolol as hydrochloride (In-house)…2.5mg |
| | Diary No. Date of R& I & fee | Dy.No 5333 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Anti Hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | BYSTOLIC tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Nibovo Tablets 2.5mgM/s. Dyson Research Laboratories |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |

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|---|---|---|
| 58. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Nebiwrd 5mg Tablet |
| | Composition | Each uncoated tablet contains:<br>Nebivolol as hydrochloride (In-house)…5mg |
| | Diary No. Date of R& I & fee | Dy.No 5334 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Anti Hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | BYSTOLIC tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Nibovo Tablets 5mgM/s. Dyson Research Laboratories |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 59. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Ivowel 5mg Tablets |
| | Composition | Each film coated tablet contains:<br>Ivabradine (as HCl)…5mg |
| | Diary No. Date of R& I & fee | Dy.No 5331 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antiangina |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ivabradine tablet of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Sivab tablets of M/s Getz |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | Decision: Approved with innovator's specification. | |
| 60. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals.Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Ivowel 7.5mg Tablets |
| | Composition | Each film coated tablet contains:<br>Ivabradine (as HCl)…7.5mg |
| | Diary No. Date of R& I & fee | Dy.No 5332 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Antiangina |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ivabradine tablet of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Sivab tablets of M/s Getz |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 61. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Etrowrd 60mg Tablet |

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|---|---|---|
| | Composition | Each film coated tablet contains:<br>Etoricoxib (In-house)…60mg |
| | Diary No. Date of R& I & fee | Dy.No 5330 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | ACOXXEL 60 MG of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Oraxib 60mg Table M/s. Atco Lab |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 62. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Riswrd 1mg Tablet |
| | Composition | Each film coated tablet contains:<br>Risperidone (USP)…1mg |
| | Diary No. Date of R& I & fee | Dy.No 5335 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Sedative |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | RISPERDAL 1MG of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Rislet 1mg Tablet M/s. High-Q Pharmaceuticals |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 63. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Riswrd 2mg Tablet |
| | Composition | Each film coated tablet contains:<br>Risperidone (USP)…2mg |
| | Diary No. Date of R& I & fee | Dy.No 5336 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Sedative |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | RISPERDAL 2MG of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Rislet 2mg Tablet M/s. High-Q Pharmaceuticals |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 64. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK |
| | Brand Name +Dosage Form + Strength | Doxwrd 400mg Tablets |
| | Composition | Each uncoated tablet contains:<br>Doxofylline (In-House)…400mg |

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| | Diary No. Date of R& I & fee | Dy.No 5329 dated 14-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Anti-Asthamatic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ansimar 400 mg tabletABC International Pharma Srl Ivrea, Italy |
| | Me-too status (with strength and dosage form) | Unifyline 400mg Tablets M/s. Platinum Pharmaceuticals |
| | GMP status | The last GMP inspection conducted on 14-06-2017 and report concludes that overall the firm is GMP compliant |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 65. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan |
| | Brand Name +Dosage Form + Strength | Sitag Tablet |
| | Composition | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin…50mg |
| | Diary No. Date of R& I & fee | Dy.No 5177 dated 13-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Antihyperglycemic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2 x 7's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Januvia tablets of (FDA approved) |
| | Me-too status (with strength and dosage form) | A-Glip Tablets of M/s Atco Labs |
| | GMP status | GMP Certificate issued based on inspection dated 15 March, 2018. GMP inspection report dated 15-03-2018 rated GMP as Good. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 66. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan |
| | Brand Name +Dosage Form + Strength | Sitag Tablet |
| | Composition | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin…100mg |
| | Diary No. Date of R& I & fee | Dy.No 5176 dated 13-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | oral blood glucose lowering drugs |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2 x 7's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Sitagliptin 100 mg film-coated tablets by M/s Laboratoires Biogaran (MHRA Approved) |
| | Me-too status (with strength and dosage form) | A-Glip 100mg Tablets by M/s Atco Laboratories Ltd (Reg#053096) |
| | GMP status | GMP Certificate issued based on inspection dated 15 March, 2018. GMP inspection report dated 15-03-2018 rated GMP as Good. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 67. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan |
| | Brand Name +Dosage Form + Strength | Metco Tablet |

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| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate Monohydrate) …50mg<br>Metformin HCl…500mg |
| | Diary No. Date of R& I & fee | Dy.No 5175 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antihyperglycemic |
| | Type of Form | Form-5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 2 x 7's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Janumet tablets of (TGA approved) |
| | Me-too status (with strength and dosage form) | S-Gliptin Plus Tablets of M/s Barrett Hodgson |
| | GMP status | GMP Certificate issued based on inspection dated 15 March, 2018. GMP inspection report dated 15-03-2018 rated GMP as Good. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 68. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals (Pvt) Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan |
| | Brand Name +Dosage Form + Strength | Metco Tablet |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate Monohydrate) …50mg<br>Metformin HCl…850mg |
| | Diary No. Date of R& I & fee | Dy.No 5174 dated 13-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Antihyperglycemic |
| | Type of Form | Form-5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 2 x 7's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Janumet tablets of (TGA approved) |
| | Me-too status (with strength and dosage form) | S-Gliptin Plus Tablets of M/s Barrett Hodgson |
| | GMP status | GMP Certificate issued based on inspection dated 15 March,2018. GMP inspection report dated 15-03-2018 rated GMP as Good. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 69. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals Pvt Ltd. Plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan |
| | Brand Name +Dosage Form + Strength | Metco Tablet |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate Monohydrate) …50mg<br>Metformin HCl…1000mg |
| | Diary No. Date of R& I & fee | Dy.No 5173 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antihyperglycemic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 2 x 7's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Janumet tablets of (TGA approved) |
| | Me-too status (with strength and dosage form) | Silmax-M 50mg/1000mg Tablet by M/s High-Q Pharmaceuticals |
| | GMP status | GMP Certificate issued based on inspection dated 15 March,2018. GMP inspection report dated 15-03-2018 rated GMP as Good. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |

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| 70. | Name and address of manufacturer / Applicant | M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi |
| | Brand Name +Dosage Form + Strength | Lowsartan 25mg Tablet |
| | Composition | Each film coated tablet contains:<br>Losartan potassium…25mg |
| | Diary No. Date of R& I & fee | Dy.No 5179 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 14's, 20's, 30's, 100's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Janumet tablets of (TGA approved) |
| | Me-too status (with strength and dosage form) | Rosar 25mg Tablets of M/s Rock Pharmaceuticals |
| | GMP status | Last inspection report 5-12-2017 Manufacturer's overall rating is good compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 71. | Name and address of manufacturer / Applicant | M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi |
| | Brand Name +Dosage Form + Strength | Lowsartan 50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Losartan potassium…50mg |
| | Diary No. Date of R& I & fee | Dy.No 5180 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 14's, 20's, 30's, 100's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Cozaar, 50 mg of ( USFDA Approved) |
| | Me-too status (with strength and dosage form) | Jasartan Tablets 50mg of M/S Jawa Pharmaceutical |
| | GMP status | Last inspection report 5-12-2017 Manufacturer's overall rating is good compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 72. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot# E.145-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | VilGlip-M Tablet 50/500 |
| | Composition | Each film coated Tablet contains:<br>Vildagliptin…50mg<br>Metformin HCl…500mg |
| | Diary No. Date of R& I & fee | Dy.No 5183 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antihyperglycemic agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities | GA Galvumet Tablet Of (TGA Approved) |
| | Me-too status (with strength and dosage form) | Galmet 50mg/500mg Table M/s Vision Pharmaceuticals, |
| | GMP status | Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator[4] | Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu. |
| | **Decision: Approved with innovator's specification.** | |

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| 73. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | VilGlip-M Tablet 50/1000 |
| | Composition | Each film coated Tablet contains:<br>Vildagliptin…50mg<br>Metformin HCl…1000mg |
| | Diary No. Date of R& I & fee | Dy.No 5182 dated 13-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Antihyperglycemic agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities | GA Galvumet Tablet Of (TGA Approved) |
| | Me-too status (with strength and dosage form) | Galmet 50mg/1000mg Table M/s Vision Pharma, |
| | GMP status | Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator[4] | Shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu. |
| | **Decision: Approved with Innovator's specifications.** | |
| 74. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd.<br>Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Fosmicin Capsule 500mg |
| | Composition | Each Capsule contains:<br>Fosfomycin (as Calcium)…500mg |
| | Diary No. Date of R& I & fee | Dy.No 5184 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Anti Bacterial Agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities | Fosfomicina calcica solufos 500mg capsule by Spain |
| | Me-too status (with strength and dosage form) | Cynfo 500mg Capsule of M/s Sami |
| | GMP status | Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with Innovator's specifications** | |
| 75. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot# E.145-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | Fosmicin Suspension 250mg/5ml |
| | Composition | Each 5ml contains:<br>Fosfomycin (as Calcium)…250mg |
| | Diary No. Date of R& I & fee | Dy.No 5181 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Anti Bacterial Agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities | FOSFOCINA Suspension 250mg/5ml by Spain |
| | Me-too status (with strength and dosage form) | Fosfonex 250mg/5ml Suspension of M/s Nexus Pharma |

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| | GMP status | Last GMP inspection conducted on 07-09-2017, and the report concludes that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with JP specifications.** | |
| 76. | Name and address of manufacturer / Applicant | M/s Nabiqasim Industries Pvt Ltd.<br>17/24, Korangi Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Norlim-M Tablet 2/500mg |
| | Composition | Each fim coated tablet Contains:<br>Glimipride…2mg<br>Metformin HCl USP…500mg |
| | Diary No. Date of R& I & fee | Dy.No 5194 dated 13-02-2018 Rs. 20,000/-<br>Dated 13-02-2018 |
| | Pharmacological Group | Anti-Diabetic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 30's, ; As per PRC |
| | Approval status of product in Reference Regulatory Authorities | Not found |
| | Me-too status (with strength and dosage form) | Gpride-M SR Tablet M/s Sami pharamaceuticals |
| | GMP status | Last GMP of Nabi qasim Inspection conducted on 03-8-2018 and report concludes that firm is considered to be operating at an acceptable level of compliance of GMP requirements. . |
| | Remarks of the Evaluator[4] | • Evidence of approval of applied formulation in reference regulatory authorities/agencies |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 77. | Name and address of manufacturer / Applicant | M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Sinofex 5mg Tablets |
| | Composition | Each film coated tablet contains:<br>Solifenacin succinate…….5mg |
| | Diary No. Date of R& I & fee | Dy.No 4817 dated 09-02-2018 Rs. 20,000/-<br>Dated 09-02-2018 |
| | Pharmacological Group | Urologicals |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 10's, 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | SEYLACINE 5 MG of MHRA approved |
| | Me-too status (with strength and dosage form) | Urgesin 5mg Tablet of AGP |
| | GMP status | Routine GMP inspection conducted on 17-10-2017 concluded that the firm is operating at agood level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 78. | Name and address of manufacturer / Applicant | M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Sinofex 10mg Tablets |
| | Composition | Each film coated tablet contains:<br>Solifenacin succinate…….10mg |
| | Diary No. Date of R& I & fee | Dy.No 4818 dated 09-02-2018 Rs. 20,000/- 09-02-2018 |
| | Pharmacological Group | Urologicals |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |

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| | Pack size & Demanded Price | 10's, 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | SEYLACINE 10 MG of MHRA approved |
| | Me-too status (with strength and dosage form) | Urgesin 10mg Tablet of AGP |
| | GMP status | Routine GMP inspection conducted on 17-10-2017 concluded that the firm is operating at agood level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 79. | Name and address of manufacturer / Applicant | M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Ketolite |
| | Composition | Each film coated tablet contains:<br>α-Ketoanalogue to DL-isoleucine (Calcium-salt)…67mg<br>α-Ketoanalogue to isoleucine (Calcium-salt)…101mg<br>α-Ketoanalogue to phenylalanine (Calcium-Salt)…68mg<br>α-Ketoanalogue to valine (Calcium-Salt)…86mg<br>α-hydroxyanalogue to DL-methionine (Calcium-Salt)...59mg<br>L-lysine acetate...105mg corresponding to...75mg L-lysine<br>L-threonine...53mg<br>L-tryptophan...23mg<br>L-histidine...38mg<br>L-tyrosine...30mg<br>Total nitrogen content per tablet....36mg<br>Calcium content per tablet...1.25mmol = 50mg |
| | Diary No. Date of R& I & fee | Dy.No 4815 dated 09-02-2018 Rs. 20,000/- 09-02-2018 |
| | Pharmacological Group | Calcium and analogue of essential amino acids |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 10's x 10's, ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | KETOSTERIL by Fresenius Kabi, Germany.<br>(Bfarm Approved) |
| | Me-too status (with strength and dosage form) | Ketoalfa Tablets M/s Genome Pharmaceuticals |
| | GMP status | Routine GMP inspection conducted on 17-10-2017 concluded that the firm is operating at agood level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 80. | Name and address of manufacturer / Applicant | M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Urexa 40mg Tablets |
| | Composition | Each film coated tablet contains:<br>Febuxostat…40mg |
| | Diary No. Date of R& I & fee | Dy.No 4819 dated 09-02-2018 Rs. 20,000/- 09-02-2018 |
| | Pharmacological Group | Antigout preparation (Non-purine xanthine oxidase Inhibitor) |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Uloric 40mg Tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Febuxin 40mg Tablet of M/s AGP |
| | GMP status | Routine GMP inspection conducted on 17-10-2017 concluded that the firm is operating at agood level of GMP compliance. |
| | Remarks of the Evaluator[4] | |

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| | **Decision: Approved with innovator's specification.** | |
| 81. | Name and address of manufacturer / Applicant | M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Urexa 80mg Tablets |
| | Composition | Each film coated tablet contains:<br>Febuxostat…80mg |
| | Diary No. Date of R& I & fee | Dy.No 4820 dated 09-02-2018 Rs. 20,000/- 09-02-2018 |
| | Pharmacological Group | Antigout preparation(Non-purine xanthine oxidase Inhibitor) |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Uloric 80mg Tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Febuxin 80mg Tablet of M/s AGP |
| | GMP status | Routine GMP inspection conducted on 17-10-2017 concluded that the firm is operating at agood level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 82. | Name and address of manufacturer / Applicant | M/s Crystolite Pharmaceuticals. Plot # 1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Frocit 10mEq Tablet |
| | Composition | Each extended release tablet contains:<br>Potassium citrate …10mEq |
| | Diary No. Date of R& I & fee | Dy.No 4816 dated 09-02-2018 Rs. 20,000/-<br>Dated 09-02-2018 |
| | Pharmacological Group | Urinary Alkalinizing agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Urocit-K ( of USFDA approved |
| | Me-too status (with strength and dosage form) | Lospin Tablets by Valor Pharmaceuticals |
| | GMP status | Routine GMP inspection conducted on 17-10-2017 concluded that the firm is operating at agood level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 83. | Name and address of manufacturer / Applicant | M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K |
| | Brand Name +Dosage Form + Strength | Wellverin 135mg Tablet |
| | Composition | Each film coated tablet contains:<br>Mebeverine hydrochloride (BP)…135mg |
| | Diary No. Date of R& I & fee | Dy.No 5342 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Anti-Spasmodic |
| | Type of Form | Form 5 |
| | Finished product Specifications | BP |
| | Pack size & Demanded Price | 3 x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Mebeverine hydrochloride 135 mg of MHRA approved |
| | Me-too status (with strength and dosage form) | Mevos Tablets 135mg of M/s. Dyson Research Laboratories |
| | GMP status | Last GMP inspection report dated 08-08-2018 recommending renewal of DML. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |

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| 84. | Name and address of manufacturer / Applicant | M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K |
| | Brand Name +Dosage Form + Strength | Winfo 500mg Capsules |
| | Composition | Each capsules contains:<br>Fosfomycin calcium eq. to fosfomycin (BP)…500mg |
| | Diary No. Date of R& I & fee | Dy.No 5340 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Anti Bacterial Agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1 x 10's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Fosfomicina calcica solufos 500mg capsule by Spain |
| | Me-too status (with strength and dosage form) | Cynfo 500mg Capsule of M/s Sami |
| | GMP status | Last GMP inspection report dated 08-08-2018 recommending renewal of DML. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 85. | Name and address of manufacturer / Applicant | M/s Wellborne Pharmachem & Biologicals. Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K |
| | Brand Name +Dosage Form + Strength | Werison 50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Eperisone HCl…50mg |
| | Diary No. Date of R& I & fee | Dy.No 5339 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Other centrally acting agents |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 2 x 10's, 3 x 10's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Expose 50mg film coated tablets by ALFASIGMA S.P.A.(AIFA Italy Approved) |
| | Me-too status (with strength and dosage form) | Perispa 50 Mg Tablets by Platinum Pharma (Reg# 039302) |
| | GMP status | Last GMP inspection report dated 08-08-2018 recommending renewal of DML. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 86. | Name and address of manufacturer / Applicant | M/s Wellborne Pharmachem & Biologicals.Plot No. 51/1, 52/2, Phase I & II, Hattar Industrial Estate, Hattar, K.P.K |
| | Brand Name +Dosage Form + Strength | Zumax 200mg Tablet |
| | Composition | Each film coated tablet contains:<br>Cefixime as trihydrate…200mg |
| | Diary No. Date of R& I & fee | Dy.No 5341 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1 x 10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Cefixime 200mg of MHRA approved |
| | Me-too status (with strength and dosage form) | Caricef 200mg Tablet of M/s Sami |
| | GMP status | Last GMP inspection report dated 08-08-2018 recommending renewal of DML. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Deferred for confirmation of manufacturing facility for applied product.** | |
| 87. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals.<br>Plot #122 Phase 5, Block B, Industrial Hattar |
| | Brand Name +Dosage Form + Strength | Mark-Aid 500mg |
| | Composition | Each film coated tablet contains:<br>Diflunisal…500mg |

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| | Diary No. Date of R& I & fee | Dy.No 4826 dated 09-02-2018 Rs. 20,000/- 08-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Diflunisal 500mg of MHRA approved |
| | Me-too status (with strength and dosage form) | Dolobis-500 Tablets of M/s Genome Pharmaceuticals |
| | GMP status | Last GMP inspection was conducted on 16-09-2017 and report concludes that firm was GMP compliant. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 88. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals.<br>Plot #122 Phase 5, Block B, Industrial Hattar |
| | Brand Name +Dosage Form + Strength | Noximark 4mg Tablet |
| | Composition | Each film coated tablet contains:<br>Lornoxicam…4mg |
| | Diary No. Date of R& I & fee | Dy.No 4827 dated 09-02-2018 Rs. 20,000/- Dated 08-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Xefo 4 mg tablet (EMA approved) |
| | Me-too status (with strength and dosage form) | Lorfix 4mg Tablet of M/s AGP |
| | GMP status | Last GMP inspection was conducted on 16-09-2017 and report concludes that firm was GMP compliant. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 89. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals.<br>Plot #122 Phase 5, Block B, Industrial Hattar |
| | Brand Name +Dosage Form + Strength | WelVit Injection |
| | Composition | Each 3ml Injection contains:<br>Cyanocobalamin……..1000mcg<br>Pyridoxine…….. 100mg<br>Thiamine HCl (Vitamin B1) …… 100mg |
| | Diary No. Date of R& I & fee | Dy.No 4828 dated 09-02-2018 Rs. 20,000/- Dated 08-02-2018 |
| | Pharmacological Group | Vitamin B compounds |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 5's :As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Neurobion solution for Injection 3ml by M/s Merck Selbstmedikation GmbH (Germany Approved) |
| | Me-too status (with strength and dosage form) | Neurolina Injection 3ml by M/s Alina Combine (Reg#076143) |
| | GMP status | Last GMP inspection was conducted on 16-09-2017 and report concludes that firm was GMP compliant. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 90. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals.<br>Plot #122 Phase 5, Block B, Industrial Hattar |
| | Brand Name +Dosage Form + Strength | Atrawel 50mg/5ml Injection |
| | Composition | Each ampoule contains:<br>Atracurium Besylate (USP)…50mg |
| | Diary No. Date of R& I & fee | Dy.No 4829 dated 09-02-2018 Rs. 20,000/- 08-02-2018 |

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| | Pharmacological Group | Non depolarizing muscle relaxant |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA approved |
| | Me-too status (with strength and dosage form) | Atrium Injections by M/s Searle Pakistan, Karachi (Reg#053342) |
| | GMP status | Last GMP inspection was conducted on 16-09-2017 and report concludes that firm was GMP compliant. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 91. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals.<br>Plot #122 Phase 5, Block B, Industrial Hattar |
| | Brand Name +Dosage Form + Strength | Weloskiren 150mg |
| | Composition | Each film coated tablet contains:<br>Aliskiren (as hemifumerate)…150mg |
| | Diary No. Date of R& I & fee | Dy.No 4830 dated 09-02-2018 Rs. 20,000/- 08-02-2018 |
| | Pharmacological Group | Renin inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Tekturna USFDA approved |
| | Me-too status (with strength and dosage form) | Stay Tablet 150mg of M/s Wilson's Pharmaceuticals, |
| | GMP status | Last GMP inspection was conducted on 16-09-2017 and report concludes that firm was GMP compliant. |
| | Remarks of the Evaluator[4] | Correction of salt Aliskiren (as hemifumerate) without submission of fee. Now fee of 5000/- is being submitted chalan # 0821046 dated 13/2/2019 |
| | **Decision: Approved with innovator's specification.** | |
| 92. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar |
| | Brand Name +Dosage Form + Strength | Weloskiren 300mg |
| | Composition | Each film coated tablet contains:<br>Aliskiren(as hemifumerate)…300mg |
| | Diary No. Date of R& I & fee | Dy.No 4831 dated 09-02-2018 Rs. 20,000/- 08-02-2018 |
| | Pharmacological Group | Renin inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Tekturna USFDA approved |
| | Me-too status (with strength and dosage form) | Stay Tablet 300mg of M/s Wilson's Pharmaceuticals, |
| | GMP status | Last GMP inspection was conducted on 16-09-2017 and report concludes that firm was GMP compliant. |
| | Remarks of the Evaluator[4] | Firm has submitted correction of salt form of API i.e., Aliskiren (as hemifumerate) with fee of 5000/- vide chalan # 0821048 dated 13/2/2019. |
| | **Decision: Approved with innovator's specification.** | |
| 93. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar |
| | Brand Name +Dosage Form + Strength | Weloskiren HCt |
| | Composition | Each film coated tablet contains:<br>Aliskiren(as hemifumerate)…150mg<br>Hydrochlorthiazide…25mg |
| | Diary No. Date of R& I & fee | Dy.No 4832 dated 09-02-2018 Rs. 20,000/- 08-02-2018 |

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| | Pharmacological Group | Renin inhibitors and diuretic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Tekturna HCT USFDA approved |
| | Me-too status (with strength and dosage form) | Stay Tablet 300mg of M/s Wilson's Pharmaceuticals, |
| | GMP status | Last GMP inspection was conducted on 16-09-2017 and report concludes that firm was GMP compliant. |
| | Remarks of the Evaluator[4] | Firm has submitted correction of salt form of API i.e., Aliskiren (as hemifumerate) with fee of 5000/- vide chalan # 0821047 dated 13/2/2019 |
| | **Decision: Approved with innovator's specification.** | |
| 94. | Name and address of manufacturer / Applicant | M/s Bajwa Pharmaceuticals (Pvt) Ltd.<br>36-Km, GT Road Khori Murredke,Sheikhupura |
| | Brand Name +Dosage Form + Strength | Ioprowa Injection |
| | Composition | Each ml contains:<br>Iopromide…623.4mg (equivalent to 300mg Iodine). |
| | Diary No. Date of R& I & fee | Dy.No 5319 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | Radiographic contrast medium |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 100ml x 1's As per PRC |
| | Approval status of product in Reference Regulatory Authorities | Ultravist® 300 of MHRA approved |
| | Me-too status (with strength and dosage form) | Ultravist® 300 of M/s. Medipharm |
| | GMP status | Last GMP inspection was conducted on 21-02-2018 and report concludes that Overall hygienic condition of firm is satisfactory at the time of inspection. They were advised improve further their documentation as mention in above. They agreed." |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 95. | Name and address of manufacturer / Applicant | M/s Bajwa Pharmaceuticals (Pvt) Ltd.<br>36-Km, GT Road Khori Murredke,Sheikhupura |
| | Brand Name +Dosage Form + Strength | Falfin Injection |
| | Composition | Each ml contains:<br>Nalbuphine HCl…10mg |
| | Diary No. Date of R& I & fee | Dy.No 5320 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | Opiate analgesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1ml Rs: 45/ Ampoule |
| | Approval status of product in Reference Regulatory Authorities | Nalbuphine Hydrochloride of USFDA approved |
| | Me-too status (with strength and dosage form) | Nalphin 20mg Injection of M/s Pharmatec |
| | GMP status | Last GMP inspection was conducted on 21-02-2018 and report concludes that Overall hygienic condition of firm is satisfactory at the time of inspection. They were advised improve further their documentation as mention in above. They agreed." |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 96. | Name and address of manufacturer / Applicant | M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura |
| | Brand Name +Dosage Form + Strength | B-CIN 50 Injection |

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| | Composition | Each ml contains:<br>Amikacin (as Sulphate)…50mg |
| | Diary No. Date of R& I & fee | Dy.No 5321 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1ml x 1's & 1ml x 05;As per PRC |
| | Approval status of product in Reference Regulatory Authorities | Amikacin of USFDA approved |
| | Me-too status (with strength and dosage form) | Grasil 50mg Injection of M/s Sami Pharmaceuticals, |
| | GMP status | Last GMP inspection was conducted on 21-02-2018 and report concludes that Overall hygienic condition of firm is satisfactory at the time of inspection. They were advised improve further their documentation as mention in above. They agreed." |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 97. | Name and address of manufacturer / Applicant | M/s Bajwa Pharmaceuticals (Pvt) Ltd.<br>36-Km, GT Road Khori Murredke,Sheikhupura |
| | Brand Name +Dosage Form + Strength | B-CIN 100mg/2ml Injection |
| | Composition | Each ml contains:<br>Amikacin (as Sulphate)…50mg |
| | Diary No. Date of R& I & fee | Dy.No 5322 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2ml x 1's : 2ml x 5's & 2ml x 10's ;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Amikin Injection Of MHRA Approved |
| | Me-too status (with strength and dosage form) | Nekrocin 100 Injection of M/s Safe Pharmaceuticals, |
| | GMP status | Last GMP inspection was conducted on 21-02-2018 and report concludes that overall hygienic condition of firm is satisfactory at the time of inspection. They were advised improve further their documentation as mention in above. They agreed." |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 98. | Name and address of manufacturer / Applicant | M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura |
| | Brand Name +Dosage Form + Strength | B-CIN 250mg/2ml Injection |
| | Composition | Each ml contains:<br>Amikacin (as Sulphate)…125mg |
| | Diary No. Date of R& I & fee | Dy.No 5323 dated 14-02-2018 Rs. 20,000/- (14-02-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2ml x 1's : 2ml x 5's & 2ml x 10's ;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Briklin 250mg/2ml by EMA |
| | Me-too status (with strength and dosage form) | Aminocin 250mg Injection of M/s Macquins International, |
| | GMP status | Last GMP inspection was conducted on 21-02-2018 and report concludes that overall hygienic condition of firm is satisfactory at the time of inspection. They were advised improve further their documentation as mention in above. They agreed." |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |

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| 99. | Name and address of manufacturer / Applicant | M/s Bajwa Pharmaceuticals (Pvt) Ltd.<br>36-Km, GT Road Khori Murredke,Sheikhupura |
| | Brand Name +Dosage Form + Strength | B-CIN 500mg/2ml Injection |
| | Composition | Each ml contains:<br>Amikacin (as Sulphate)…250mg |
| | Diary No. Date of R& I & fee | Dy.No 5324 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2ml x 1's : 2ml x 5's & 2ml x 10's ;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Amikacin Injection Of USFDA Approved |
| | Me-too status (with strength and dosage form) | Dunkin 500mg Injection of M/s Amros Karachi. |
| | GMP status | Last GMP inspection was conducted on 21-02-2018 and report concludes that Overall hygienic condition of firm is satisfactory at the time of inspection. They were advised improve further their documentation as mention in above. They agreed." |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 100. | Name and address of manufacturer / Applicant | M/s Aries Pharmaceuticals.<br>1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k |
| | Brand Name +Dosage Form + Strength | Amoston conti Tablet |
| | Composition | Each blister pack contains:<br>14 White film coated Tablet Contains:<br>Estradiol as Hemihydrate (USP)……1mg<br>14 Brown Film Coated Tablet Contains:<br>Estradiol as Hemihydrate (USP)…….1mg<br>Dydrogesterone (USP)…5mg |
| | Diary No. Date of R& I & fee | Dy.No 5026 dated 12-02-2018 Rs. 20,000/- (12-02-2018) |
| | Pharmacological Group | Progestogen and synthetic steroid |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 1 x 28's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities | FEMOSTON 1/5 tablet by Netherland Approved |
| | Me-too status (with strength and dosage form) | Femoston Conti Tablets Of M/S ABOTT |
| | GMP status | Last GMP inspection was conducted on 21-03-2017 and report concludes that panel recommend the grant of additional sections |
| | Remarks of the Evaluator[4] | Tablet Hormone section available |
| | **Decision: Deferred for confirmation of manufacturing facility of co-blistering.** | |
| 101. | Name and address of manufacturer / Applicant | M/s Aries Pharmaceuticals.<br>1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k |
| | Brand Name +Dosage Form + Strength | Amoston Tablet |
| | Composition | Each blister pack contains:<br>14 White film coated Tablet Contains:<br>Estradiol as Hemihydrate (USP)…1mg<br>14 Brown Film Coated Tablet Contains:<br>Estradiol as Hemihydrate (USP)…1mg<br>Dydrogesterone (USP)…10mg |
| | Diary No. Date of R& I & fee | Dy.No 5025 dated 12-02-2018 Rs. 20,000/- Dated 12-02-2018 |
| | Pharmacological Group | Progestogen and synthetic steroid |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 1 x 28's : As per SRO |

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| | Approval status of product in Reference Regulatory Authorities | FEMOSTON 1/10 tablet by Netherland Approved |
| | Me-too status (with strength and dosage form) | Femoston 1/10 Tablets Of M/S ABOTT |
| | GMP status | Last GMP inspection was conducted on 21-03-2017 and report concludes that panel recommend the grant of additional sections |
| | Remarks of the Evaluator[4] | Tablet Hormone section available |
| | **Decision: Deferred for confirmation of manufacturing facility of co-blistering.** | |
| 102. | Name and address of manufacturer / Applicant | M/s Magns Pharmaceuticals.<br>Plot No. 7-B, Value Addition City Faisalabad |
| | Brand Name +Dosage Form + Strength | Cilox Dry Powder Suspension |
| | Composition | Each 5ml contains:<br>Ciprofloxacin (as taste mask granules 35%)…125mg |
| | Diary No. Date of R& I & fee | Dy.No 5209 dated 13-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Macrolide Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 60ml; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Biaxin granules for oral suspension 125mg/5ml by M/s Abbvie, USFDA approved |
| | Me-too status (with strength and dosage form) | Rethro 125mg/5ml Dry Suspension by M/s Regal Pharmaceuticals |
| | GMP status | Last GMP inspection conducted on 07-12-2017, & report concludes that the firm was considerd to be opeating at Good level of compliance. |
| | Remarks of the Evaluator[4] | • Source of granules: Vision |
| | **Decision: Deferred for further deliberation upon salt form of API, in view of reference product** | |
| 103. | Name and address of manufacturer / Applicant | M/s Macter International Limited.<br>F-216, S.I.T.E. Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Dapozin-M 5mg+850mg |
| | Composition | Each tablet contain:<br>Dapagliflozin……..5mg<br>Metformin…….850mg |
| | Diary No. Date of R& I & fee | Dy.No 5281 dated 14-02-2018 Rs. 50,000/- 14-02-2018 |
| | Pharmacological Group | Antidiabetic |
| | Type of Form | Form 5-D |
| | Finished product Specifications | Manufacturer specification. |
| | Pack size & Demanded Price | 14's, 28's (RS: 5000/14's & 10500/28's) |
| | Approval status of product in Reference Regulatory Authorities | EMA approved |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Last GMP inspection was conducted on 23-05-2018 and report concludes The firm is found to be complying at good level of GMP compliance at the time of inspection. Continuous improvement for procedures shall be followed in letter and spirit as per the Drug Act, 1976, DRAP Act, 2012 and the rules framed there under. |
| | Remarks of the Evaluator[4] | Stability data required |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith 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 278th meeting of registration Board.** | |
| 104. | Name and address of manufacturer / Applicant | M/S Wahaabsons Pharma (Pvt) Ltd. 4 KM Buner Road Barikot, Swat. |
| | Brand Name +Dosage Form + Strength | Wablex L Syrup |
| | Composition | Each 5ml contains<br>Vitamin B1... 4.16mg |

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|---|---|---|
| | | Vitamin B2... 1.66mg<br>Vitamin B6....1mg<br>Vitamin B12... 8.33mcg<br>Niacinamide….18mg<br>Sodium d-pantothenate…..2.5mg (Calcium d Pantothene……2.5mg)<br>Vitamin C….75mg<br>Inositol…...5mg<br>Lysine Monohydrochloride….33.33mg |
| | Diary No. Date of R& I & fee | Dy.No.2289; 22-02-2017; Rs.20,000/- (22-02-2017) |
| | Pharmacological Group | Nutritional supplements |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture's specification |
| | Pack size & Demanded Price | 120ml ;As Rs: 60/ |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Lyodex Syrup of M/s Cardex Pharmaceutical, |
| | GMP status | Last GMP inspection conducted on 25-10-2018<br>Recommendations:<br>Apart from the aforementioned recommendations, the firm is further advised to:<br>1- To develop an independent quality assurance department and appoint an experienced quality assurance manager.<br>2- To improve the water treatment system by installing double RO system along with the currently installed de-ionizer system.<br>All the above points were discussed with the firm's management and they agreed comply them at the earliest under intimation to the area FID. |
| | Remarks of the Evaluator | Revision in master formulation Sodium d pantothenate is replaced with Calcium d-pantothenat. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **For submission of fee for revision of formulation** | |
| 105. | Name and address of manufacturer / Applicant | M/s Pharmedic Laboratories (Pvt) Ltd,Lahore |
| | Brand Name +Dosage Form + Strength | Nofat 60mg Capsule |
| | Composition | Each capsule contains:<br>Orlistat.....60mg |
| | Diary No. Date of R& I & fee | Dy.No.12292 1-10-2015 Rs. 20,000 |
| | Pharmacological Group | Lipase inhibitor |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 3 x 10's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Beacita 120mg Capsules of( MHRA approved) |
| | Me-too status (with strength and dosage form) | Orlisat 120mg Capsules by M/s Merck Sharp & Dhome, |
| | GMP status | Last inspection conducted on 31-08-2018and report concludes that firm was considered to be operating at satisfactory level of compliance with GMP |
| | Remarks of the Evaluator[4] | • Source of pellets: Vision |
| | **Decision: Registration Board deferred for following reasons:**<br>• **Submission of accelerated stability study data of pellets by M/s Vision Pharmaceuticals, Islamabad.**<br>• **Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |

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| 106. | Name and address of manufacturer / Applicant | M/s Pharmedic Laboratories (Pvt) Ltd,Lahore |
| | Brand Name +Dosage Form + Strength | Peta 20mg Tablet |
| | Composition | Each tablet contains:<br>Piroxicam β-Cyclodextrin Eq.to Piroxicam.....20mg. |
| | Diary No. Date of R& I & fee | Dy. No. 1226 21-10-2015 Rs. 20,000 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer Specs |
| | Pack size & Demanded Price | 2 x 10's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Cycladol tablet ( ANSM approved) |
| | Me-too status (with strength and dosage form) | Pirujin Tablet M/s Jupiter Pharma |
| | GMP status | Last inspection conducted on 31-08-2018 and report concludes that firm was considered to be operating at satisfactory level of compliance with GMP |
| | Remarks of the Evaluator[4] | |
| | **Decision: Deferred for updated status of GMP of the firm from QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 107. | Name and address of manufacturer / Applicant | M/s Sharex Laboratories (Pvt) Ltd, Sadiqabad |
| | Brand Name +Dosage Form + Strength | Tracodil-Cough Syrup |
| | Composition | Each 5ml contains:<br>Ammonium Chloride…125<br>Sodium Citrate……55mg<br>Chlorpheniramine maleate……2.5mg<br>Menthol……..1mg |
| | Diary No. Date of R& I & fee | Dy. No. 2439 07-06-2016 Rs. 20,000 |
| | Pharmacological Group | Anti-tussive |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer Specs |
| | Pack size & Demanded Price | 120ml Rs; 59/- |
| | Approval status of product in Reference Regulatory Authorities | Not provided |
| | Me-too status (with strength and dosage form) | Sypriton Syrup of M/s Sayyed Pharmaceuticals (but no menthol Remisole-neo of M/s Remington pharmaceuticals (Glycerin 150mg) |
| | GMP status | Last GMP inspection conducted on 29-03-2017, and the report concludes that firm is at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator[4] | Change of Brand Names<br>• Tracodil C<br>• Tracodil P<br>• Tracodil Koff |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 108. | Name and address of manufacturer / Applicant | M/s Axis Pharmaceuticals, Value Addition City, 3-B, 1.5Km, Khurrianwala-Sahianwala Road, Faislabad |
| | Brand Name +Dosage Form + Strength | Glovin Tablet 850mg |
| | Composition | Each film coated tablet contains:-<br>Metformin-HCl (BP)……..850mg |
| | Diary No. Date of R& I & fee | Dy. No. 2329/R&I dated 03.04.2015<br>Rs.12000/= 31.03.2015<br>Dy. No. 742/DDC-R-V dated. 13.04.2015<br>8000/-04-06-11 |
| | Pharmacological Group | Biguanide |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |

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| | Pack size & Demanded Price | 30's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Glucophage 850 Mg Of USFDA Approved |
| | Me-too status (with strength and dosage form) | Glucophage 850 mg of M/s Merck |
| | GMP status | Last GMP inspection conducted on 19-09-2018 & 03-10-2018,and the report concludes that firm is at Operating fair level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 109. | Name and address of manufacturer / Applicant | M/s Axis Pharmaceuticals, Value Addition City, 3-B, 1.5Km, Khurrianwala-Sahianwala Road, Faislabad |
| | Brand Name +Dosage Form + Strength | Transix 500mg Capsule |
| | Composition | Each capsule contains:-<br>Tranexamic Acid (BP)……500mg |
| | Diary No. Date of R& I & fee | Dy. No. 2329/R&I dated 03.04.2015<br>Rs.12000/= 31.03.2015<br>Dy. No. 742/DDC-R-V (13.04.2015) Rs.8000/-04-06-11 |
| | Pharmacological Group | Haemostatic/ Fibrinolytic |
| | Type of Form | Form 5 |
| | Finished product Specifications | JP |
| | Pack size & Demanded Price | 20's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Tranxe of AIFa Italy approved |
| | Me-too status (with strength and dosage form) | Bleex 500 .mg Capsule of M/s Navegal Laboratories |
| | GMP status | Last GMP inspection conducted on 19-09-2018 & 03-10-2018,and the report concludes that firm is at operating fair level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 110. | Name and address of manufacturer / Applicant | M/S Saibins Pharmaceuticals Plot # 316 Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Saipram 5mg tablet |
| | Composition | Each film coated tablet contains:<br>Escitalopram (as oxalate).....5mg |
| | Diary No. Date of R& I & fee | Dy. No. 2913 21-12-2015 Rs. 20,000/- |
| | Pharmacological Group | Selective Serotonin Reuptake Inhibitors (SSRIs) |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1 x 14's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Escitalopram 5 mg Of ( MHRA Approved) |
| | Me-too status (with strength and dosage form) | Gentle 5mg Tablet Of M/S Wilson's Pharmaceuticals, |
| | GMP status | Last GMP inspection conducted on 26-07-2018 & 28-12-2018 and the report concludes that panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 111. | Name and address of manufacturer / Applicant | M/S Saibins Pharmaceuticals Plot # 316 Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Saipram 20mg tablet |
| | Composition | Each film coated tablet contains:<br>Escitalopram (as oxalate).....20mg |
| | Diary No. Date of R& I & fee | Dy. No. 2913 21-12-2015 Rs. 20,000/- |
| | Pharmacological Group | Selective Serotonin Reuptake Inhibitors (SSRIs) |
| | Type of Form | Form 5 |

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| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1 x 14's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Escitalopram 20 mg Of ( MHRA Approved) |
| | Me-too status (with strength and dosage form) | Gentle 20mg Tablet Of M/S Wilson's harmaceuticals, |
| | GMP status | Last GMP inspection conducted on 26-07-2018 & 28-12-2018 and the report concludes that panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad.. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 112. | Name and address of manufacturer / Applicant | M/S Saibins Pharmaceuticals Plot # 316 Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Topira 50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Topiramate…….50mg |
| | Diary No. Date of R& I & fee | Dy.No.20483; 09-11-2017; Rs.20,000/- (08-11-2017) |
| | Pharmacological Group | Antiepileptic agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 6 x 10's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Topamax Of ( USFDA Approved) |
| | Me-too status (with strength and dosage form) | Lowseiz 50mg Tablets of M/S Helix Pharma |
| | GMP status | Last GMP inspection conducted on 26-07-2018 & 28-12-2018 and the report conclude that panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad. |
| | Remarks of the Evaluator | The official monograph is available in USP |
| | **Decision: Approved with USP specification.** | |
| 113. | Name and address of manufacturer / Applicant | M/S Saibins Pharmaceuticals Plot # 316 Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Topira 100mg Tablet |
| | Composition | Each film coated tablet contains:<br>Topiramate…….100mg |
| | Diary No. Date of R& I & fee | Dy.No.20484; 09-11-2017; Rs.20,000/- (08-11-2017) |
| | Pharmacological Group | Antiepileptic agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 6 x 10's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Topamax Of ( USFDA Approved) |
| | Me-too status (with strength and dosage form) | Epilock 100 mg Tablets of M/S Welmark Pharmaceuticals |
| | GMP status | Last GMP inspection conducted on 26-07-2018 & 28-12-2018 and the report concludes that panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad. |
| | Remarks of the Evaluator | The official monograph is available in USP |
| | **Decision: Approved with USP specification.** | |
| 114. | Name and address of manufacturer / Applicant | M/S Saibins Pharmaceuticals Plot # 316 Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Tazip 15mg tablet |
| | Composition | Each film coated tablet contains:<br>Mirtazapine ……. 15mg |
| | Diary No. Date of R& I & fee | Dy.No.20486; 09-11-2017; Rs.20,000/- (08-11-2017) |
| | Pharmacological Group | Antidepressant |

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| | Type of Form | Form-5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 2 x 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Mirtazapine of (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Tazemir 15mg Tablet of M/s Lisko Pakistan |
| | GMP status | Last GMP inspection conducted on 26-07-2018 & 28-12-2018 and the report concludes that panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad. |
| | Remarks of the Evaluator | The official monograph is available in USP |
| | **Decision: Approved with USP specification.** | |
| 115. | Name and address of manufacturer / Applicant | M/S Saibins Pharmaceuticals Plot # 316 Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Tazip 30mg tablet |
| | Composition | Each film coated tablet contains:<br>Mirtazapine ……. 30mg |
| | Diary No. Date of R& I & fee | Dy.No.20485; 09-11-2017; Rs.20,000/- (08-11-2017) |
| | Pharmacological Group | Antidepressant |
| | Type of Form | Form-5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 2 x 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Mirtazapine of (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Tazemir 30mg Tablet of M/s Lisko Pakistan |
| | GMP status | Last GMP inspection conducted on 26-07-2018 & 28-12-2018 and the report concludes that panel unanimously recommended the renewal of DML 000773 by way of formulation of M/s Saibins Pharmaceuticals Islamabad. |
| | Remarks of the Evaluator | The official monograph is available in USP |
| | **Decision: Approved with USP specification.** | |
| 116. | Name and address of manufacturer / Applicant | M/S Global Pharmaceuticals (Pvt) Ltd, Plot # 204-205, Industrial Triangle, Kahuta Road Islamabad. |
| | Brand Name +Dosage Form + Strength | Mecomed 1000mcg Injection |
| | Composition | Each ml contains:<br>Mecobalamine JP …….1000mcg |
| | Diary No. Date of R& I & fee | Dy.No.20379; 08-11-2017; Rs.20,000/- (08-11-2017) |
| | Pharmacological Group | Vitamin |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1ml x 10's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Not found |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Last GMP inspection was conducted on 11 & 24-10-2018 and the report concludes that panel unanimously decided to recommend the issuance of GMP |
| | Remarks of the Evaluator[4] | • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/ drug already approved by DRAP (generic / me-too status)** | |

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| | **alongwith registration number, brand name and name of firm**<br>• **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 117. | Name and address of manufacturer / Applicant | M/s Werrick Pharmaceuticals.<br>216-217,I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | EbaSoft Liquid |
| | Composition | Each 5ml Contains:<br>Ebastine…5mg |
| | Diary No. Date of R& I & fee | Dy.No 4643 dated 08-02-2018 Rs. 20,000/- 08-02-2018 |
| | Pharmacological Group | Anti-histamine |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 30ml, 60ml ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ebastel oral solution 1mg/ml of Almirall, Spanish medicine agency |
| | Me-too status (with strength and dosage form) | Sebastine syrup of Vision Pharma |
| | GMP status | Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 118. | Name and address of manufacturer / Applicant | M/s Werrick Pharmaceuticals.<br>216-217,I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Flueze-Extra Tablets 200/5mg |
| | Composition | Each film coated tablet contains:<br>Ibuprofen…200mg<br>Phenylephrine Hydrochloride…5mg |
| | Diary No. Date of R& I & fee | Dy.No 4651 dated 08-02-2018 Rs. 20,000/- 08-02-2018 |
| | Pharmacological Group | NSAID & Sympathomimetic decongestant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 10's, 20's, 30's, ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Nurofen Cold & Flu Relief 200mg/5mg Tablets. |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance. |
| | Remarks of the Evaluator[4] | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 119. | Name and address of manufacturer / Applicant | M/s Werrick Pharmaceuticals.<br>216-217,I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Flueze-Extra Tablets 200/10mg |
| | Composition | Each film coated tablet contains:<br>Ibuprofen…200mg<br>Phenylephrine Hydrochloride…10mg |
| | Diary No. Date of R& I & fee | Dy.No 4652 dated 08-02-2018 Rs. 20,000/- Dated 08-02-2018 |
| | Pharmacological Group | NSAID & Sympathomimetic decongestant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 10's, 20's, 30's, ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | ADVIL CONGESTION RELIEF of USFDA approved |

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| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance |
| | Remarks of the Evaluator[4] | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 120. | Name and address of manufacturer / Applicant | M/s Werrick Pharmaceuticals. 216-217,I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Flueze Expectorant |
| | Composition | Each 5ml contains:<br>Guaifenesin…50mg |
| | Diary No. Date of R& I & fee | Dy.No 4646 dated 08-02-2018 Rs. 20,000/- 08-02-2018 |
| | Pharmacological Group | Expectorant |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 60ml ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Lemsip Cough for Chesty Cough of MHRA approved |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance. |
| | Remarks of the Evaluator[4] | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 121. | Name and address of manufacturer / Applicant | M/s Werrick Pharmaceuticals, 216-217,I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Flueze-Extra Sachets |
| | Composition | Each Sachet contains:<br>Paracetamol…1000mg<br>Phenylephrine Hydrochloride…12.2mg<br>Guaifenesin…200mg |
| | Diary No. Date of R& I & fee | Dy.No 4649 dated 08-02-2018 Rs. 20,000/-<br>Dated 08-02-2018 |
| | Pharmacological Group | NSAID & Sympathomimetic decongestant & Expectorant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 1 x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Lemsip Cough Max for Mucus Cough & Cold 1000mg/ 200mg/12.2mg Powder for Oral Solution of MHRA approved |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance. |
| | Remarks of the Evaluator[4] | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

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| 122. | Name and address of manufacturer / Applicant | M/s Werrick Pharmaceuticals, 216-217,I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Flueze-Extra Capsules |
| | Composition | Each Capsule contains:<br>Paracetamol…500mg<br>Phenylephrine Hydrochloride…6.1mg<br>Guaifenesin…100mg |
| | Diary No. Date of R& I & fee | Dy.No 4650 dated 08-02-2018 Rs. 20,000/-<br>Dated 08-02-2018 |
| | Pharmacological Group | NSAID & Sympathomimetic decongestant & Expectorant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 1 x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Lemsip Cough Max for Mucus Cough & Cold 500mg/ 100mg/6.1mg Powder for Oral Solution of MHRA approved |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance. |
| | Remarks of the Evaluator[4] | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 123. | Name and address of manufacturer / Applicant | M/s Werrick Pharmaceuticals, 216-217,I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Fluezo Pro Tablets |
| | Composition | Each film coated tablet contains:<br>Ibuprofen…150mg<br>Paracetamol…500mg |
| | Diary No. Date of R& I & fee | Dy.No 5284 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 10's, 20's, 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Combogesic 500 Mg/150 Mg Film-Coated Tablets of MHRA approved |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Routine GMP inspection conducted on 07-12-2017 concluded that the firm is operating at a very good level of GMP compliance. |
| | Remarks of the Evaluator[4] | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 124. | Name and address of manufacturer / Applicant | M/s Atco Laboratories Limited.B-18, S.I.T.E. Karachi |
| | Brand Name +Dosage Form + Strength | Eskazole Tablets 200mg |
| | Composition | Each film coated tablet contains:<br>Albendazole …200mg |
| | Diary No. Date of R& I & fee | Dy.No 5186 dated 13-02-2018 Rs. 20,000/- Dated 12-02-2018 |
| | Pharmacological Group | ANTHELMINTICS |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |

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| | Pack size & Demanded Price | 2's, 7's, 14's, 20's, 28's, 30's & 60's<br>RS: 100/2's, 350/7's, 500/10's,700/14's 1000/20's, 1400/28's, 1500/30's & 3000/60's |
| | Approval status of product in Reference Regulatory Authorities | ALBENZA Of USFDA Approved |
| | Me-too status (with strength and dosage form) | Bentil Tablets of M/s Alliance Pharmaceuticals |
| | GMP status | Last GMP inspection was conducted on 21-07-2017 and report concludes that firm was considered to be operating at good level of compliance |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 125. | Name and address of manufacturer / Applicant | M/s Atco Laboratories Limited.B-18, S.I.T.E. Karachi |
| | Brand Name +Dosage Form + Strength | Eskazole Tablets 400mg |
| | Composition | Each film coated tablet contains:<br>Albendazole …400mg |
| | Diary No. Date of R& I & fee | Dy.No 5185 dated 13-02-2018 Rs. 20,000/- 12-02-2018 |
| | Pharmacological Group | ANTHELMINTICS |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2's, 7's, 14's, 20's, 28's, 30's & 60's<br>RS: 200/2's, 700/7's, 1000/10's,1400/14's 2000/20's, 2800/28's, 3000/30's & 6000/60's |
| | Approval status of product in Reference Regulatory Authorities | Eskazole 400mg tablet by GSK Austrailia |
| | Me-too status (with strength and dosage form) | Wormgo Tablets of M/s Mediceena Pharma |
| | GMP status | Last GMP inspection was conducted on 21-07-2017 and report concludes that firm was considered to be operating at good level of compliance |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved.** | |
| 126. | Name and address of manufacturer / Applicant | M/s Atco Laboratories Limited.B-18, S.I.T.E. Karachi |
| | Brand Name +Dosage Form + Strength | Carizole Topical Solution 1%w/v |
| | Composition | Each ml contains:<br>Clotrimazole …10mg (1%w/v) |
| | Diary No. Date of R& I & fee | Dy.No 5187 dated 13-02-2018 Rs. 20,000/- Dated 12-02-2018 |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 5ml, 10ml, 15ml, 20ml, 30ml, &60ml<br>RS: 250/5ml, 500/10ml, 750/15ml, 1000/20ml, 1500/30ml, &300/60ml |
| | Approval status of product in Reference Regulatory Authorities | Canesten Solution Of MHRA Approved |
| | Me-too status (with strength and dosage form) | Not found (Firm provided Clotrimazole Solution 1% w/v in 137 meeting Registration No: 022958 Registration date 01-01-1999 Karachi chemicals Industries. |
| | GMP status | Last GMP inspection was conducted on 21-07-2017 and report concludes that firm was considered to be operating at good level of compliance |
| | Remarks of the Evaluator[4] | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

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| 127. | Name and address of manufacturer / Applicant | M/s Aspin Pharma Pvt Ltd. Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan |
| | Brand Name +Dosage Form + Strength | Obzinq 20mg Disperable Tablets |
| | Composition | Each disperible tablet contains:<br>Zinc Sulfate monohydrate 54.90mg eq. to Zinc…..20mg |
| | Diary No. Date of R& I & fee | Dy.No 5009 dated 12-02-2018 Rs. 20,000/- 12-02-2018 |
| | Pharmacological Group | Antidiarrheal |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 100's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities | WHO prequalified Zincfant Tablet 20 mg manufactured by Laboratoires Pharmaceutique s Rodael -France |
| | Me-too status (with strength and dosage form) | Zinxus Tablet of M/s Ferozsons |
| | GMP status | Last GMP inspection was conducted on 20-02-2018 and report concludes firm was operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with BP specifications.** | |
| 128. | Name and address of manufacturer / Applicant | M/s Asian Continental Pvt Ltd. Continental House, D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Roxam Uncoated Tablet |
| | Composition | Each uncoated tablet contains:<br>Piroxicam-β-Cyclodextrin…191.2mg eq. to Piroxicam ……20mg |
| | Diary No. Date of R& I & fee | Dy.No 5315 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 10's ,20's, ; As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | Cycladol 20 mg Tablets of ( ANSM approved) |
| | Me-too status (with strength and dosage form) | Pirujin Tablet M/s Jupiter Pharma |
| | GMP status | Last GMP inspection was conducted on 6-14-2018 and report concludes that their current GMP compliance level is rated as Good. |
| | Remarks of the Evaluator[4] | |
| | Decision: Approved with innovator's specification. | |
| 129. | Name and address of manufacturer / Applicant | M/s Asian Continental Pvt Ltd. Continental House, D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Prazo 0.25mg Tablet |
| | Composition | Each uncoated tablet contains:<br>Alprazolam …0.25mg |
| | Diary No. Date of R& I & fee | Dy.No 5316 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 3 x 10's , ; As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | Xanax 250 microgram Tablets by M/s Pfizer Limited (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Alprazolam 0.25mg Tablets by M/s Heal Pharmaceutical |
| | GMP status | Last GMP inspection was conducted on 6/14/2018 and report concludes that their current GMP compliance level is rated as Good. |
| | Remarks of the Evaluator[4] | Psychotropic section is not available. |
| | **Decision: Deferred for confirmation of Tablet (Narcotic/Psychotropic) section.** | |

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| 130. | Name and address of manufacturer / Applicant | M/s Asian Continental Pvt Ltd. Continental House, D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Prazo 0.5mg Tablet |
| | Composition | Each uncoated tablet contains:<br>Alprazolam (USP)…0.5mg |
| | Diary No. Date of R& I & fee | Dy.No 5317 dated 14-02-2018 Rs. 20,000/- 14-02-2018 |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 3 x 10's , ; As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | Xanax 500 microgram Tablets by M/s Pfizer Limited (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Alprazolam 0.5mg Tablets by M/s Heal Pharmaceutical |
| | GMP status | Last GMP inspection was conducted on 19-09-2017 and report concludes that their current GMP compliance level is rated as Good. |
| | Remarks of the Evaluator[4] | Psychotropic section is not available |
| | **Decision: Deferred for confirmation of Tablet (Narcotic/Psychotropic) section** | |

**Evaluator PEC-V**

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| 131. | Name and address of manufacturer / Applicant | M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A Sundar Industrial Estate, Raiwind Road ,Lahore |
| | Diary No. Date of R& I & fee | Diary No:3061, 23/01/2018, Rs: 20,000/- 18/01/2018 |
| | Brand Name +Dosage Form + Strength | Diafax Tablet 550mg |
| | Composition | Each film coated tablet contains:<br>Rifaximin……550mg |
| | Pharmacological Group | Antibiotics (A07AA11) |
| | Type of Form | Form 5 |
| | Finished product Specification | Inhouse |
| | Pack size & Demanded Price | 10's, 14's, 20's,30's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | XIFAXAN®<br>USFDA Approved |
| | Me-too status | 081073; Rixago 550mg<br>M/s OBS Pharma Karachi. |
| | GMP status | GMP dated 12-2-2018, the GMP compliance status of firm can't be verified because firm was not operational at the time of inspection however premises were found well maintained and at satisfactory level. |
| | Remarks of the Evaluator. | Tablet Section is approved. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 132. | Name and address of manufacturer / Applicant | M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A Sundar Industrial Estate, Raiwind Road ,Lahore |
| | Diary No. Date of R& I & fee | Diary No:3060, 23/01/2018, Rs: 20,000/- 18/01/2018 |
| | Brand Name +Dosage Form + Strength | Diafax Tablet 200mg |
| | Composition | Each film coated tablet contains:<br>Rifaximin……200mg |
| | Pharmacological Group | Antibiotics (A07AA11) |
| | Type of Form | Form 5 |
| | Finished product Specification | Inhouse |
| | Pack size & Demanded Price | 10's, 14's, 20's, 30's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | XIFAXAN®<br>USFDA Approved |
| | Me-too status | 081074; Rixago 200mg<br>M/s OBS Pharma Karachi. |
| | GMP status | GMP dated 12-2-2018, the GMP compliance status of firm can't be verified because firm was not operational at |

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| | | the time of inspection however premises were found well maintained and at satisfactory level. |
| | Remarks of the Evaluator. | Tablet Section is approved. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 133. | Name and address of manufacturer / Applicant | M/s Bloom Pharmaceuticals Pvt. Ltd.<br>Plot No. 30, Phase I and II, Industrial Estate, Hattar |
| | Diary No. Date of R& I & fee | Diary No:3045, 23/01/2018, Rs: 20,000/- 23/01/2018 |
| | Brand Name +Dosage Form + Strength | Austaban Cream |
| | Composition | Each g contains:<br>Mupirocin as Calcium….20mg |
| | Pharmacological Group | Antibiotics For Topical Use<br>D06AX09 |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 15g, 30g, As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Bactroban<br>USFDA Approved |
| | Me-too status | 055229 ; Mupicin Cream.<br>M/s Shrooq Pharmaceuticals (Pvt) Ltd, Lahore. |
| | GMP status | 07-04-2018. Conclusion:<br>Overall the firm was operating under good level of cGMP. |
| | Remarks of the Evaluator. | Cream section is present. |
| | Decision: **Approved** | |
| 134. | Name and address of manufacturer / Applicant | M/s Bloom Pharmaceuticals Pvt. Ltd.<br>Plot No. 30, Phase I and II, Industrial Estate, Hattar |
| | Diary No. Date of R& I & fee | Diary No:3047, 23/01/2018, Rs: 20,000/- 23/01/2018 |
| | Brand Name +Dosage Form + Strength | Blofol Syrup |
| | Composition | Each 5 ml contains:<br>Iron III hydroxide polymaltose complex eq. to elemental iron…50mg<br>Folic acid…..0.35mg |
| | Pharmacological Group | Hematinic |
| | Type of Form | Form 5 |
| | Finished product Specification | Inhouse |
| | Pack size & Demanded Price | 60ml, 120ml in an amber glass bottle |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | 054851; Bioron F Syrup 120ml<br>M/s Shaheen Pharmaceuticals,Swat |
| | GMP status | 07-04-2018. Conclusion:<br>Overall the firm was operating under good level of cGMP. |
| | Remarks of the Evaluator. | Liquid syrup section approval is present. |
| | **Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.** | |
| 135. | Name and address of manufacturer / Applicant | M/s Bloom Pharmaceuticals Pvt. Ltd.<br>Plot No. 30, Phase I and II, Industrial Estate, Hattar |
| | Diary No. Date of R& I & fee | Diary No:3046, 23/01/2018, Rs: 20,000/- 23/01/2018 |
| | Brand Name +Dosage Form + Strength | Blomine Tablet 500mcg |
| | Composition | Each sugar coated tablet contains:<br>Mecobalamin….500mcg |
| | Pharmacological Group | Vitamin B12. |
| | Type of Form | Form 5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | 2x10's, 3x10's, 10x10's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | PMDA Approved sugar coated |
| | Me-too status | 081876; Heam 500 mcg Tablet M/s Linear Parma. |

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| | GMP status | 07-04-2018. Conclusion:<br>Overall the firm was operating under good level of cGMP. |
| | Remarks of the Evaluator. | Firm has revised their formulation from film coated to sugar coated tablet without the submission of requisite fee. |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| 136. | Name and address of manufacturer / Applicant | M/sWelmed Pharmaceutical Industries (Pvt)Ltd. Plot No. 108- R-2,IndustrialEstate Gadoon, Dist. Swabi, KPK |
| | Brand Name +Dosage Form + Strength | Mecowel Tablet 500mcg |
| | Diary No. Date of R& I & fee | Diary No:19684, 1/11/2017, Rs: 20,000/- 19-Oct-2017 |
| | Composition | Each film coated tablet contains:<br>Mecobalamin…500mcg |
| | Pharmacological Group | WHO ATC index also classifies Mecobalamin as "Antianemic preparations" |
| | Type of Form | Form 5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | 7's, 14;s, 28's. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PMDA approved (as sugar coated) |
| | Me-too status | 039173 Nervon 500ug Tablets<br>Each film coated tablet contains:<br>Mecobalamin….500ug Getz Pharma, Karachi |
| | GMP status | 04-03-2017,<br>Renewal of DML and grant of additional sections. |
| | Remarks of the Evaluator. | PMDA approved (as sugar coated). While the firm has applied as film coated tablet. |
| | **Decision: Deferred for submission of Form-5 and revised master formulation as per reference product along with requisite fee for change of formulation.** | |
| 137. | Name and address of manufacturer / Applicant | M/sWelmed Pharmaceutical Industries (Pvt)Ltd. Plot No. 108- R-2,IndustrialEstate Gadoon, Dist. Swabi, KPK |
| | Brand Name +Dosage Form + Strength | Sitamin Tablet 500mg/50mg |
| | Diary No. Date of R& I & fee | Diary No:19691, 1/11/2017, Rs: 20,000/- 19-Oct-2017 |
| | Composition | Each film coated tablet contains:<br>Sitagliptin(as phosphate monohydrate)…50mg<br>Metformin hydrochloride…..500mg |
| | Pharmacological Group | Dipeptidyl peptidase-4 inhibitor/Biguanide |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 2x7's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Glusimet 50mg/500mg Tablet of Opal Lab. Karachi. |
| | GMP status | Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 138. | Name and address of manufacturer / Applicant | M/sWelmed Pharmaceutical Industries(Pvt)Ltd. Plot No. 108- R-2,IndustrialEstate Gadoon, Dist. Swabi, KPK |
| | Brand Name +Dosage Form + Strength | Sitamin Tablet 1000mg/50mg |
| | Diary No. Date of R& I & fee | Diary No:19692, 1/11/2017, Rs: 20,000/- 19-Oct-2017 |
| | Composition | Each film coated tablet contains:<br>Sitagliptin(as phosphate monohydrate)…50mg<br>Metformin hydrochloride…..1000mg |
| | Pharmacological Group | Dipeptidyl peptidase-4 inhibitor/Biguanide |

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| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 2x7's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Silmax-M 50mg/1000mg tablet of M/s. High-Q Pharmaceuticals |
| | GMP status | Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 139. | Name and address of manufacturer / Applicant | M/s Treat Pharmaceutical Industry Pvt. Ltd, A-37, Small Industrial Estate, Township, Kohat Road, Bannu |
| | Diary No. Date of R& I & fee | Diary No:2986, 22/01/2018, Rs: 20,000/- 10/01/2018 |
| | Brand Name +Dosage Form + Strength | Titamin Injection 500mg/10ml<br>Kemin, Treat me, Trimitek |
| | Composition | Each ampoule contains:<br>Ketamine as Hydrochloride…..500mg/10ml |
| | Pharmacological Group | General anesthetics (N01AX03) |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10ml glass ampoule, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Ketalar<br>USFDA Approved<br>10-mL multi-dose vial |
| | Me-too status | 026630 ; Ketarol Injection 50mg/ml<br>M/s Global Pharmaceuticals, Islamabad. |
| | GMP status | Routine GMP inspection dated 06-11-2018 concluded, the firm may be considered to be operating at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | International availability is in vial.<br>Section Approval: Liquid infusion. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in ampoule container closiure system from reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**<br>• **Evidence of approval of required manufacturing facility i.e. Liquid injectable ampoule (general) section from Central Licensing Board.** | |
| 140. | Name and address of manufacturer / Applicant | M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd., L-4/1, A & B, Block-21, Federal B, Industrial Area, Karachi |
| | Diary No. Date of R& I & fee | Diary No:3062, 23/01/2018, Rs: 20,000/- 22/01/2018 |
| | Brand Name +Dosage Form + Strength | Biozaf Tablet 150mg |
| | Composition | Each film coated tablet contains:<br>Ibandronate monosodium monohydrate, equivalent to Ibandronic acid…150mg |
| | Pharmacological Group | Drugs Affecting Bone Structure And Mineralization<br>Bisphosphonates (M05BA06) |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 1's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Boniva Tablets<br>USFDA Approved |
| | Me-too status | 081130; Franjic 150mg Tablet M/s Martin Dow Ltd. |

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| | GMP status | 11-01-2018, Renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 141. | Name and address of manufacturer / Applicant | M/s English Pharmacetuicals Industries, Link Kattar Band Road, Thokar Niaz Baig, Multan Road |
| | Diary No. Date of R& I & fee | Diary No:2978, 22/01/2018, Rs: 20,000/- 22/01/2018 |
| | Brand Name +Dosage Form + Strength | Water for Injection 10ml |
| | Composition | Each ampoule contains:<br>Water for injection …10ml |
| | Pharmacological Group | N/A |
| | Type of Form | Form 5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 10ml ampoule, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | 073671; Water for Injection<br>M/s Genix Pharma Karachi . |
| | GMP status | 16-01-2018, Fair compliance except for penicillin section. |
| | Remarks of the Evaluator. | Liquid Injection ampoule SVP is present. |
| | **Decision: Approved** | |
| 142. | Name and address of manufacturer / Applicant | M/s Medera Pharmaceuticals Pvt. Ltd, Plot 2, Street 4, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | Terbinafine Tablet 250 mg<br>Terbimed, Finomed, Binomed |
| | Diary No. Date of R& I & fee | Duplicate dossier |
| | Composition | Each film coated tablet contains:<br>Terbinafine Hydrochloride eq. to Terbinafine ..250mg |
| | Pharmacological Group | Antifungals for systemic use (D01BA02) |
| | Type of Form | Form-5 |
| | Finished product Specification | Inhouse |
| | Pack size & Demanded Price | 10's Alu Alu Blister, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lamisil terbinafine 250mg (as hydrochloride)<br>TGA Approved uncoated. |
| | Me-too status | 081184; Cutis 250mg Tablet M/s Tabros Pharma Karachi. |
| | GMP status | 06-02-2018 Conclusion:<br>Keeping in view of the above facts, overall GMP compliance is found Good as of today. |
| | Remarks of the Evaluator. | • Evidence of international availability and me-too as film coated tablet is required.<br>• Firm has provided evidence of film coated tablets which could not be confirmed.<br>• Present in USP |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Confirmation from R&I section for date of submission of original dossier along with details of submitted fee.** | |
| 143. | Name and address of manufacturer / Applicant | M/s Medera Pharmaceuticals Pvt. Ltd<br>Plot 2, Street 4, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | Orlimed Capsules 120 mg<br>Statomed, Obestat Capsule |
| | Diary No. Date of R& I & fee | Duplicate dossier |
| | Composition | Each Capsule Contains:<br>Orlistat…120mg |
| | Pharmacological Group | Peripherally acting anti-obesity products (A08AB01) |
| | Type of Form | Form-5 |

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|---|---|---|
| | Finished product Specification | Inhouse |
| | Pack size & Demanded Price | 30's Alu Alu Blister, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Beacita 120mg Capsules, hard<br>MHRA Approved |
| | Me-too status | 055576; Orlisat 120mg Capsules<br>M/s Sharp & Dhome, Karachi |
| | GMP status | 06-02-2018 *Conclusion:*<br>Keeping in view of the above facts, overall GMP compliance is found Good as of today. |
| | Remarks of the Evaluator. | Present in USP.<br>Provide source of pellets. |
| | **Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of Supplier and differential fee in case of import of pellets.** | |
| 144. | Name and address of manufacturer / Applicant | M/s OBS Pakistan Private Limited.<br>C-14, S.I.T.E, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3194 dated 24-01-2018 Rs. 20,000/- Dated 24-01-2018 |
| | Brand Name +Dosage Form + Strength | Mezeron 15mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Mirtazapine…15mg" |
| | Pharmacological Group | Antidepressants |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | REMERON<br>USFDA Approved with box warning. |
| | Me-too status | 081646<br>Mirtazameron Tablet 15mg<br>M/s Akson Pharmaceuticals Pvt Ltd, Islamabad |
| | GMP status | 15/11/17. Conclusion:<br>"Based on the areas visited people met and documentation reviewed and found good and compliant as per GMP requirement."<br>Approval of Amendments in Approved Sections/ Facility (03-12-018):<br>1-Warehouse Hormone (Section) Amendment<br>2-Sachet section Hormone (Section) Amendment<br>3-Tablet section Hormone (Section) Amendment<br>4-Capsule Hormone Section Amendment |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board decided to defer the case on the basis of inspection report conducted on 22nd June, 2018. Hence Registration Board decided to defer above case for GMP assessment after renovation of tablet section. Two members panel will evaluate GMP status of tablet section after information by the firm.** | |
| 145. | Name and address of manufacturer / Applicant | M/s OBS Pakistan Private Limited.<br>C-14, S.I.T.E, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3195 dated 24-01-2018 Rs. 20,000/- Dated 24-01-2018 |
| | Brand Name +Dosage Form + Strength | Mezeron 45mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Mirtazapine…45mg |
| | Pharmacological Group | Antidepressants |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved. |
| | Me-too status | 055311; Charmfil 45mg Tablet M/s. Wilshire Lab.. |

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| | GMP status | 15/11/17. Conclusion:<br>"Based on the areas visited people met and documentation reviewed and found good and compliant as per GMP requirement."<br>Approval of Amendments in Approved Sections/ Facility (03-12-018):<br>1-Warehouse Hormone (Section) Amendment<br>2-Sachet section Hormone (Section) Amendment<br>3-Tablet section Hormone (Section) Amendment<br>4-Capsule Hormone Section Amendment |
| | Remarks of the Evaluator. | Approved in USFDA with box warning. |
| | **Decision: Registration Board decided to defer the case on the basis of inspection report conducted on 22nd June, 2018. Hence Registration Board decided to defer above case for GMP assessment after renovation of tablet section. Two members panel will evaluate GMP status of tablet section after information by the firm.** | |
| 146. | Name and address of manufacturer / Applicant | M/s Spencer & Company Pvt Ltd., D-105, S.I.T.E Karachi |
| | Diary No. Date of R& I & fee | Dy.No 2720 dated 19-01-2018 Rs. 20,000/- 19-01-2018 |
| | Brand Name +Dosage Form + Strength | Ibuflam 100mg/5ml Suspension, Inflagesic, Influben |
| | Composition | Each 5ml Contains:<br>Ibuprofen…100mg |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 60ml, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Company: ACTAVIS MID ATLANTIC<br>USFDA Approved |
| | Me-too status | 054571; Ibo-Z Suspension 100mg.<br>Z-Jans Pharmaceuticals (Pvt) Ltd, Peshawar. |
| | GMP status | 29-08-2017, Satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for confirmation of valid DML status from Licensing Division.** | |
| 147. | Name and address of manufacturer / Applicant | M/s Spencer & Company Pvt Ltd., D-105, S.I.T.E Karachi" |
| | Diary No. Date of R& I & fee | Dy.No 2713 dated 19-01-2018 Rs. 20,000/- 19-01-2018 |
| | Brand Name +Dosage Form + Strength | Calpen 50mg Tablets, Calate, Calviden |
| | Composition | Each Uncoated Tablet Contains:<br>Calcium D Pantothenate…50mg" |
| | Pharmacological Group | Vitamin B5 |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 5x10's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Not provided |
| | Me-too status | 006348; Capcipan-T 50mg Tablet<br>M/s Ambrosia Pharmaceuticals, Islamabad |
| | GMP status | 29-08-2017, Satisfactory. |
| | Remarks of the Evaluator. | International availability could not be confirmed. |
| | **Decision: Deferred for following:**<br>• **For confirmation of valid DML status from Licensing Division.**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 148. | Name and address of manufacturer / Applicant | M/s Spencer & Company Pvt Ltd., D-105, S.I.T.E Karachi" |
| | Diary No. Date of R& I & fee | Dy.No 2714 dated 19-01-2018 Rs. 20,000/- 19-01-2018 |
| | Brand Name +Dosage Form + Strength | Tenor 50mg Tablets, Tenocard, Betasel |

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|---|---|---|
| | Composition | Each Film Coated Tablet Contains:<br>Atenolol…50mg |
| | Pharmacological Group | Beta blocking agents, selective |
| | Type of Form | Form 5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 2x10's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | 079888; M-Nol 50 mg Tablet<br>M/s Mafins Karachi . . |
| | GMP status | 29-08-2017, Satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for confirmation of valid DML status from Licensing Division.** | |
| 149. | Name and address of manufacturer / Applicant | M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi |
| | Diary No. Date of R& I & fee | Diary No:3186, 24/01/2018, Rs: 20,000/- 23/01/2018 |
| | Brand Name +Dosage Form + Strength | Pregsafe Capsule 100mg |
| | Composition | Each Capsule contains:<br>Pregabalin…..100mg |
| | Pharmacological Group | Antiepileptic (N03AX16) |
| | Type of Form | Form 5 |
| | Finished product Specification | Inhouse |
| | Pack size & Demanded Price | As per DRAP policy. |
| | Approval status of product in Reference Regulatory Authorities. | Lyrica USFDA Approved. |
| | Me-too status | 081972; Balin 100mg<br>M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad |
| | GMP status | The firm was last inspected on 07.04.2018, wherein the firm was at good cGMP. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 150. | Name and address of manufacturer / Applicant | M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi |
| | Diary No. Date of R& I & fee | Diary No:3185, 24/01/2018, Rs.20,000/- 23/01/2018 |
| | Brand Name +Dosage Form + Strength | Pregsafe Capsule 50mg |
| | Composition | Each Capsule contains:<br>Pregabalin….50mg |
| | Pharmacological Group | Antiepileptic<br>N03AX16 |
| | Type of Form | Form 5 |
| | Finished product Specification | Inhouse |
| | Pack size & Demanded Price | As per DRAP policy. |
| | Approval status of product in Reference Regulatory Authorities. | Lyrica USFDA Approved. |
| | Me-too status | 081970; Balin 50mg<br>M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad |
| | GMP status | The firm was last inspected on 07.04.2018, wherein the firm was at good cGMP. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 151. | Name and address of manufacturer / Applicant | "M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Dy.No 2972 dated 22-01-2018 Rs. 20,000/- 19-01-2018 |
| | Brand Name +Dosage Form + Strength | Tizolex 2mg Tablets |

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|---|---|---|
| | Composition | "Each Tablet Contains:<br>Tizanidine as HCl…2mg" |
| | Pharmacological Group | Muscle Relaxants |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Tizanidine 2 mg Tablets<br>MHRA Approved |
| | Me-too status | 076416 ; Tandolax 2mg Tablet by High-Q Pharmaceuticals, Karachi. |
| | GMP status | The firm was last inspected on 07.09.2017, wherein the firm was rated at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 152. | Name and address of manufacturer / Applicant | "M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Dy.No 2971 dated 22-01-2018 Rs. 20,000/- 19-01-2018 |
| | Brand Name +Dosage Form + Strength | Tizolex 4mg Tablets |
| | Composition | "Each Tablet Contains:<br>Tizanidine as HCl…4mg" |
| | Pharmacological Group | Muscle Relaxants |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Tizanidine 4 mg Tablets<br>MHRA Approved |
| | Me-too status | 076414; Tandolax 4mg Tablet by High-Q Pharmaceuticals, Karachi. |
| | GMP status | The firm was last inspected on 07.09.2017, wherein the firm was rated at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 153. | Name and address of manufacturer / Applicant | "M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Dy.No 2601 dated 19-01-2018 Rs. 20,000/- 17-01-2018 |
| | Brand Name +Dosage Form + Strength | Rosuvast 5mg Tablet |
| | Composition | "Each Film Coated Tablet Contains:<br>Rosuvastatin as Calcium…5mg |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg. Specs. |
| | Pack size & Demanded Price | 10's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Crestor USFDA Approved |
| | Me-too status | 081461; Rosan Tablet 5mg of M/s Sante, Karachi. |
| | GMP status | The firm was last inspected on 07.09.2017, wherein the firm was rated at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 154. | Name and address of manufacturer / Applicant | "M/s Hiranis Pharmaceuticals (Pvt.) Ltd.<br>Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Dy.No 2594 dated 19-01-2018 Rs. 20,000/- 17-01-2018 |
| | Brand Name +Dosage Form + Strength | Caweda 125mg Tablet |
| | Composition | "Each Tablet Contains:<br>Terbinafine as HCL…125mg" |

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| | Pharmacological Group | Antifungal |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved. |
| | Me-too status | 080846; Logirid Tablet 125mg<br>by Lowitt Pharmaceutical (Pvt) Ltd,<br>Plot.No.24 Industrial Estate, Peshawar. |
| | GMP status | The firm was last inspected on 29.01.2019, wherein the firm was rated at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 155. | Name and address of manufacturer / Applicant | "M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Dy.No 2595 dated 19-01-2018 Rs. 20,000/- 17-01-2018 |
| | Brand Name +Dosage Form + Strength | Caweda 250mg Tablet |
| | Composition | "Each Tablet Contains:<br>Terbinafine as HCL…250mg" |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved. |
| | Me-too status | 080847; Logirid Tablet 250mg by Lowitt Pharmaceutical (Pvt) Ltd, Peshawar. |
| | GMP status | The firm was last inspected on 29.01.2019, wherein the firm was rated at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 156. | Name and address of manufacturer / Applicant | "M/s Hiranis Pharmaceuticals (Pvt.) Ltd.<br>Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan" |
| | Diary No. Date of R& I & fee | Dy.No 6184 dated 20-02-2018 Rs. 20,000/- 19-02-2018 |
| | Brand Name +Dosage Form + Strength | Dolact Tablet 75mg/200mcg |
| | Composition | "Each film coated tablet contains:<br>Diclofenac Sodium (as enteric coated)…75mg<br>Misoprostol (1% HPMC Dispersion)…200mcg" |
| | Pharmacological Group | NSAID/Prostaglandin |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Arthrotec<br>USFDA Approved |
| | Me-too status | 074966; Misocot 75 Tablet By M/s Nabiqasim Karachi. |
| | GMP status | The firm was last inspected on 29.01.2019, wherein the firm was rated at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | Approved in USFDA with box warming. |
| | **Decision: Approved.** | |
| 157. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street#S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Alvas Tablets 10mg |
| | Composition | Each film coated tablet contains:<br>Atorvastatin as calcium trihydrate....10mg |
| | Diary No. Date of R& I & fee | Dy.No. 6396 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |

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| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Lipitor 10mg Film coated Tablets, Pfizer Ireland Pharmaceuticals, Ireland (MHRA Approved) |
| | Me-too status | 080816 ; Hitor 10mg Tablet<br>M/s Hygeia Pharmaceuticals, Islamabad |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite Manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | Present in USP. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 158. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street#S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Alvas Tablets 20mg |
| | Composition | Each film coated tablet contains:<br>Atorvastatin as calcium trihydrate….. 20mg |
| | Diary No. Date of R& I & fee | Dy.No. 6397 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Lipitor 20mg Film coated Tablets, Pfizer Ireland Pharmaceuticals, Ireland (MHRA Approved) |
| | Me-too status | 080817; Hitor 20mg Tablet<br>M/s Hygeia Pharmaceuticals, Islamabad |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | Present in USP. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 159. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street#S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Alvas Tablets 40mg |
| | Composition | Each film coated tablet contains:<br>Atorvastatin as calcium trihydrate ....40mg |
| | Diary No. Date of R& I & fee | Dy.No. 6398 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per in-house Specifications. |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Lipitor 40mg Film coated Tablets, Pfizer Ireland Pharmaceuticals, Ireland (MHRA Approved) |
| | Me-too status | 031862 ; Atorscot Tablets 40mg |

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| | | M/s Scotmann Pharmaceuticals, Plot NoE-5, Sector I-10/3 Islamabad. |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | Present in USP. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 160. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Alvas Tablets 80mg |
| | Composition | Each film coated tablet contains:<br>Atorvastatin as calcium trihydrate ....80mg |
| | Diary No. Date of R& I & fee | Dy.No. 6399 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Lipitor 80mg Film coated Tablets, Pfizer Ireland Pharmaceuticals, Ireland (MHRA Approved) |
| | Me-too status | 044769 ; "Lipirex Tablets 80mg.<br>"M/s Highnoon Laboratories, Lahore |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | Present in USP. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 161. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Alvas-EZ Tablets 10/10mg |
| | Composition | Each film coated tablet contains:<br>Atorvastatin as calcium trihydrate...10mg<br>Ezetimibe ……..10mg |
| | Diary No. Date of R& I & fee | Dy.No. 6400 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Atozet 10mg/10mg Film coated Tablets, Merck Sharp & Dohme Ltd. UK (MHRA Approved) |
| | Me-too status | 078838 ; Atorax-E Tablets<br>"M/s. Dyson Research Laboratories (Pvt) Ltd, Lahore. |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can |

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| | | only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 162. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Alvas-EZ Tablets 20/10mg |
| | Composition | Each film coated tablet contains:<br>Atorvastatin as calcium trihydrate....20mg<br>Ezetimibe ……..10mg |
| | Diary No. Date of R& I & fee | Dy.No.6401 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / Cholesterol Absorption Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Atozet 20mg/10mg Film coated Tablets, Merck Sharp & Dohme Ltd. UK (MHRA Approved) |
| | Me-too status | 073715<br>Lipiget EZ 40mg+10mg<br>M/s Getz Pharma Karachi . |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 163. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Alvas Plus Tablets 10/20mg |
| | Composition | Each film coated tablet contains:<br>Amlodipine as besylate……....10mg<br>Atorvastatin as calcium trihydrate……...20mg |
| | Diary No. Date of R& I & fee | Dy.No. 6402 (21-02-2018); Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Calcium Antagonist / Statin |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 7's, 10's, 14's & 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Caduet Tablets 10/20mg, Pfizer Inc.USA (USFDA Approved) |
| | Me-too status | 047164; AM-Descol 10/20 OF Nabiqasim Indus, Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |

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| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 164. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Tablets 10mg |
| | Composition | Each film coated tablet contains:<br>Simvastatin……..10mg |
| | Diary No. Date of R& I & fee | Dy.No. 6403 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Zocor 10mg Tablets, Accord Healthcare Inc., USA (USFDA Approved) |
| | Me-too status | 081604 ; Mistin 10mg Tablet.<br>M/s Mission Pharma. Karachi . . |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 165. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Tablets 20mg |
| | Composition | Each film coated tablet contains:<br>Simvastatin……..20mg |
| | Diary No. Date of R& I & fee | Dy.No.6404 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Zocor 20mg Tablets, Accord Healthcare Inc., USA (USFDA Approved) |
| | Me-too status | 081601 ; Mistin 20mg Tablet.<br>M/s Mission Pharma. Karachi. |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 166. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Tablets 40mg |
| | Composition | Each film coated tablet contains: |

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| | | Simvastatin……..40mg |
| | Diary No. Date of R& I & fee | Dy.No. 6405 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Simvastatin 40mg Tablets, Accord Healthcare Inc., USA (USFDA Approved) |
| | Me-too status | 057988 ; Tavam 40mg Tablet<br>M/s Zanctok Pharmaceuticals, Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 167. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street#S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Tablets 80mg |
| | Composition | Each film coated tablet contains:<br>Simvastatin……..80mg |
| | Diary No. Date of R& I & fee | Dy.No. 6406 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | Statin / HMG-CoA Reductase Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Zocor 80mg Tablets, Accord Healthcare Inc., USA (USFDA Approved) |
| | Me-too status | 049985; Modlip 80mg Tablets<br>"M/s Wilshire Laboratories, 124/A, Kotlakhpat, Indus. Area, Township Scheme, Lahore. |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 168. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street#S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Plus Tablets 10/10mg |
| | Composition | Each tablet contains:<br>Simvastatin ……...10mg<br>Ezetimibe ……..…10mg |
| | Diary No. Date of R& I & fee | Dy.No. 6407 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors in combination with other lipid modifying agents |
| | Type of Form | Form-5 |

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| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 7's, 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vytorin 10mg/10mg Tablets, MSD International GmbH. (USFDA Approved) |
| | Me-too status | 055527 ; Iril 10/10 Tablet<br>By M/s Genix Pharma (Pvt.) Ltd Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however,keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 169. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street#S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Plus Tablets 20/10mg |
| | Composition | Each tablet contains:<br>Simvastatin ……...20mg<br>Ezetimibe ……..…10mg |
| | Diary No. Date of R& I & fee | Dy.No. 6408 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors in combination with other lipid modifying agents |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 7's, 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vytorin 20mg/10mg Tablets, MSD International GmbH. (USFDA Approved) |
| | Me-too status | 055528; Iril 10/20 Tablet<br>By M/s Genix Pharma (Pvt.) Ltd Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 170. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Plus Tablets 40/10mg |
| | Composition | Each tablet contains:<br>Simvastatin ……...40mg<br>Ezetimibe ……..…10mg |
| | Diary No. Date of R& I & fee | Dy.No. 6409 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors in combination with other lipid modifying agents |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 7's, 10's; As per SRO |
| | Approval status of product in Reference | Vytorin 40mg/10mg Tablets, MSD International GmbH. |

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| | Regulatory Authorities | (USFDA Approved) |
| | Me-too status | 055529; Iril 10/40 Tablet<br>By M/s Genix Pharma (Pvt.) Ltd Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however,keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 171. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Simvax Plus Tablets 80/10mg |
| | Composition | Each tablet contains:<br>Simvastatin ……...80mg<br>Ezetimibe ……..…10mg |
| | Diary No. Date of R& I & fee | Dy.No. 6410 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors in combination with other lipid modifying agents |
| | Type of Form | Form-5 |
| | Finished product Specification | As per Inhouse Specifications |
| | Pack size & Demanded Price | 7's, 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vytorin 80mg/10mg Tablets, MSD International GmbH. (USFDA Approved) |
| | Me-too status | 055530; Iril 10/80 Tablet<br>By M/s Genix Pharma (Pvt.) Ltd Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however,keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 172. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Rovastat Tablets 5mg |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin as Calcium……..5mg |
| | Diary No. Date of R& I & fee | Dy.No. 6388 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | As per inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Crestor 5mg film coated Tablets, Astrazeneca UK , Ltd. (MHRA Approved) |
| | Me-too status | 044043 ; Rovista 5mg Tablets<br>M/s Getz Pharma, Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations: |

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| | | "As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 173. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Rovastat Tablets 10mg |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin as Calcium……..10mg |
| | Diary No. Date of R& I & fee | Dy.No.6389 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | As per inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Crestor 10mg film coated Tablets, Astrazeneca UK , Ltd. (MHRA Approved) |
| | Me-too status | 044044; Rovista 10mg Tablets<br>M/s Getz Pharma, Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 174. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Rovastat Tablets 20mg |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin as Calcium……..20mg |
| | Diary No. Date of R& I & fee | Dy.No.6390 dated 21-02-2018; Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | As per inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Crestor 20mg film coated Tablets, Astrazeneca UK , Ltd. (MHRA Approved) |
| | Me-too status | 044045; Rovista 20mg Tablets<br>M/s Getz Pharma, Karachi |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator [XIII] | |

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| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 175. | Name and address of manufacturer / Applicant | M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Rovastat Tablets 40mg |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin as Calcium……..40mg |
| | Diary No. Date of R& I & fee | Dy.No 6391 dated 21-02-2018 Rs. 20,000/- 19-02-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | As per inhouse Specifications |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Crestor 40mg film coated Tablets, Astrazeneca UK , Ltd. (MHRA Approved) |
| | Me-too status | 076862; Rosocard Tablets<br>"M/s Himont Pharma (Pvt.) Ltd., 17 Km Ferozpur Road, Lahore. |
| | GMP status | Last inspection report dated 25-10-2018 with following recommendations:<br>"As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 176. | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | DEPRE-F Capsule 3mg/ 25mg |
| | Composition | Each Capsule contains:<br>Olanzapine……..3mg<br>Fluoxetine as hydrochloride…25mg |
| | Diary No. Date of R& I & fee | Dy.No 6266 dated 20-02-2018 Rs. 20,000/- 20-02-2018 |
| | Pharmacological Group | Antidepressant ( SSRI), Antipsychotic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 14's, Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | SYMBAX Capsule USA (USFDA) |
| | Me-too status | Co-Depricap capsule (Reg 076136) of M/s Nabi Qasim |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Approved in USFDA with box warning. |
| | **Decision: Approved with USP specification** | |
| 177. | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | DEPRE-F Capsule 6mg /25mg |
| | Composition | Each Capsule contains:<br>Olanzapine……..6mg<br>Fluoxetine as hydrochloride…25mg |
| | Diary No. Date of R& I & fee | Dy.No 6267 dated 20-02-2018 Rs. 20,000/- 20-02-2018 |
| | Pharmacological Group | Antidepressant ( SSRI), Antipsychotic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 14's Price: As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | SYMBAX capsule USFDA |
| | Me-too status | Co-Depricap capsule (Reg 076135) Nabi Qasim |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Approved in USFDA with box warning. |
| | **Decision: Approved with USP specification** | |
| 178. | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | DEPRE-F Capsule 12mg/ 25mg |
| | Composition | Each Capsule contains:<br>Olanzapine……..12mg<br>Fluoxetine as hydrochloride…25mg |
| | Diary No. Date of R& I & fee | Dy.No 6268 dated 20-02-2018 Rs. 20,000/- 20-02-2018 |
| | Pharmacological Group | Antidepressant ( SSRI), Antipsychotic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 14's, Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | SYMBAX capsule USFDA |
| | Me-too status | 081975; Olanzo F 12/25mg M/s Regal Pharma, Rawat |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Approved in USFDA with box warning. |
| | **Decision: Approved with USP specification** | |
| 179. | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd. Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | Flucona Capsule 150mg |
| | Composition | Each capsule contains:<br>Fluconazole ……150mg |
| | Diary No. Date of R& I & fee | Dy.No 6256 dated 20-02-2018 Rs. 20,000/- 20-02-2018 |
| | Pharmacological Group | Antifungal Agent |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | Pack Size: 7's Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | DIFLUCAN Fluconazole 150mg Capsules Blister<br>TGA Approved. |
| | Me-too status | 081934 ; Jutrazole Capsule<br>M/s Jupiter Pharma, Rawat Islamabad |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and<br>The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Present in BP not in USP. |
| | **Decision: Approved with BP's specification** | |
| 180. | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd. Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | Convulsant Capsule 4mg |
| | Composition | Each Capsule contains:<br>Thiocolchicoside…4mg |
| | Diary No. Date of R& I & fee | Dy.No 6252 dated 20-02-2018 Rs. 20,000/- 20-02-2018 |
| | Pharmacological Group | Muscle relaxant |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 20's Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Myoplege 4mg capsule France<br>(ANSM APPROVED) |
| | Me-too status | 039261 ; Colril Capsules |

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| | | M/s Searle Pakistan, Karachi |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and the report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification** | |

**Evaluator PEC-VI**

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| 181. | Name and address of manufacturer / Applicant | M/s Remington Pharmaceuticals Industries Pvt Ltd. Lahore |
| | Brand Name +Dosage Form + Strength | Citapram 5mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Escitalopram Oxalate eq to Escitalopram.....5mg |
| | Diary No. Date of R& I & fee | Dy.No 22194 dated 27-11-2017 Rs. 20,000 24-11-2017 |
| | Pharmacological Group | SSRI |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Citanew by Hilton Pharma |
| | GMP status | GMP certificate issued based on inspection dated 15& 16th Jan, 2018 showed good compliance. |
| | Remarks of Evaluator | Firm has initially applied as:<br>Each film coated tablet contains:<br>Escitalopram oxalate….5mg<br>Now they corrected the composition with Rs.5000/ fee Deposited (0796405) dated 16-11-2018. |
| | **Decision: Approved** | |
| 182. | Name and address of manufacturer / Applicant | M/s Remington Pharmaceuticals Industries Pvt Ltd. Lahore |
| | Brand Name +Dosage Form + Strength | Citapram 10mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Escitalopram Oxalate eq to Escitalopram.....10mg |
| | Diary No. Date of R& I & fee | Dy.No 22195 dated 27-11-2017 Rs. 20,000 24-11-2017 |
| | Pharmacological Group | SSRI |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Zavget10mg Tablets by Getz Pharma, Reg. No. 45279 |
| | GMP status | GMP certificate issued based on inspection dated 15& 16th Jan, 2018 showed good compliance. |
| | Remarks of Evaluator | Firm has initially applied as:<br>Each film coated tablet contains:<br>Escitalopram oxalate….10mg<br>Now they corrected the composition with Rs.5000/ fee Deposited (0796410) dated 16-11-2018. |
| | **Decision: Approved** | |
| 183. | Name and address of manufacturer / Applicant | M/s Remington Pharmaceuticals Industries Pvt Ltd. Lahore |
| | Brand Name +Dosage Form + Strength | Citapram 20mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Escitalopram Oxalate eq to Escitalopram.....20mg |
| | Diary No. Date of R& I & fee | Dy.No 22196 dated 27-11-2017 Rs. 20,000 24-11-2017 |
| | Pharmacological Group | SSRI |
| | Type of Form | Form-5 |

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| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Repram 20mg tablet of M/s Regal Pharma (Reg.# 081963) |
| | GMP status | GMP certificate issued based on inspection dated 15& 16th Jan, 2018 showed good compliance. |
| | Remarks of Evaluator | Firm has initially applied as:<br>Each film coated tablet contains:<br>Escitalopram oxalate….20mg<br>Now they corrected the composition with Rs.5000/ fee Deposited (0796409) dated 16-11-2018. |
| | **Decision: Approved.** | |
| 184. | Name and address of manufacturer / Applicant | M/s Remington Pharmaceuticals Industries Pvt Ltd. Lahore |
| | Brand Name +Dosage Form + Strength | Resert 50mg Tablets |
| | Composition | Each Film Coated Tablet Contains:<br>Sertraline HCL eq to Sertraline……50mg |
| | Diary No. Date of R& I & fee | Dy.No 22192 dated 27-11-2017 Rs. 20,000 24-11-2017 |
| | Pharmacological Group | Antidepressant |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 20's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Zoloft Tablets 50mg of M/s Pfizer (Reg. # 020855) |
| | GMP status | GMP certificate issued based on inspection dated 15& 16th Jan, 2018 showed good compliance. |
| | Remarks of Evaluator | Firm has initially applied as:<br>Each film coated tablet contains:<br>Sertraline HCL…50mg<br>Now they corrected the composition with Rs.5000/ fee Deposited (0796408) dated 16-11-2018. |
| | **Decision: Approved** | |
| 185. | Name and address of manufacturer / Applicant | M/s Remington Pharmaceuticals Industries Pvt Ltd. Lahore |
| | Brand Name +Dosage Form + Strength | Resert 100mg Tablets |
| | Composition | Each Film Coated Tablet Contains:<br>Sertraline HCL eq to Sertraline……100mg |
| | Diary No. Date of R& I & fee | Dy.No 22193 dated 27-11-2017 Rs. 20,000 24-11-2017 |
| | Pharmacological Group | Antidepressant |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 20's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Zoloft Tablets 100mg by M/s Pfizer (Reg.# 020856) |
| | GMP status | GMP certificate issued based on inspection dated 15& 16th Jan, 2018 showed good compliance. |
| | Remarks of Evaluator | Firm has initially applied as:<br>Each film coated tablet contains:<br>Sertraline HCL…100mg<br>Now they corrected the composition with Rs.5000/ fee Deposited (0796407) dated 16-11-2018. |
| | **Decision: Approved.** | |
| 186. | Name and address of manufacturer / | M/s Remington Pharmaceuticals Industries Pvt Ltd. |

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| | Applicant | Lahore |
| | Brand Name +Dosage Form + Strength | Reflit 20mg Capsule |
| | Composition | Each Hard Gelatin Capsule Contains:<br>Fluoxetine HCL eq to Fluoxetine…20mg |
| | Diary No. Date of R& I & fee | Dy.No 22191 dated 27-11-2017 Rs. 20,000 24-11-2017 |
| | Pharmacological Group | Antidepressant |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 30's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Flufa 20mg Capsules of Farm Aid Group |
| | GMP status | GMP certificate issued based on inspection dated 15& 16th Jan, 2018 showed good compliance. |
| | Remarks of Evaluator | Firm has initially applied as:<br>Each film coated tablet contains:<br>Fluoxetine HCL…20mg Now they corrected the composition with Rs.5000/ fee Deposited (0796406) dated 16-11-2018. |
| | **Decision: Approved** | |
| 187. | Name and address of manufacturer / Applicant | M/s Medicraft Pharmaceuticals Pvt Ltd.<br>126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Riximid 200mg Tablet |
| | Composition | Each Film Coated tablet Contains:<br>Rifaximin…….200mg |
| | Diary No. Date of R& I & fee | Dy.No 834 dated 05-01-2018 Rs. 20,000 05-01-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manfacturer's |
| | Pack size & Demanded Price | 10's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Nixaf 200mg tablet of Sami Pharma (Reg#076310) |
| | GMP status | Last GMP Inspection conducted on 30-1-2018 with conclusive remarks of cGMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification** | |
| 188. | Name and address of manufacturer / Applicant | M/s Medicraft Pharmaceuticals Pvt Ltd.<br>126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Riximid 550mg Tablet |
| | Composition | Each Film Coated tablet Contains:<br>Rifaximin…….550mg |
| | Diary No. Date of R& I & fee | Dy.No 835 dated 05-01-2018 Rs. 20,000 05-01-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manfacturer's |
| | Pack size & Demanded Price | 10's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Rixago 550mg Tablet by M/s OBS Pharma Karachi (Reg#081073) |
| | GMP status | Last GMP Inspection conducted on 30-1-2018 with conclusive remarks of cGMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification** | |

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| 189. | Name and address of manufacturer / Applicant | M/s Medicraft Pharmaceuticals Pvt Ltd.<br>126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Bestine-D 8mg Tablet |
| | Composition | Each Tablet Contains:<br>Betahistine Dihydrochloride…….8mg |
| | Diary No. Date of R& I & fee | Dy.No 836 dated 05-01-2018 Rs. 20,000 05-01-2018 |
| | Pharmacological Group | Anti-vertigo |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 3 x 10's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | TGA approved |
| | Me-too status | VR-Tigo Tablets 8mg by Himont Pharmaceuticals (Pvt) Ltd. Reg. No. 79703 |
| | GMP status | Last GMP Inspection conducted on 30-1-2018 with conclusive remarks of cGMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |
| 190. | Name and address of manufacturer / Applicant | M/s Medicraft Pharmaceuticals Pvt Ltd.<br>126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Dasron 8mg/4ml Injection |
| | Composition | Each 4ml Ampoule Contains:<br>Ondansetron Hydrochloride…….8mg |
| | Diary No. Date of R& I & fee | Dy.No 837 dated 05-01-2018 Rs. 20,000 05-01-2018 |
| | Pharmacological Group | Serotonin type 3 receptor antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 4ml, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Zofran injection of M/s GSK (Reg. # 020669) |
| | GMP status | Last GMP Inspection conducted on 30-1-2018 with conclusive remarks of cGMP compliance. |
| | Remarks of Evaluator | Salt factor is incorrect. |
| | **Decision: Deferred for clarification of salt factor as per Reference product as in reference regulatory authority ondansetron is approved as ondansetron (as ondansetron hydrochloride dihydrate) along with correction fee.** | |
| 191. | Name and address of manufacturer / Applicant | M/s Medicraft Pharmaceuticals Pvt Ltd.<br>126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Flupixol Depot 40mg/2ml |
| | Composition | Each 2ml Ampoule Contains:<br>Flupentixol Decanoate…40mg |
| | Diary No. Date of R& I & fee | Dy.No 833 dated 05-01-2018 Rs. 20,000 05-01-2018 |
| | Pharmacological Group | Antipsychotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manfacturer's |
| | Pack size & Demanded Price | 2ml, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Luixol 40mg Depot Injection Reg # 068464 |
| | GMP status | Last GMP Inspection conducted on 30-1-2018 with conclusive remarks of cGMP compliance. |
| | Remarks of Evaluator | International availability could not be confirmed |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |

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| 192. | Name and address of manufacturer / Applicant | M/s Medicraft Pharmaceuticals Pvt Ltd.<br>126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Telmi 40mg Tablet |
| | Composition | Each Tablet Contains:<br>Telmisartan…40mg |
| | Diary No. Date of R& I & fee | Dy.No 839 dated 05-01-2018 Rs. 20,000 05-01-2018 |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 2 x 7's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Tasmi 40mg tablet of M/s Getz Pharma (Reg. # 047482) |
| | GMP status | Last GMP Inspection conducted on 30-1-2018 with conclusive remarks of cGMP compliance. |
| | Remarks of Evaluator | |
| | **Decision:Approved** | |

**Evaluator PEC-VII**

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| 193. | Name and address of manufacturer / Applicant | M/s Medicraft Pharma, Peshawar |
| | Brand Name +Dosage Form + Strength | Linezomed 600 mg tablet |
| | Composition | Each film-coated tablet contains:<br>Linezolid .....600mg |
| | Diary No. Date of R& I & fee | D#43488, 3-Aug 2016; Rs. 20,000/- (Duplicate) |
| | Pharmacological Group | Antibacterial |
| | Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO 3x4's |
| | Approval status of product in Reference Regulatory Authorities | Zyvox 600 mg film-coated tablets by Pharmacia Limited (MHRA Approved) |
| | Me-too status | Ecasil tablet of M/s Sami Pharmaceuticals (Reg. # 066904) |
| | GMP status | Last GMP inspection was conducted on 30-1-2018 and the report shows good GMP c. |
| | Remarks of evaluator [VII] | |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 194. | Name and address of manufacturer / Applicant | M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | Ferric-C 50mg/ml Injection |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 26348 dated 28-12-2017 Rs. 20,000<br>Dated 28-12-2017 |
| | Composition | Each ml Contains:<br>Ferric Carboxymaltose…50mg |
| | Pharmacological Group | Hematinic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovators specifications |
| | Pack Size & Demanded Price | Type 1 glass.<br>2ml solution containing 100 mg iron<br>10 ml solution containing 500 mg iron<br>20 ml solution containing 1000 mg iron<br>As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Ferinject by Vifor Pharma (TGA) |
| | Me-too Status | Ferinject imported by M/s. RG Pharmaceutica (Pvt.) Ltd.,Karachi.(R. No. 072548) |
| | GMP status | M/s Bio-Labs (Pvt.) Ltd., Islamabad was granted GMP certificate based on inspection conducted on 05 & 06th December, 2017. |

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| | Remarks of the Evaluator [VII] | |
| | **Decision: Approved with innovator's specification.** | |
| 195. | Name and address of manufacturer / Applicant | M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | Voric 200mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 26346 dated 28-12-2017 Rs. 20,000/- Dated 28-12-2017 |
| | Composition | Each Film Coated Tablet Contains:<br>Voriconazole…200mg |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovators specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | V-fend tablet of M/s Pfizer Pharma (UK) |
| | Me-too Status | Vorif tablets of M/s Ferozesons Laboratories |
| | GMP status | M/s Bio-Labs (Pvt.) Ltd., Islamabad was granted GMP certificate based on inspection conducted on 5th & 06th -12-2017 |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Approved with JP specification.** | |
| 196. | Name and address of manufacturer / Applicant | M/S Biolabs (Pvt) Ltd, Plot # 145, industrial Triangle, Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | Epilepto-D 250mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 26346 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017 |
| | Composition | Each delayed release Tablet Contains:<br>Divalproex Sodium…250mg |
| | Pharmacological Group | Anticonvulsants & Anti-epileptics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovators specifications |
| | Pack Size & Demanded Price | 30's<br>As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Divalproex Sodium delayed-release tablet (USFDA Approved) |
| | Me-too Status | Epival tablet 250mg of M/s Abbott Laboratories (Reg. # 007160) |
| | GMP status | M/s Bio-Labs (Pvt.) Ltd., Islamabad was granted GMP certificate based on inspection conducted on 5th & 06th -12-2017 |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Approved with USP specification.** | |
| 197. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Fulliron 800mg/15ml Dry Suspension |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3586 dated 29-01-2018 Rs. 20,000 Dated 17-01-2018 |
| | Composition | Each 15ml Contains:<br>Iron Protein Succinylate…800mg |
| | Pharmacological Group | Anti-Anemic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's Specs. |
| | Pack Size & Demanded Price | 30ml: 80 Rupees, 60ml:160 rupees, 90ml:220 rupees, 100ml:250 rupees, 120ml: 300 rupees. |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | Follinemic suspension by Epharm Labs (Reg # 044349) |
| | GMP status | Latest inspection dated 24-04-2018 |

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| | | Conclusion:<br>"Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance.<br>(Show cause notice revoked on 27-04-2018)" |
| | Remarks of the Evaluator [VII] | Firm has requested to change the formulation to Liquid<br>Each 15ml contains:<br>Iron Protein Succinylate 800mg equivalent to<br>elemental Iron … 40mg<br>Firm has also submitted fee PKR 5,000/- (Chalan No. 0747452) for change in formulation |
| | **Decision: Deferred for submission of differential fee of Rs. 15,000/- fee for revision of dosage form.** | |

**Evaluator PEC-VIII**

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| 198. | Name and address of Manufacturer / Applicant | M/s Barrett Hodgson Pakistan (Private) Limited. |
| | Brand Name + Dosage Form + Strength | Baritral SR tablet 100mg |
| | Composition | Each sustained release film coated tablet contains:<br>Tramadol hydrochloride…. 100mg |
| | Diary No. Date of R&I & fee | DyNo.3972; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's: Rs. 320/- Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Zultra SR 100mg tablet of M/s. Wilshire Lab.(Pvt) Ltd |
| | GMP status | Panel inspection conducted on 19-09-17 unanimously recommended grant of cGMP Certificate. |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |
| 199. | Name and address of Manufacturer / Applicant | M/s Barrett Hodgson Pakistan (Private) Limited. |
| | Brand Name + Dosage Form + Strength | Fidaxo tablet 30mg |
| | Composition | Each film coated tablet contains:<br>Fexofenadine hydrochloride…. 30mg |
| | Diary No. Date of R&I & fee | DyNo.3973; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's: Rs. 60/- Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Fexinol Tablets 30mg of Martin Dow Pharmaceuticals |
| | GMP status | Panel inspection conducted on 19-09-17 unanimously recommended grant of cGMP Certificate. |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |
| 200. | Name and address of Manufacturer / Applicant | M/s Barrett Hodgson Pakistan (Private) Limited. |
| | Brand Name + Dosage Form + Strength | Fidaxo tablet 120mg |
| | Composition | Each film coated tablet contains:<br>Fexofenadine hydrochloride…. 120mg |
| | Diary No. Date of R&I & fee | DyNo.3975; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 10's: Rs. 200/- Or As per SRO |

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| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Telfast Tablets 120mg of Hoechst Marion Roussel |
| | GMP status | Panel inspection conducted on 19-09-17 unanimously recommended grant of cGMP Certificate. |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |
| 201. | Name and address of Manufacturer / Applicant | M/s Barrett Hodgson Pakistan (Private) Limited. |
| | Brand Name + Dosage Form + Strength | Fidaxo tablet 180mg |
| | Composition | Each film coated tablet contains:<br>Fexofenadine hydrochloride…. 180mg |
| | Diary No. Date of R&I & fee | DyNo.3976; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 10's: Rs. 585/- Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Telfast Tablets 120mg of Hoechst Marion Roussel |
| | GMP status | GMP inspection conducted on 08-08-17 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved** | |
| 202. | Name and address of Manufacturer / Applicant | M/s Unexolabs (Private) Limited, Fine chemical & Pharmaceuticals Manufacturer's |
| | Brand Name + Dosage Form + Strength | Uvastin tablet 10mg |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin (as calcium) …. 10mg |
| | Diary No. Date of R&I & fee | DyNo.3914; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 10's: Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Lolipid Tablets 10mg of Alliance Pharmaceuticals. |
| | GMP status | GMP inspection conducted on 20-04-16 concluded that firm is has shown positive approach towards compliance of GMP advices given for further up gradation. |
| | Remarks of Evaluator | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 203. | Name and address of Manufacturer / Applicant | M/s Unexolabs (Private) Limited, Fine chemical & Pharmaceuticals Manufacturer's |
| | Brand Name + Dosage Form + Strength | Uvastin tablet 5mg |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin (as calcium) …. 5mg |
| | Diary No. Date of R&I & fee | DyNo.3916; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 10's: Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Could not be confirmed |
| | GMP status | GMP inspection conducted on 20-04-16 concluded that |

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| | | firm is has shown positive approach towards compliance of GMP advices given for further up gradation. |
| | Remarks of Evaluator | Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 204. | Name and address of Manufacturer / Applicant | M/s Unexolabs (Private) Limited, Fine chemical & Pharmaceuticals Manufacturer's |
| | Brand Name + Dosage Form + Strength | Uvastin tablet 20mg |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin (as calcium) …. 20mg |
| | Diary No. Date of R&I & fee | DyNo.3919; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 10's: Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Lolipid Tablets 20mg of Alliance Pharmaceuticals. |
| | GMP status | GMP inspection conducted on 20-04-16 concluded that firm is has shown positive approach towards compliance of GMP advices given for further up gradation. |
| | Remarks of Evaluator | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 205. | Name and address of Manufacturer / Applicant | M/s Unexolabs (Private) Limited, Fine chemical & Pharmaceuticals Manufacturer's |
| | Brand Name + Dosage Form + Strength | Umrazole-20 Plus Capsule |
| | Composition | Each Capsule Contains:<br>Omeprazole…20mg<br>Sodium Bicarbonate…1100mg |
| | Diary No. Date of R&I & fee | DyNo.3915; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | PPIs/Antacid |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 2×7's: Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Omsod 40 mg Capsules ofReliance Pharma |
| | GMP status | GMP inspection conducted on 20-04-16 concluded that firm is has shown positive approach towards compliance of GMP advices given for further up gradation. |
| | Remarks of Evaluator | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 206. | Name and address of Manufacturer / Applicant | M/s Unexolabs (Private) Limited, Fine chemical & Pharmaceuticals Manufacturer's |
| | Brand Name + Dosage Form + Strength | Umrazole-40 Plus Capsule |
| | Composition | Each Capsule Contains:<br>Omeprazole…40mg<br>Sodium Bicarbonate…1100mg |
| | Diary No. Date of R&I & fee | DyNo.3917; 31-01-2018; Rs. 20,000/- |
| | Pharmacological Group | PPIs/Antacid |
| | Type of Form | Form-5 |

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| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 2×7's: Or As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Omsod 20 mg Capsules ofReliance Pharma |
| | GMP status | GMP inspection conducted on 20-04-16 concluded that firm is has shown positive approach towards compliance of GMP advices given for further up gradation. |
| | Remarks of Evaluator | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 207. | Name and address of Manufacturer / Applicant | M/s Genix Private Limited, 44, 45-B Koangi Creek Road, Karachi. |
| | Brand Name + Dosage Form +Strength | Mep-B Insta 20mg/1680 |
| | Composition | Each Sachet contains:<br>Omeprazole…….20mg<br>Sodium bicarbonate…1680mg |
| | Diary No. Date of R&I & fee | DyNo.24658; 15-12-2017; Rs. 20,000/- |
| | Pharmacological Group | PPIs/Antacid |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in USFDA |
| | Me-too status | RisekInsta Sachet 20mg/1680mg of Getz Pharma. |
| | GMP status | GMP Inspection conducted on 08-08-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved** | |
| 208. | Name and address of Manufacturer / Applicant | M/s Genix Private Limited, 44, 45-B Koangi Creek Road, Karachi. |
| | Brand Name + Dosage Form +Strength | Mep-B Insta 40mg/1680 |
| | Composition | Each Sachet contains:<br>Omeprazole…40mg<br>Sodium bicarbonate…1680mg |
| | Diary No. Date of R&I & fee | DyNo.24656; 15-12-2017; Rs. 20,000/- |
| | Pharmacological Group | PPIs/Antacid |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in USFDA |
| | Me-too status | RisekInsta Sachet 40mg/1680mg of Getz Pharma. |
| | GMP status | GMP Inspection conducted on 08-08-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved** | |
| 209. | Name and address of Manufacturer / Applicant | M/s Sami Pharmaceuticals Pvt Limited.<br>F-95, S.I.T.E, Karachi, Pakistan |
| | Brand Name + Dosage Form + Strength | Co-Sevia Tablet 5mg/160mg/25 |
| | Composition | Each film coated tablet contains:<br>Amlodipine(as besylate)…5mg<br>Valsartan…..160mg<br>Hydrochlorothiazide…25mg |
| | Diary No. Date of R&I & fee | DyNo.3735; 30-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihypertensive<br>Calcium antagonist/Angiotensin II antagonist/Diuretic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |

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| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Valtec AMH 5/160/25 Tablet of Tabros Pharma Karachi |
| | GMP status | Certificate of cGMP is issued to the firm based on evaluation conducted on 14-06-218 with following sections:<br>1- Oral Liquid Syrup/suspension/drops/dry powder suspension (Gen/Gen Antibiotic).<br>2- Granualtion/Pelletization/taste masking (Gen/Gen Antibiotic).<br>3- Liquid Injectable-LVP (Gen/Gen Antibiotic).<br>4- Tablet/Capsule/Sachet (Gen/Gen Antibiotic).<br>5- Liquid Freeze Dried Injectable-SVP (Gen/Gen Antibiotic).<br>6- Tablet (Hormone)<br>7- Gel/Cream/Ointment (Gen/Gen Antibiotic).<br>8- Tablet/Capsule/Liquid Injectable (Psychotropic). |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |
| 210. | Name and address of Manufacturer / Applicant | M/s Sami Pharmaceuticals Pvt Limited.<br>F-95, S.I.T.E, Karachi, Pakistan |
| | Brand Name+DosageForm+Strength | Co-Sevia Tablet 5 mg/160mg/12.5mg |
| | Composition | Each film coated tablet contains:<br>Amlodipine (as besylate)…5mg<br>Valsartan….....160mg<br>Hydrochlorothiazide…....12.5mg |
| | Diary No. Date of R&I & fee | DyNo.3734; 30-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihypertensive Calcium antagonist/Angiotensin II antagonist/Diuretic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Tri-Velker Tablet 5/160/12.5 Tablet of High-Q Karachi |
| | GMP status | Certificate of cGMP is issued to the firm based on evaluation conducted on 14-06-218 with following sections:<br>1- Oral Liquid Syrup/suspension/drops/dry powder suspension (Gen/Gen Antibiotic).<br>2- Granualtion/Pelletization/taste masking (Gen/Gen Antibiotic).<br>3- Liquid Injectable-LVP (Gen/Gen Antibiotic).<br>4- Tablet/Capsule/Sachet (Gen/Gen Antibiotic).<br>5- Liquid Freeze Dried Injectable-SVP (Gen/Gen Antibiotic).<br>6- Tablet(Hormone)<br>7- Gel/Cream/Ointment (Gen/Gen Antibiotic).<br>8- Tablet/Capsule/Liquid Injectable (Psychotropic). |
| | Remarks of Evaluator | |
| | **Decision: Approved** | |
| 211. | Name and address of Manufacturer / Applicant | M/s Sami Pharmaceuticals Pvt Limited.<br>F-95, S.I.T.E, Karachi, Pakistan |
| | Brand Name + Dosage Form + Strength | Co-Sevia tablet 10 mg/160mg/12.5mg |
| | Composition | Each film coated tablet contains:<br>Amlodipine(as besylate)…10mg<br>Valsartan…..160mg<br>Hydrochlorothiazide…12.5mg |

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| | Diary No. Date of R&I & fee | DyNo.3736; 30-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihypertensive<br>Calcium antagonist/Angiotensin II antagonist/Diuretic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Valtec AMH 10/160/12.5 Tablet of Tabros Pharma Karachi |
| | GMP status | Certificate of cGMP is issued to the firm based on evaluation conducted on 14-06-218 with following sections:<br>1- Oral Liquid Syrup/suspension/drops/dry powder suspension (Gen/Gen Antibiotic).<br>2- Granualtion/Pelletization/taste masking (Gen/Gen Antibiotic).<br>3- Liquid Injectable-LVP (Gen/Gen Antibiotic).<br>4- Tablet/Capsule/Sachet (Gen/Gen Antibiotic).<br>5- Liquid Freeze Dried Injectable-SVP (Gen/Gen Antibiotic).<br>6- Tablet (Hormone)<br>7- Gel/Cream/Ointment (Gen/Gen Antibiotic).<br>8- Tablet/Capsule/Liquid Injectable (Psychotropic). |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |
| 212. | Name and address of Manufacturer / Applicant | M/s Sami Pharmaceuticals Pvt Limited.<br>F-95, S.I.T.E, Karachi, Pakistan |
| | Brand Name + Dosage Form + Strength | Co-Sevia tablet 10 mg/160mg/25mg |
| | Composition | Each film coated tablet contains:<br>Amlodipine(as besylate)…10mg<br>Valsartan…..160mg<br>Hydrochlorothiazide…25mg |
| | Diary No. Date of R&I & fee | DyNo.3737; 30-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihypertensive<br>Calcium antagonist/Angiotensin II antagonist/Diuretic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Valtec AMH 5/160/25 Tablet of Tabros Pharma Karachi |
| | GMP status | Certificate of cGMP is issued to the firm based on evaluation conducted on 14-06-218 with following sections:<br>1- Oral Liquid Syrup/suspension/drops/dry powder suspension (Gen/Gen Antibiotic).<br>2- Granualtion/Pelletization/taste masking (Gen/Gen Antibiotic).<br>3- Liquid Injectable-LVP (Gen/Gen Antibiotic).<br>4- Tablet/ Capsule/Sachet (Gen/Gen Antibiotic).<br>5- Liquid Freeze Dried Injectable-SVP (Gen/Gen Antibiotic).<br>6- Tablet (Hormone)<br>7- Gel/Cream/Ointment (Gen/Gen Antibiotic).<br>8- Tablet/Capsule/Liquid Injectable (Psychotropic). |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |

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| 213. | Name and address of Manufacturer / Applicant | M/s Sami Pharmaceuticals (Pvt.) Limited, F-95, S.I.T.E, Karachi, Pakistan |
| | Brand Name + Dosage Form + Strength | Co-Sevia tablet 10 mg/320mg/25mg |
| | Composition | Each film coated tablet contains:<br>Amlodipine(as besylate)…10mg<br>Valsartan…..320mg<br>Hydrochlorothiazide…25mg |
| | Diary No. Date of R&I & fee | DyNo.3738; 30-01-2018; Rs. 20,000/- |
| | Pharmacological Group | Antihypertensive<br>Calcium antagonist/Angiotensin II antagonist/Diuretic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Valtec AMH 10/320/25 Tablet of Tabros Pharma Karachi |
| | GMP status | Certificate of cGMP is issued to the firm based on evaluation conducted on 14-06-218 with following sections:<br>1- Oral Liquid Syrup/suspension/drops/dry powder suspension (Gen/Gen Antibiotic).<br>2- Granualtion/Pelletization/taste masking (Gen/Gen Antibiotic).<br>3- Liquid Injectable-LVP (Gen/Gen Antibiotic).<br>4- Tablet/Capsule/Sachet (Gen/Gen Antibiotic).<br>5- Liquid Freeze Dried Injectable-SVP (Gen/Gen Antibiotic).<br>6- Tablet (Hormone)<br>7- Gel/Cream/Ointment (Gen/Gen Antibiotic).<br>8- Tablet/Capsule/Liquid Injectable (Psychotropic). |
| | Remarks of Evaluator | |
| | **Decision: Approved.** | |
| 214. | Name and address of Manufacturer / Applicant | M/s Welmark Pharmaceuticals Plot # 122, Block-B, Phase-V, Industrial Estate Hattar. |
| | Brand Name + Dosage Form + Strength | Weltriptan tablet 40mg |
| | Composition | Each tablet contains:<br>Eletriptan hydrobromide…. 40mg |
| | Diary No. Date of R&I & fee | Dy.No.3983;31-01-18: Rs. 20,000 |
| | Pharmacological Group | Anti-Migraine |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in USFDA |
| | Me-too status | Relpax 40mg Tablets of Pfizer Laboratories Ltd. |
| | GMP status | Certificate of cGMP is issued to firm based on inspection conducted on 16-8-2018 & is valid for one year. |
| | Remarks of Evaluator | Reference product is approved as Eletriptan (as hydrobromide) 40mg film coated tablet which is different from that of applied formulation i.e. Eletriptan hydrobromide 40mg uncoated tablet. Submit Form 5, master formulation & manufacturing method in line with reference product.<br>Monograph for test/analysis of applied formulation is not present in available USP/BP. |
| | **Decision: Registration board deferred the case for revision of formulation in accordance with reference product i.e. Eletriptan (as hydrobromide) 40mg film coated tablet along with submission of requisite fee.** | |

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| 215. | Name and address of Manufacturer / Applicant | M/s Welmark Pharmaceuticals Plot # 122, Block-B, Phase-V, Industrial Estate Hattar. |
| | Brand Name + Dosage Form + Strength | Weltriptan tablet 20mg |
| | Composition | Each tablet contains:<br>Eletriptan hydrobromide…. 20mg |
| | Diary No. Date of R&I & fee | Dy.No.3982;31-01-18: Rs. 20,000 |
| | Pharmacological Group | Anti-Migraine |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Elle Tablets 20mg of M/s Wilshire Laboratories. |
| | GMP status | Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year. |
| | Remarks of Evaluator | Reference product is approved as Eletriptan (as hydrobromide) 20mg film coated tablet which is different from that of applied formulation i.e. Eletriptanhydrobromide 20mg uncoated tablet. Submit Form 5, master formulation & manufacturing method in line with reference product.<br>Monograph for test/analysis of applied formulation is not present in available USP/BP. |
| | **Decision: Registration board deferred the case for revision of formulation in accordance with reference product i.e. Eletriptan (as hydrobromide) 20mg film coated tablet along with submission of requisite fee.** | |
| 216. | Name and address of Manufacturer / Applicant | M/s Welmark Pharmaceuticals Plot # 122, Block-B, Phase-V, Industrial Estate Hattar. |
| | Brand Name + Dosage Form + Strength | Welpure tablet 300mg |
| | Composition | Each film coated tablet contains:<br>Allopurinol…. 300mg |
| | Diary No. Date of R&I & fee | Dy.No.3981; 31-01-18: Rs. 20,000 |
| | Pharmacological Group | Anti-Gout |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP Specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Zyuric-300 Tablet of M/s Rasco Pharma |
| | GMP status | Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year. |
| | Remarks of Evaluator | |
| | **Decision: Approved** | |
| 217. | Name and address of Manufacturer / Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>**Now:** M/s Horizon Healthcare (Pvt Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | NEBULA Tablets 10mg |
| | Composition | Each Film Coated Tablet Contains:<br>Nebivolol…10mg |
| | Diary No. Date of R&I & fee | Dy No. 6141 ; 19-02-18: Rs.20,000 |
| | Pharmacological Group | Beta blocker |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator |
| | Pack Size & Demanded Price | 10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |

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| | Me-too status | Nebil 10mg Tablet of Getz Karachi |
| | GMP status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Reference product in approved as uncoated tablet but you have applied with coating. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet.<br>Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product i.e. uncoated tablet along with submission of requisite fee.** | |
| 218. | Name and address of Manufacturer / Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form+ Strength | NEBULA Tablets 5mg |
| | Composition | Each Film Coated Tablet Contains:<br>Nebivolol…5mg |
| | Diary No. Date of R&I & fee | Dy No. 6140 ; 19-02-18: Rs.20,000 |
| | Pharmacological Group | Beta blocker |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator |
| | Pack Size & Demanded Price | 10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Nebil 5mg Tablet of Getz Karachi |
| | GMP status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Reference product in approved as uncoated tablet but you have applied with coating. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet.<br>Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product i.e uncoated tablet along with submission of requisite fee.** | |
| 219. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt.) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | NEBULA Tablets 2.5mg |
| | Composition | Each Film Coated Tablet Contains:<br>Nebivolol…….2.5mg |
| | Diary No. D of R & I & Fee | Dy No. 6139 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Beta blocker |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Nebil 2.5mg Tablet of Getz Karachi |

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| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Reference product in approved as uncoated tablet but you have applied with coating. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet.<br>Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product i.e. uncoated tablet along with submission of requisite fee.** | |
| 220. | Name and address of Manufacturer/Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | DANZSTINE Tablets 8mg |
| | Composition | Each Film Coated Tablet Contains:<br>Betahistine dihydrochloride…8mg |
| | Diary No. D of R & I & Fee | Dy No. 6142 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anti-vertigo |
| | Type of Form | Form 5 |
| | Finished product Specifications | BP |
| | Pack Size & demanded price | 30's, 60's, 100's, : As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Betalin Tablet 8mg of M/s Linear Parma |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs.20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Approved.** | |
| 221. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | DANZSTINE Tablets 16mg |
| | Composition | Each Film Coated Tablet Contains:<br>Betahistine dihydrochloride …16mg |
| | Diary No. D of R & I & Fee | Dy No. 6143 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anti-vertigo |
| | Type of Form | Form 5 |
| | Finished product Specifications | BP |
| | Pack Size & demanded price | 30's, 60's, 100's : As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Betalin Tablet 16mg of M/s Linear Parma |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Approved.** | |

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| 222. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | DANZSTINE Tablets 24mg |
| | Composition | Each Film Coated Tablet Contains:<br>Betahistine dihydrochloride ….24mg |
| | Diary No. D of R & I & Fee | Dy No. 6143 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anti vertigo |
| | Type of Form | Form 5 |
| | Finished product Specifications | BP |
| | Pack Size & demanded price | 30's, 60's, 100's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in MHRA |
| | Me-too status | Serc 24mg tablet of M/s Abbott Pakistan |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs.20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt) Ltd. |
| | **Decision: Approved.** | |
| 223. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | LIPTIN Tablets 25mg |
| | Composition | Each Film Coated Tablet Contains:<br>Sitagliptin……..…25mg |
| | Diary No. D of R & I & Fee | Dy No. 6130 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Duvel 25mg Tablet of Martin Dow |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Reference product in approved as Sitagliptin (as phosphate monohydrate) 25mg tablet but you have applied for Sitagliptin 25mg tablet. Submit Form 5, master formulation & manufacturing method either in-line with reference product or evidence of approval of applied drug product as Sitagliptin 25mg tablet.<br>Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Deferred for revision of salt form of the API in the formulation as per the reference product along with submission of requisite fee for revision of formulation.** | |
| 224. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | LIPTIN Tablets 50mg |
| | Composition | Each Film Coated Tablet Contains:<br>Sitagliptin …50mg |
| | Diary No. D of R & I & Fee | Dy No. 6131; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anti-diabetic |

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| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Duvel 50mg Tablet of Martin Dow |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Reference product in approved as Sitagliptin (as phosphate monohydrate) 50mg tablet but you have applied for Sitagliptin 50mg tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product or evidence of approval of applied drug product as Sitagliptin 50mg tablet. Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt) Ltd. |
| | **Decision: Deferred for revision of salt form of the API in the formulation as per the reference product along with submission of requisite fee for revision of formulation.** | |
| 225. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | Solicept Tablets 5mg |
| | Composition | Each Film Coated Tablet Contains:<br>Solifenacin Succinate…5mg |
| | Diary No. D of R & I & Fee | Dy No. 6128 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anticholinergic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Fenaso 5mg of M/s Highnoon |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Approved with innovator's specification.** | |
| 226. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | Solicept Tablets 10mg |
| | Composition | Each Film Coated Tablet Contains:<br>Solifenacin Succinate…10mg |
| | Diary No. D of R & I & Fee | Dy No. 6129 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anticholinergic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Fenaso 10mg of M/s Highnoon |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Approved with innovator's specification.** | |

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|---|---|---|
| 227. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | ITON Tablets 50mg |
| | Composition | Each Tablet Contains:<br>Itopride hydrochloride…50mg |
| | Diary No. D of R & I & Fee | Dy No. 6134 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Gastrokinetic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's,30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in PMDA |
| | Me-too status | Ganaton by M/s Abbott Pakistan |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Reference product in approved as film coated tablet but you have applied for uncoated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as uncoated tablet.<br>Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Deferred for submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** | |
| 228. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | ITON Tablets 150mg |
| | Composition | Each Tablet Contains:<br>Itopride hydrochloride …150mg |
| | Diary No. D of R & I & Fee | Dy No. 6143 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Gastrokinetic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's,30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Ganaton by Abbott USA (as provided by the firm) |
| | Me-too status | Ganaton by M/s Abbott Pakistan (pharmaguide, as provided by the firm) |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Evidence of approval of applied formulation i.e. Itopride hydrochloride 150mg uncoated tablet in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required.<br>Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Deferred for submission of evidence of approval of applied formulation as i.e. Itopride hydrochloride 150mg uncoated tablet in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |

| | | |
|---|---|---|
| 229. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | ITON Capsule 50mg |
| | Composition | Each Capsule Contains:<br>Itopride hydrochloride …50mg |
| | Diary No. D of R & I & Fee | Dy No. 6143 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Gastrokinetic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's,30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Ganaton by Abbott USA (as provided by the firm) |
| | Me-too status | Ganaton by M/s Abbott Pakistan (pharmaguide, as provided by the firm) |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Evidence of approval of applied formulation i.e. Itopride hydrochloride 50mg capsule in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.<br>Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 230. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | Roxab Tablets 10mg |
| | Composition | Each Film Coated Tablet Contains:<br>Rivaroxaban…10mg |
| | Diary No. D of R & I & Fee | Dy No. 6136 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anticoagulant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 14's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Xarelto by BAYER Germany |
| | Me-too status | Xarelto by M/s Bayer Pakistan |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Approved with innovator's specification.** | |
| 231. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | Roxab Tablets 15mg |
| | Composition | Each Film Coated Tablet Contains:<br>Rivaroxaban…15mg |
| | Diary No. D of R & I & Fee | Dy No. 6137 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anticoagulant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |

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|---|---|---|
| | Pack Size & demanded price | 14's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Xarelto by BAYER Germany |
| | Me-too status | Xarelto by M/s Bayer Pakistan |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Approved with innovator's specification.** | |
| 232. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | Roxab Tablets 20mg |
| | Composition | Each Film Coated Tablet Contains:<br>Rivaroxaban…20mg |
| | Diary No. D of R & I & Fee | Dy No. 6138 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anticoagulant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 14's, 30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Xarelto by BAYER Germany |
| | Me-too status | Xarelto by M/s Bayer Pakistan |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Decision: Approved with innovator's specification.** | |
| 233. | Name and address of Manufacturer/ Applicant | Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore.<br>Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore. |
| | Brand Name + Dosage Form + Strength | LIPTIN Tablets 100mg |
| | Composition | Each Film Coated Tablet Contains:<br>Sitagliptin …100mg |
| | Diary No. D of R & I & Fee | Dy No. 6132 ; 19-02-18: Rs.20,000 |
| | Pharmacological group | Anti-diabetic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's,30's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Duvel 100mg Tablet of Martin Dow |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | Reference product in approved as Sitagliptin (as phosphate monohydrate) 100mg tablet but you have applied for Sitagliptin 100mg tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as Sitagliptin 100mg tablet. Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd. |
| | **Deferred for revision of salt form of the API in the formulation as per the reference product along with submission of requisite fee for revision of formulation.** | |

R-V vides its letter No. F.8-6/2013-Reg-V dated 21st of January, 2019 forwarded two original dossiers of below mentioned products of Nova-Med Pharma, Lahore for Evaluation having following information on the letter.

| Sr.# | Name of firm | Name of drug(s) with composition | Date of submission of fee |
|---|---|---|---|
| 1. | M/s Novamed Pharma, Lahore. | Each 3 ml ampoule Contains:<br>Thiamine hydrochloride…100mg<br>Pyridoxine hydrochloride… 100mg<br>Cyanocobalamin…. 1000mcg | Dy. No. 8933<br>Dated 17-07-2017 |
| 2. | M/s Novamed Pharma, Lahore. | Nuphine injection 10mg/ml<br>Each ml ampoule Contains:<br>Nalbuphine hydrochloride…. 10mg | Dy. No. 12496<br>Dated 18-08-2017 |

| | | |
|---|---|---|
| 234. | Name and address of Manufacturer/ Applicant | M/s Novamed Pharma, Lahore. |
| | Brand Name + Dosage Form + Strength | Nerin- B Ampoule |
| | Composition | Each 3 ml ampoule Contains:<br>Thiamine hydrochloride…100mg<br>Pyridoxine hydrochloride… 100mg<br>Cyanocobalamin…. 1000mcg |
| | Diary No. D of R & I & Fee | Dy No. 8933 ; 17-07-17: Rs.20,000 |
| | Pharmacological group | Vitamin Supplement |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's Specifications |
| | Pack Size & demanded price | 25's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in Germany (as provided by the firm) |
| | Me-too status | Neurobion of Martin Dow (001486) (pharmaguide) |
| | GMP Status | GMP Certificate issued on 03-01-2018 with following sections:<br>1- Tablet section (Non-Antibiotic, Antibiotic & Psychotropic)<br>2- Capsule Section (Non Antibiotic, Antibiotic & Cephalosporin)<br>3- Oral Liquid section (Non Antibiotic)<br>4- Dry powder for oral suspension section(Non Antibiotic, Antibiotic & Cephalosporin)<br>5- Liquid Inject able section (Vial and Ampoule) (Non Antibiotic,)<br>6- Dry powder inject able section (Cephalosporin)<br>7- Cream/ Ointment / Gel (General)<br>8- Eye Drops (General)<br>9- Tulle Dressing (General). |
| | Remarks of Evaluator | |
| | **Decision: Deferred for confirmation of approval status of reference regulatory authorities and generic status.** | |
| 235. | Name and address of Manufacturer/Applicant | M/s Novamed Pharma, Lahore. |
| | Brand Name + Dosage Form + Strength | Nuphine injection 10mg/ml |
| | Composition | Eachml ampoule Contains:<br>Nalbuphine hydrochloride…. 10mg |
| | Diary No. D of R & I & Fee | Dy No. 12496 ; 18-08-17: Rs.20,000 |
| | Pharmacological group | Opioid Analgesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's Specifications |
| | Pack Size & demanded price | 5's(1ml): As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Neurobionof Martin Dow (001486) (pharmaguide) |
| | GMP Status | GMP Certificate issued on 03-01-2018 with following sections: |

| | | |
|---|---|---|
| | | 1- Tablet section (Non Antibiotic, Antibiotic & Psychotropic)<br>2- Capsule Section (Non Antibiotic, Antibiotic & Cephalosporin)<br>3- Oral Liquid section (Non Antibiotic)<br>4- Dry powder for oral suspension section(Non Antibiotic, Antibiotic & Cephalosporin)<br>5- Liquid Inject able section (Vial and Ampoule) (Non Antibiotic,)<br>6- Dry powder inject able section (Cephalosporin)<br>7- Cream/ Ointment / Gel (General)<br>8- Eye Drops (General)<br>9- Tulle Dressing (General). |
| | Remarks of Evaluator | Applied formulation is not present in USP & B.P.<br>Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.<br>Mention type of primary packaging material of applied formulation. |

**Decision: Registration Board deferred the case for the following reasons:**

- **Justification on scientific basis for not performing terminal sterilization during manufacturing of applied formulation.**
- **Clarification regarding container closure system for applied formulation.**

| | | |
|---|---|---|
| 236. | Name and address of manufacturer/ Applicant | M/s Medizan Laboratories Limited. |
| | Brand Name+Dosage Form+Strength | P-Nec XR 12.5mg Tablets |
| | Diary No. Date of R&I &fee | DiaryNo:6123; 19/02/2018; Rs:20,000/- |
| | Composition | Each enteric film coated extended release tablet contains:<br>Paroxetine (as hydrochloride) …12.5mg |
| | Pharmacological Group | Anti-depressant |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size &Demanded Price | 10's, 30's, ;As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA |
| | Me-too status | Deroxat CR tablet 12.5mg by Global Pharma |
| | GMP status | GMP Inspection conducted on 20-11-2017 concluded that firm is operating at satisfactory level of GMP Compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 237. | Name and address of manufacturer/ Applicant | M/s Medizan Laboratories Limited. |
| | Brand Name+Dosage Form+Strength | P-Nec XR 25mg Tablets |
| | Diary No. Date of R&I &fee | DiaryNo:6124; 19/02/2018; Rs:20,000/- |
| | Composition | Each enteric film coated extended release tablet contains:Paroxetine (as hydrochloride) …25mg |
| | Pharmacological Group | Anti-depressant |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP specification |
| | Pack size &Demanded Price | 10's, 30's;As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA |
| | Me-too status | Deroxat CR tablet 25mg by Global Pharma |
| | GMP status | GMP Inspection conducted on 20-11-2017 concluded that firm is operating at satisfactory level of GMP Compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |

R-II vides its letter No. F.6-10/2013-Reg-II dated 21th of June, 2018, forwarded one duplicate dossier of below mentioned product of Macquin's International, Karachi for further action if the case has already not been considered.

| Sr. N. | Name of firm | Name of drug (s) with composition | Date & diary number | Remarks |
|---|---|---|---|---|
| 1. | M/s. Macquin's International, Karachi | Ocu-Drozol Eye drop (5ml)<br>Each ml contains:<br>Dorzolamide (as hydrochloride)….. 20mg<br>Timolol (as maleate)…. 5mg | Dy. No. Nill<br>06-06-2016<br>Form 5<br>Rs. 20,000<br>06-06-2016<br>(Duplicate) | Duplicate dossier |

*Evaluation by PEC:The case of applied formulation has not been found registered with the name of firm as per record available with us till to date so the case has been evaluated and placed in the agenda for the consideration of Registration Board.*

| | | |
|---|---|---|
| 238. | Name and address of manufacturer/ Applicant | M/s. Macquin's International, Karachi |
| | Brand Name +Dosage Form+Strength | Ocu-Drozol Eye drop (5ml) |
| | Diary No. Date of R&I &fee | DiaryNo: duplicate dossier |
| | Composition | Each ml contains:<br>Dorzolamide (as hydrochloride)….. 20mg<br>Timolol (as maleate)…. 5mg |
| | Pharmacological Group | Anti-gluocoma |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP specification |
| | Pack size &Demanded Price | 5ml : As Per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in USFDA |
| | Me-too status | Dorlol Dye Drops of Genix Karachi |
| | GMP status | GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance. |
| | Remarks of the Evaluator. | Submit manufacturing method & master formulation |
| | **Decision: Deferred for Submision of manufacturing method & master formulation for applied formulation.** | |

**Evaluator PEC-IX**

| | | |
|---|---|---|
| 239. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Proton 50 mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Itopride HCl…..50mg |
| | Diary No. Date of R& I & fee | Dy No. 6898: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Drugs for functional gastrointestinal disorders |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 3x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Itopride hydrochloride tablet 50 mg. PMDA approved |
| | Me-too status | Itoride Tablet. Reg No. 42040 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specification and change of brand name.** | |
| 240. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Fission 50 mg Tablet |
| | Composition | Each tablet contains:<br>Clomiphene citrate…..50mg |
| | Diary No. Date of R& I & fee | Dy No. 6895: 22.02.2018<br>PKR 20,000/-: 22.02.2018 PKR 5000/-: 04.02.2019 |

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|---|---|---|
| | Pharmacological Group | Ovulation stimulants, synthetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Clomid™ 50mg Tablets. MHRA approved |
| | Me-too status | Gynofen 50mg Tablet. Reg No. 53337 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | • The firm revised the formulation to plain tablet with submission of Rs. 5000/-.<br>• The brand name shall be changed. |
| | **Decision: Approved with change of brand name. Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.** | |
| 241. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Glip-Met Tablet 50/500mg |
| | Composition | Each film-coated tablet contains:<br>Sitagliptin (as phosphate monohydrate)…50mg<br>Metformin HCl…….500mg |
| | Diary No. Date of R& I & fee | Dy No. 6904: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 2x7's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | JANUMET® (sitagliptin and metformin HCl) tablet, 50/500mg film-coated. USFDA approved |
| | Me-too status | Neoglip 50/500mg Tablets. Reg. No. 53099 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | • The firm revised Sitagliptin (as phosphate) to Sitagliptin (as phosphate, monohydrate) in label claim. |
| | **Decision: Approved with Innovator's specification.** | |
| 242. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar. |
| | Brand Name +Dosage Form + Strength | Glip-Met Tablet 50/1000mg |
| | Composition | Each film-coated tablet contains:<br>Sitagliptin (as phosphate monohydrate)…50mg<br>Metformin HCl…….1000mg |
| | Diary No. Date of R& I & fee | Dy No. 6904: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 2x7's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. USFDA approved |
| | Me-too status | Neoglip 50/1000mg Tablets. Reg. No. 53100 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | • The firm revised Sitagliptin (as phosphate) to Sitagliptin (as phosphate, monohydrate) in label claim. |
| | **Decision: Approved with Innovator's specification.** | |
| 243. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar. |
| | Brand Name +Dosage Form + Strength | Zyrova Tablet 20mg |
| | Composition | Each film-coated tablet contains:<br>Rosuvastatin as calcium…20mg |

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|---|---|---|
| | Diary No. Date of R& I & fee | Dy No. 6901: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 1x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 20mg film-coated tablets. MHRA approved |
| | Me-too status | Rostat 20mg Tablet. Reg. No. 55731 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specification.** | |
| 244. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Zyrova Tablet 10mg |
| | Composition | Each film-coated tablet contains:<br>Rosuvastatin as calcium…10mg |
| | Diary No. Date of R& I & fee | Dy No. 6900: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 1x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 10mg film-coated tablets. MHRA approved |
| | Me-too status | Rostat 10mg Tablet. Reg. No. 55730 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specification.** | |
| 245. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Zyrova Tablet 5mg |
| | Composition | Each film-coated tablet contains:<br>Rosuvastatin as calcium…5mg |
| | Diary No. Date of R& I & fee | Dy No. 6899: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 1x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 5mg film-coated tablets. MHRA approved |
| | Me-too status | Rostat 5mg Tablet. Reg. No. 55729 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved with Innovator's specification.** | |
| 246. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Roger Tablet 5/160/12.5mg |
| | Composition | Each film-coated tablet contains:<br>Amlodipine as besylate…5mg<br>Valsartan…..160mg<br>Hydrochlorthiazide……12.5 |
| | Diary No. Date of R& I & fee | Dy No. 6899: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 4x7's; as per SRO |

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|---|---|---|
| | Approval status of product in Reference Regulatory Authorities. | EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved |
| | Me-too status | Exforge HCT 5/160/12.5MG film coated tablets by Novatris Pharma. Reg. No. 69548 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | The brand name shall be changed. |
| | **Decision: Approved with change of brand name** | |
| 247. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Roger Tablet 10/160/12.5mg |
| | Composition | Each film-coated tablet contains:<br>Amlodipine as besylate…10mg<br>Valsartan…..160mg<br>Hydrochlorthiazide……12.5 |
| | Diary No. Date of R& I & fee | Dy No. 6896: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 4x7's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved |
| | Me-too status | Exforge HCT 10/160/25MG film coated tablets by Novatris Pharma. Reg. No. 69551 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | • The brand name shall be changed. |
| | **Decision: Approved with change of brand name** | |
| 248. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Vilda-Met 50/500mg |
| | Composition | Each film-coated tablet contains:<br>Vildagliptin…50mg<br>Metformin HCl…..500mg |
| | Diary No. Date of R& I & fee | Dy No. 6897: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications. |
| | Pack size & Demanded Price | 2x7's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/500 vildagliptin 50 mg/metformin hydrochloride 500 mg film coated tablet. **TGA** approved |
| | Me-too status | Galmet 50mg/500mg Tablet. Reg No. 81905 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specification.** | |
| 249. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Vilda-Met 50/1000mg |
| | Composition | Each film-coated tablet contains:<br>Vildagliptin…50mg<br>Metformin HCl…..1000mg |
| | Diary No. Date of R& I & fee | Dy No. 6892: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications. |
| | Pack size & Demanded Price | 2x7's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/1000 vildagliptin 50 mg/metformin hydrochloride 1000 mg film coated tablet. TGA approved |

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| | Me-too status | Valiant-M Tablets. Reg No. 77485 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specification.** | |
| 250. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Vilda-Met 50/850mg |
| | Composition | Each film-coated tablet contains:<br>Vildagliptin…50mg<br>Metformin HCl…..850mg |
| | Diary No. Date of R& I & fee | Dy No. 6893: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications. |
| | Pack size & Demanded Price | 2x7's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/850 vildagliptin 50 mg/metformin hydrochloride 850 mg film coated tablet. TGA approved |
| | Me-too status | Galmet 50mg/850mg Tablet. Reg No. 81906 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications.** | |
| 251. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Hist Tablet 16mg |
| | Composition | Each tablet contains:<br>Betahistine dihydrochloride…16mg |
| | Diary No. Date of R& I & fee | Dy No. 6890: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Antivertigo preparations |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 3x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Betahistine 16 mg uncoated tablets. MHRA approved |
| | Me-too status | Histogen 16mg Tablets. Reg. No. 56092 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 252. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Uric-Cure Tablet 80mg |
| | Composition | Each film-coated tablet contains:<br>Febuxostat……80mg |
| | Diary No. Date of R& I & fee | Dy No. 6902: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Preparations inhibiting uric acid production |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications. |
| | Pack size & Demanded Price | 2x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ULORIC (febuxostat) tablet for oral use. USFDA approved |
| | Me-too status | Febulos 80mg Tablet. Reg. No. 82695 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specification.** | |

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| 253. | Name and address of manufacturer / Applicant | Polyfine Chempharma, 51-Industrial Estate, Hayatabad Peshawar Pakistan |
| | Brand Name +Dosage Form + Strength | Uric-Cure Tablet 40mg |
| | Composition | Each film-coated tablet contains:<br>Febuxostat……40mg |
| | Diary No. Date of R& I & fee | Dy No. 6889: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Preparations inhibiting uric acid production |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications. |
| | Pack size & Demanded Price | 2x10's; as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ULORIC (febuxostat) tablet for oral use. USFDA approved |
| | Me-too status | Febulos 40mg Tablet. Reg. No. 82694 |
| | GMP status | The firm was inspected on 17.03.2017 wherein the GMP was rated satisfactory. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specification.** | |
| 254. | Name and address of manufacturer / Applicant | Mediate Pharmaceutical (Pvt.) Ltd., Plot # 150, 151 Sector 24, Korangi Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Tacromed 1mg Capsule |
| | Composition | Each capsule contains:<br>Tacrolimus (as monohydrate)……..1mg |
| | Diary No. Date of R& I & fee | Dy No. 32233: 27.09.2018 PKR 20,000/-: 27.09.2018 |
| | Pharmacological Group | Immunosuppressants |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per DRAP Policy |
| | Approval status of product in Reference Regulatory Authorities. | Adoport 1 mg hard capsules. **MHRA** approved |
| | Me-too status | Tacrosan 1mg Capsule. Reg. No. 78164 |
| | GMP status | The firm was inspected on 15.02.2017 with the following conclusion:<br>"Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Mediate Pharmaceuticals Pvt. Ltd Karachi has demonstrated both the drive and ability to implement appropriate corrective actions and improved production facility was considered to be operating at acceptable level of compliance with GMP guidelines as of today." |
| | Remarks of the Evaluator. | • |
| | **Decision: The Board was apprised that the application was considered out of queue as per decision of 257th meeting of Registration Board. Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.** | |
| 255. | Name and address of manufacturer / Applicant | Mission Pharmaceuticals (Pvt.) Ltd., Plot No. A-94, SITE Super Highway, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Cipro Tablet 250mg |
| | Composition | Each film-coated tablet contains:<br>Ciprofloxacin as HCl……..250mg |
| | Diary No. Date of R& I & fee | Dy No. 6827: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's; Rs. 286.70 |
| | Approval status of product in Reference Regulatory Authorities. | CIPRO® 250mg film-coated tablets. USFDA approved |
| | Me-too status | Cipra 250mg Tablet. Reg. No. 82229 |

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| | GMP status | The firm was inspected on 10.10.2017, wherein the GMP level was rated as GOOD.<br>The firm was advised to purchase TOC analyzer and one climatic chamber, and to hire more persons, especially in QA department. |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| 256. | Name and address of manufacturer / Applicant | Mission Pharmaceuticals (Pvt.) Ltd., Plot No. A-94, SITE Super Highway, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Cipro Tablet 500mg |
| | Composition | Each film-coated tablet contains:<br>Ciprofloxacin as HCl……..500mg |
| | Diary No. Date of R& I & fee | Dy No. 6833: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's; Rs. 504.60 |
| | Approval status of product in Reference Regulatory Authorities. | Ciprofloxacin 500 mg film-coated Tablets. MHRA approved |
| | Me-too status | Cibo 500mg Tablet. Reg. No. 81583 |
| | GMP status | The firm was inspected on 10.10.2017, wherein the GMP level was rated as GOOD.<br>The firm was advised to purchase TOC analyzer and one climatic chamber, and to hire more persons, especially in QA department. |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| 257. | Name and address of manufacturer / Applicant | M/s ZAFA Pharmaceutical Laboratories (Private) Limited L1/B Block-22 Federal B Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Trimezat Tablet 100mg |
| | Composition | Each tablet contains:<br>Trimebutine maleate…….100mg |
| | Diary No. Date of R& I & fee | Dy No. NIL: 21.05.2011<br>PKR 8,000/-: 21.05.2011 (Duplicate Dossier)<br>PKR 12,000/-: 09.01.2019 |
| | Pharmacological Group | Synthetic anticholinergics, esters with tertiary amino group |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 2 x10's; Rs. 131.45<br>10 x 10's; Rs. 657.25 |
| | Approval status of product in Reference Regulatory Authorities. | Debricalm 100mg film-coated tablets. ANSM approved |
| | Me-too status | Tribate Tablets. Reg. No. 20257 |
| | GMP status | The firm was last inspected on 06.10.2017, wherein the panel concluded the GMP compliance as FAIR |
| | Remarks of the Evaluator. | The firm was asked for complete finished product specifications; however, the firm submitted incomplete specifications. |
| | **Decision: Deferred for consideration on its turn.** | |
| 258. | Name and address of manufacturer / Applicant | AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Gabitin Capsule 300mg |
| | Composition | Each Capsule contains:<br>Gabapentin…….300mg |
| | Diary No. Date of R& I & fee | Dy No. 6859: 22.02.2018 PKR 20,000/-: 16.02.2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1x10's; Rs. 180/- |

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| | Approval status of product in Reference Regulatory Authorities. | Gabapentin 300mg Capsules. MHRA approved |
| | Me-too status | Pentowan 300mg Capsule. Reg. No. 82103 |
| | GMP status | The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications** | |
| 259. | Name and address of manufacturer / Applicant | AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Gabitin Capsule 100mg |
| | Composition | Each tablet contains:<br>Gabapentin…….100mg |
| | Diary No. Date of R& I & fee | Dy No. 6850: 22.02.2018 PKR 20,000/-: 16.02.2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1x10's; Rs. 90/- |
| | Approval status of product in Reference Regulatory Authorities. | Gabapentin 100mg Capsules. MHRA approved |
| | Me-too status | Pentowan 100mg Capsule. Reg. No. 79688 |
| | GMP status | The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production. |
| | Remarks of the Evaluator. | • |
| | • **Decision: Registration Board deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications** | |
| 260. | Name and address of manufacturer / Applicant | AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Aplodine Tablet 10mg |
| | Composition | Each tablet contains:<br>Amlodipine as besilate…….10mg |
| | Diary No. Date of R& I & fee | Dy No. 6856: 22.02.2018 PKR 20,000/-: 16.02.2018 |
| | Pharmacological Group | Selective calcium channel blockers with mainly vascular effects |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 12x0's; Rs. 290/- |
| | Approval status of product in Reference Regulatory Authorities. | NORVASC® (amlodipine besylate) 10mg Tablets for oral administration. USFDA approved |
| | Me-too status | NORVASC 10MG TAB. Reg. No. 11826 |
| | GMP status | The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production. |
| | Remarks of the Evaluator. | • |
| | **Decision: Registration Board deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications** | |
| 261. | Name and address of manufacturer / Applicant | AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Aplodine Tablet 5mg |
| | Composition | Each tablet contains:<br>Amlodipine as besilate…….5mg |
| | Diary No. Date of R& I & fee | Dy No. 6887: 22.02.2018 PKR 20,000/-: 16.02.2018 |
| | Pharmacological Group | Selective calcium channel blockers with mainly vascular effects |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x10's; Rs. 160/- |
| | Approval status of product in Reference Regulatory Authorities. | NORVASC® (amlodipine besylate) 5mg Tablets for oral administration. USFDA approved |

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| | Me-too status | NORVASC 5MG TAB. Reg. No. 11825 |
| | GMP status | The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production. |
| | Remarks of the Evaluator. | • |
| | **Decision: Registration Board deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications** | |
| 262. | Name and address of manufacturer / Applicant | AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Levtitam 500mg/5ml Syrup |
| | Composition | Each 5ml contain:<br>Levetiracetam…….500mg |
| | Diary No. Date of R& I & fee | Dy No. 6849: 22.02.2018 PKR 20,000/-: 16.02.2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30ml; Rs. 210/- |
| | Approval status of product in Reference Regulatory Authorities. | Desitrend 100 mg/ml oral solution. MHRA approved |
| | Me-too status | Eplipsa 100mg/ml Oral Solution. Reg. No. 82200 |
| | GMP status | The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production. |
| | Remarks of the Evaluator. | • |
| | **Decision: Registration Board deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications** | |
| 263. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt) Ltd. Plot No. E-145 to E-149, North western Industrials Zone, Port Qasim, Karachi, PAKISTAN |
| | Brand Name +Dosage Form + Strength | Zilium Oral Suspension 1mg/ml |
| | Composition | Each ml contains:<br>Domperidone …….1mg |
| | Diary No. Date of R& I & fee | Dy No. 6939: 23.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Propulsives |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer specifications. |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Domperidone 1mg/ml Oral Suspension. MHRA approved |
| | Me-too status | Almedon Suspenion 1mg/ml. Reg # 020503 |
| | GMP status | The firm was last inspected on 07.09.2017, wherein the firm was rated at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved with innovator's specification.** | |
| 264. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt) Ltd. Plot No. E-145 to E-149, North western Industrials Zone, Port Qasim, Karachi, PAKISTAN |
| | Brand Name +Dosage Form + Strength | Zilium Tablet 10mg |
| | Composition | Each film-coated tablet contains:<br>Domperidone as maleate…….10mg |
| | Diary No. Date of R& I & fee | Dy No. 6939: 23.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Propulsives |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Domperidone 10mg film-coated Tablets. MHRA approved |
| | Me-too status | Arsonpedone 10mg film-coated Tablet. No. 85513 |
| | GMP status | The firm was last inspected on 07.09.2017, wherein the firm was rated at satisfactory level of cGMP compliance. |

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| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| 265. | Name and address of manufacturer / Applicant | Demont Research Laboratories 20KM, Lahore-Sharikpur Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Ketofen Tablet 1mg |
| | Composition | Each tablet contains:<br>Ketotifen as hydrogen fumarate …..1mg |
| | Diary No. Date of R& I & fee | Dy No. 26780: 29.12.2017<br>PKR 20,000/-: 29.12.2017 PKR 5000/-; 16.01.2019 |
| | Pharmacological Group | Other antihistamines for systemic use |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed innovator's specifications |
| | Pack size & Demanded Price | 1x30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ZADITEN Tablets 1mg. MHRA approved |
| | Me-too status | Ketovent Tablets 1mg by Barrett Hodgson Pakistan (Pvt) Ltd. Reg No. 30977 |
| | GMP status | The firm was last inspected on 23.02.2018 & 26.02.2018, wherein the panel the GMP compliance is satisfactory. |
| | Remarks of the Evaluator. | • The firm revised the salt form with submission of applicable fee and adjusted the quantity of API in Master Formula as per salt factor.<br>• The brand name has been changed to Zofen. |
| | **Decision: Approved with change of brand name & with Innovators specifications** | |
| 266. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt) Ltd F-748/L S.I.T.E Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Hepafaas 3 g Sachet |
| | Composition | Each Sachet contains:<br>L-ornithine L-aspartate…..3g |
| | Diary No. Date of R& I & fee | Dy No. 2149: 16.01.2018 PKR 20,000/-: 16.01.2018 |
| | Pharmacological Group | Liver therapy mentioned as ornithine oxoglurate salt |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Hepa-Merz Sachet containing ornithine aspartate (granules for solution). **AGES** approved |
| | Me-too status | Lolar Sachet. Reg. No. 76499 |
| | GMP status | The firm has been issued cGMP Certificate on 08.05.2018 on the basis of inspection dated 04.05.2018. |
| | Remarks of the Evaluator. | The firm revised the formulation from powder to granule in Sachet. |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| 267. | Name and address of manufacturer / Applicant | Demont Research Laboratories 20KM, Lahore-Sharikpur Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Bamy Tablet 100/0.35mg |
| | Composition | Each chewable tablet contains:<br>Iron (III) hydroxide polymaltose complex eq. to elemental iron….100mg<br>Folic Acid……0.35mg |
| | Diary No. Date of R& I & fee | Dy No. 26776: 29.12.2017 PKR 20,000/-: 29.12.2017 |
| | Pharmacological Group | Iron in combination with folic acid |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1x30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too status | Ferosoft F.A Tablets by Hilton Pharma (Pvt) Ltd. Reg. No. 23996 |

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| | GMP status | The firm was last inspected on 23.02.2018 & 26.02.2018, wherein the panel the GMP compliance is satisfactory. |
| | Remarks of the Evaluator. | Bamy 600mg Tab has been mentioned on the fee Challan |
| | **Decision: Deferred for undertaking from the firm that the fee challan will not be used for any other product** | |
| 268. | Name and address of manufacturer / Applicant | Demont Research Laboratories 20KM, Lahore-Sharikpur Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Cinta tablet 1mg |
| | Composition | Each tablet contains:<br>Cinitapride hydrogen tartarate eq. to Cinitapride …..1mg |
| | Diary No. Date of R& I & fee | Dy No. 26783: 29.12.2017 PKR 20,000/-: 29.12.2017 |
| | Pharmacological Group | Drugs for functional gastrointestinal disorders, Propulsives |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm claimed Manufacturer's spec |
| | Pack size & Demanded Price | 1x20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Blaston 1 mg Tablets. Approved by Spanish Agency of Medicines and Health Products |
| | Me-too status | Cint 1mg Tablet by High-Q Pharmaceuticals.<br>Reg. No. 73888 |
| | GMP status | The firm was last inspected on 23.02.2018 & 26.02.2018, wherein the panel the GMP compliance is satisfactory. |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved with innovator's specification.** | |
| 269. | Name and address of manufacturer / Applicant | Unexolab (Pvt) Ltd., 9.5 K.M. Sheikhupura Road, Lahore; Contract Manufacturing by SAFE Pharmaceuticals (Private) Limited, Plot No. C.I-20, and Sector 6-B, North Karachi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Phyxone Injection 250 mg I.M. |
| | Composition | Each vial for dry substance contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….250mg |
| | Diary No. Date of R& I & fee | Dy No. 3189: 24.01.2018 PKR 50,000/-: 28.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per DRAP Policy |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 250mg (IM). US-FDA approved |
| | Me-too status | Unixone Injection (ceftriaxone Sodium) 250mg IM. Reg.No. 82556 |
| | GMP status | The firm (SAFE Pharmaceuticals) was inspected on 20.12.2016, wherein the GMP compliance was rated as GOOD. |
| | Remarks of the Evaluator. | • The firm Unexolabs has provided a list of (08) sections.<br>• The firm Unexolabs submitted that they have no registered products for contract manufacturing<br>• The firm submitted that they have applied for (10) products for contract manufacturing.<br>• Names of witnesses are not mentioned in the contract manufacturing agreement.<br>• The firm was asked to provide complete manufacturing outlines. The firm submitted the same; however, sealing process of vials is not there.<br>• In its 285th meeting, the Registration Board referred the cases of M/s Unexolabs to QA & LT Division to conduct GMP inspection of the firm on priority. |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s safe Pharmaceuticals, Karachi for further granting contract manufacturing permission.** | |

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| 270. | Name and address of manufacturer / Applicant | Unexolab (Pvt) Ltd., 9.5 K.M. Sheikhupura Road, Lahore; Contract Manufacturing by SAFE Pharmaceuticals (Private) Limited, Plot No. C.I-20, and Sector 6-B, North Karachi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Phyxone Injection 250 mg IV |
| | Composition | Each vial for dry substance contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….250mg |
| | Diary No. Date of R& I & fee | Dy No. 3188: 24.01.2018 PKR 50,000/-: 28.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per DRAP Policy |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 250mg (IV). US-FDA approved |
| | Me-too status | Ceftirains 250mg (ceftriaxone Sodium) I.V Injection by Sunrise Pharma (Pvt) Ltd. Reg. No. 78655 |
| | GMP status | The firm (SAFE Pharmaceuticals) was last inspected on 20.12.2016, wherein the GMP compliance was rated as GOOD. |
| | Remarks of the Evaluator. | • The firm Unexolabs has provided a list of (08) sections.<br>• The firm Unexolabs submitted that they have no registered products for contract manufacturing<br>• The firm submitted that they have applied for (10) products for contract manufacturing.<br>• Names of witnesses are not mentioned in the contract manufacturing agreement.<br>• The firm was asked to provide complete manufacturing outlines. The firm submitted the same; however, sealing process of vials is not there.<br>• In its 285th meeting, the Registration Board referred the cases of M/s Unexolabs to QA & LT Division to conduct GMP inspection of the firm on priority. |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s safe Pharmaceuticals, Karachi by panel for further granting contract manufacturing permission.** | |
| 271. | Name and address of manufacturer / Applicant | Unexolab (Pvt) Ltd., 9.5 K.M. Sheikhupura Road, Lahore; Contract Manufacturing by SAFE Pharmaceuticals (Private) Limited, Plot No. C.I-20, and Sector 6-B, North Karachi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Phyxone Injection 500 mg IM |
| | Composition | Each vial for dry substance contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….500mg |
| | Diary No. Date of R& I & fee | Dy No. 3191: 24.01.2018 PKR 50,000/-: 28.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per DRAP Policy |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 500mg (IM). US-FDA approved |
| | Me-too status | Wincef 500 mg (Ceftriaxone sodium) IM injection. Reg. No. 68371 |
| | GMP status | The firm (SAFE Pharmaceuticals) was last inspected on 20.12.2016, wherein the GMP compliance was rated as GOOD. |
| | Remarks of the Evaluator. | • The firm Unexolabs has provided a list of (08) sections.<br>• The firm Unexolabs submitted that they have no registered products for contract manufacturing<br>• The firm submitted that they have applied for (10) products |

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| | | for contract manufacturing.<br>• Names of witnesses are not mentioned in the contract manufacturing agreement.<br>• The firm was asked to provide complete manufacturing outlines. The firm submitted the same; however, sealing process of vials is not there.<br>• In its 285th meeting, the Registration Board referred the cases of M/s Unexolabs to QA & LT Division to conduct GMP inspection of the firm on priority. |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s safe Pharmaceuticals, Karachi by panel for further granting contract manufacturing permission.** | |

**Evaluator PEC-XII**

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| 272. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitatin-P 50 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5445 dated 14-02-2018 Rs. 20,000/-<br>Dated 14-02-2018 |
| | Composition | Each film-coated tablet Contains:<br>Sitagliptin (as phosphate monohydrate) …50mg |
| | Pharmacological Group | Dipeptidyl peptidase 4 (DPP-4) inhibitors |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | JANUVIA 50 mg film-coated tablet by M/s Merck Sharp Dohme (USFDA Approved) |
| | Me-too status | A-Glip 50mg Tablets by M/s Atco (Reg#053097) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 273. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Telsar-AM Tablet 5/80mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5454 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …5mg<br>Telmisartan …80mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan and amlodipine tablet 5mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved) |
| | Me-too status | Telsarta-A 5/80 Tablet by M/s Pharmevo (Reg#073762) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet.<br>• Firm has not submitted evidence of double layer compression machine. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.** | |

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| 274. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Telsar-AM Tablet 5/20mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5452 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …5mg<br>Telmisartan …20mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too status | Not confirmed |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet.<br>• Firm has not submitted evidence of double layer compression machine.<br>• Approval status of product in Reference Regulatory Authorities not confirmed.<br>• Me-too status not confirmed from available database. |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**<br>• **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.** | |
| 275. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Telsar-80 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5451 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film coated tablet contains:<br>Telmisartan…80mg |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmark 80mg film-coated tablets by M/s Glenmark Pharmaceuticals s.r.o (MHRA Approved) |
| | Me-too status | Tesart 80mg Tablets by M/s 'Bosch (Reg#045083) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 276. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | BP-Ril-20 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5443 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each tablet contains:<br>Lisinopril (as dihydrate) …20mg |

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| | Pharmacological Group | ACE inhibitors, plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | LISINOPRIL 20mg TABLETS by M/s Actavis UK Limited (MHRA Approved) |
| | Me-too status | Zestril tablets 20mg by M/s ICI (Reg#012352) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 277. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitatin-P 100 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5446 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film-coated tablet Contains:<br>Sitagliptin (as phosphate monohydrate) …100mg |
| | Pharmacological Group | Dipeptidyl peptidase 4 (DPP-4) inhibitors |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | JANUVIA 100mg film-coated tablet by M/s Merck Sharp Dohme (USFDA Approved) |
| | Me-too status | A-Glip 100mg Tablets by M/s Atco (Reg#053098) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 278. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitatin-Plus Tablet 25/500mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5447 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate)…25mg<br>Metformin hydrochloride …500mg |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Sitaglu Met Tablets 25/500 by M/s Hilton (Reg#073734) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 279. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitatin-Plus Tablet 25/1000mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5448 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate)…25mg<br>Metformin hydrochloride …1000mg |

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| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Not confirmed |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed.<br>• Me-too status not confirmed from available database. |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 280. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Telsar-20 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5449 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film-coated tablet contains:<br>Telmisartan…20mg |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan STADA 20 mg film-coated tablets by M/s STADA Arzneimittel AG (Swedish Medical Producta Agency Approved) |
| | Me-too status | Mycardix 20mg Tablets by M/s Macter (Reg#044215) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 281. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Telsar-40 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5450 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film-coated tablet contains:<br>Telmisartan…40mg |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan STADA 40 mg film-coated tablets by M/s STADA Arzneimittel AG (Swedish Medical Producta Agency Approved) |
| | Me-too status | Mycardix 40mg Tablets by M/s Macter (Reg#044216) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 282. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Sitatin-P 25 Tablet |

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| | Diary No. Date of R& I & fee | Form-5 Dy.No 5444 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film-coated tablet Contains:<br>Sitagliptin (as phosphate monohydrate) …25mg |
| | Pharmacological Group | Dipeptidyl peptidase 4 (DPP-4) inhibitors |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Sitagliptin APOTEX 25 mg tablet by M/s Apotex (Pvt) Ltd (TGA Approved) |
| | Me-too status | A-Glip 25mg Tablets by M/s Atco (Reg#053096) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 283. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | BP-Ril-10 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5442 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each tablet contains:<br>Lisinopril (as dihydrate) …10mg |
| | Pharmacological Group | ACE inhibitors, plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x7's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | LISINOPRIL 10mg TABLETS by M/s Actavis UK Limited (MHRA Approved) |
| | Me-too status | Zestril tablets 20mg by M/s ICI (Reg#012351) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 284. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Amsatin Tablet 5/80mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5435 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Amlodipine (as Besylate)…5mg<br>Valsartan…80mg |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Amlodipine/Valsartan 5 mg/80 mg film-coated tablets by M/s Genus Pharmaceuticals Ltd (MHRA Approved) |
| | Me-too status | Exforge 5/80mg film coated tablets by M/s Novartis Pharma (Pakistan) Limited (Reg#047569) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 285. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Telsar-AM Tablet 5/40mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5453 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |

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| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …5mg<br>Telmisartan …40mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x7's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan and amlodipine tablet 5mg/40mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved) |
| | Me-too status | Telsarta-A 5/40 Tablet by M/s Pharmevo (Reg#073763) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet.<br>• Firm has not submitted evidence of double layer compression machine. |
| | **Decision: Deferred for following:**<br>• **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 286. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Telsar-AM Tablet 10/80mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5455 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …10mg<br>Telmisartan …80mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x7's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan and amlodipine tablet 10mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDA approved) |
| | Me-too status | Telsarta-A 10/80 Tablet by M/s Pharmevo (Reg#073767) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, firm has not applied drug as multi layered tablet.<br>• Firm has not submitted evidence of double layer compression machine. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.** | |
| 287. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | BP-Ril-5 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5441 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each tablet contains:<br>Lisinopril (as dehydrate) …20mg |
| | Pharmacological Group | ACE inhibitors, plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |

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| | Pack size & Demanded Price | 2x7's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | LISINOPRIL 5mg TABLETS by M/s Actavis UK Limited (MHRA Approved) |
| | Me-too status | Zestril tablets 5mg by M/s ICI (Reg#012350) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved with change of brand name** | |
| 288. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Lostan-K25 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5428 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film coated tablet contains:<br>Losartan potassium…25mg |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Klomentan 25 mg film-coated tablets. By M/s Amneal Pharma Europe Limited (Sweden Approved) |
| | Me-too status | Pixan-25 Tablets by M/s Medipak (Reg#023943) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 289. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Lostan-K50 Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5429 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film coated tablet contains:<br>Losartan potassium …50mg |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x7's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Losartan Potassium 50 mg Film-coated Tablets. By M/s Cadila Pharmaceuticals (MHRA Approved) |
| | Me-too status | Pixan-50 Tablets by M/s Medipak (Reg#023944) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 290. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Vildatin-Plus Tablet 50/500mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5430 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Vildagliptin…50mg<br>Metformin Hydrochloride…850mg |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 14's /As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/500 mg film coated tablet by M/s Novartis Pharmaceuticals Australia Pty Ltd (TGA Approved) |

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| | Me-too status | Galvus Met 50/500MG tablets by M/s Novartis (Reg#078106) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications.** | |
| 291. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Vildatin-Plus Tablet 50/850 |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5431 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Vildagliptin…50mg<br>Metformin Hydrochloride…850mg |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 14's /As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/850 mg film coated tablet by M/s Novartis Pharmaceuticals Australia Pty Ltd (TGA Approved) |
| | Me-too status | Glavimet 50/850mg Tablet by M/s Atco (Reg#073496) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications.** | |
| 292. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Guflinz 600mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5434 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Linezolid…600mg |
| | Pharmacological Group | Oxazolidinone antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox 600 mg film-coated tablets by M/s Pharmacia Limited, (MHRA approved.) |
| | Me-too status | Ecasil 600mg tablet by M/s Sami (Reg#066904) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 293. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Guflinz 100mg/5ml Dry Powder Suspension |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5432 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | After reconstitution Each 5ml contains:<br>Linezolid…100mg |
| | Pharmacological Group | Oxazolidinone antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox 100 mg/5 ml granules for oral suspension by M/s Pharmacia Limited (MHRA Approved) |
| | Me-too status | Lizotek Oral Suspension 100mg/5ml by M/s TabrosPharma (Reg#057941) |

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| | GMP status | |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 294. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Amsatin Tablet 10/160mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5437 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Amlodipine (as Besylate)…10mg<br>Valsartan…160mg |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Amlodipine/Valsartan 10 mg/160 mg film-coated tablets by M/s Genus Pharmaceuticals Ltd (MHRA Approved) |
| | Me-too status | Exforge 10/160mg film coated tablets by M/s Novartis Pharma (Pakistan) Limited (Reg#047571) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 295. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Erotine 150mg Capsule |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5438 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each capsule contains:<br>Erdosteine…150mg |
| | Pharmacological Group | Mucolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 2x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Erdozet Capsules 150mg by M/s S.J&G (Reg#073809) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 296. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Amsatin Tablet 5/160mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5436 (14-02-2018) Rs.20,000/- 14-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Amlodipine (as Besylate)…5mg<br>Valsartan…160mg |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's /As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Amlodipine/Valsartan 5 mg/160 mg film-coated tablets by M/s Genus Pharmaceuticals Ltd (MHRA Approved) |
| | Me-too status | Exforge 5/160mg film coated tablets by M/s Novartis Pharma (Pakistan) Limited (Reg#047570) |

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| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 297. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Guflinz 400mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5433 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Linezolid…400mg |
| | Pharmacological Group | Oxazolidinone antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 12's/As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox 400 mg film-coated tablets by M/s Pharmacia Limited, (USFDA approved.) |
| | Me-too status | Ecasil 400mg tablet by M/s Sami (Reg#067162) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 298. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Erotine 175mg Capsule |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5439 (14-02-2018) Rs.20,000/- 14-02-2018 |
| | Composition | Each capsule contains:<br>Erdosteine…175mg |
| | Pharmacological Group | Mucolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 2x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Not confirmed. |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed.<br>• Me-too status not confirmed from available database. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 299. | Name and address of manufacturer / Applicant | M/s Gulf Pharmaceuticals, Plot # 49, Street # S-5, National industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | Erotine 300mg Capsule |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5440 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each capsule contains:<br>Erdosteine…300mg |
| | Pharmacological Group | Mucolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 2x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Erdotin 300 mg Capsules by M/s Edmond Pharma Srl (MHRA Approved) |

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| | Me-too status | Erdozet Capsules 300mg by M/s S.J&G (Reg#070859) |
| | GMP status | Last GMP inspection conducted on 02-2-2018 & 07-2-2018, and report concludes recommendation for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 300. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Etam Injection |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5421 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each 2ml ampoule contains:<br>Etamsylate…250mg |
| | Pharmacological Group | Vitamin K and other hemostatics (Other systemic hemostatics) |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 6's Ampoule / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | DICYNONE 250 mg/2 ml, solution injectable (ampoule) by M/s Vifor France (ANSM Approved) |
| | Me-too status | Dicynone Injection 250mg/2ml (ampoule) by M/s |
| | GMP status | 14-12-2017; Routine GMP Inspection<br>Company is found complying GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 301. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Isolide Gel |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5422 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each gram of gel contains:<br>Isotretinoin …0.5mg (0.05%w/w)<br>Erythromycin …20mg (2%w/w) |
| | Pharmacological Group | Anti-acne preparations for topical use |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10g /As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Isotrexin Gel by M/s GlaxoSmithKline UK Limited (MHRA Approved) |
| | Me-too status | Isotrexin Gel by M/s Stiefel Laboratories (Reg#047552) |
| | GMP status | 14-12-2017; Routine GMP Inspection<br>Company is found complying GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 302. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Oronide 60mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5426 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each film caoted tablet contains:<br>Nateglinide…60mg |
| | Pharmacological Group | Other blood glucose lowering drugs, excl. insulins |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 24's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Starlix film-coated 60mg Tablets by M/s Novartis Europharm Limited (HPRA Ireland Approved) |
| | Me-too status | Starlix Film Coated Tablets 60mg by M/s Novartis (Reg#027341) |

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| | GMP status | 14-12-2017; Routine GMP Inspection<br>Company is found complying GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 303. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Oronide 120mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5427 dated 14-02-2018 Rs. 20,000/-<br>Dated 14-02-2018 |
| | Composition | Each film caoted tablet contains:<br>Nateglinide…60mg |
| | Pharmacological Group | Other blood glucose lowering drugs, excl. insulins |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 24's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Starlix film-coated 120mg Tablets by M/s Novartis Europharm Limited (HPRA Ireland Approved) |
| | Me-too status | Starlix Film Coated Tablets 60mg by M/s Novartis (Reg#027340) |
| | GMP status | 14-12-2017; Routine GMP Inspection<br>Company is found complying GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 304. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Ulgin Liquid |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5423 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each 10ml Contains:<br>Sodium Alginate…500mg<br>Sodium Bicarbonate…267mg<br>Calcium Carbonate…160mg |
| | Pharmacological Group | Antacid |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 120ml/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Gaviscon oral liquid peppermint bottle by M/s Reckitt Benckiser Pty Ltd, (TGA approved) |
| | Me-too status | Ul-Nil Suspension by M/s Z-Jans. (Reg# 052470) |
| | GMP status | 14-12-2017; Routine GMP Inspection<br>Company is found complying GMP |
| | Remarks of the Evaluator. | • Evidence of Atomic absorption apparatus not submitted by the firm. |
| | **Decision: Deferred for confirmation of availability of atomic absorption spectrophotometer.** | |
| 305. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Acetosol Infusion 1g/100ml |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5424 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each 100ml contains:<br>Paracetamol…1g |
| | Pharmacological Group | Other analgesics and antipyretics (Anilides) |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Paracetamol 1000 mg/100ml Solution for Infusion (Vial) by M/s Sandoz Limited (MHRA Approved) |

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| | Me-too status | Bofalgan 1g/100ml Infusion (Vial) M/s Bosch Pharmaceuticals (Reg#070607) |
| | GMP status | 14-12-2017; Routine GMP Inspection<br>Company is found complying GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 306. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 KM Adyala Raod Post Office Daghal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Vomipreg Tablets 10/10mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5425 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Enteric coated tablet contains:<br>Doxylamine Succinate …10mg<br>Pyridoxine hydrochloride …10mg |
| | Pharmacological Group | Anti-Histamine + Vitamin B6 |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 30's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Doxylamine Succinate And Pyridoxine Hydrochloride Tablet, Delayed Release by M/s Actavis Labs Fl Inc. (USFDA Approved) |
| | Me-too status | Nausidox 10mg/10mg Tablet OBS Pakistan. (Reg#076292) |
| | GMP status | 14-12-2017; Routine GMP Inspection<br>Company is found complying GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification and change of brand name.** | |
| 307. | Name and address of manufacturer / Applicant | M/s Brookes Pharma Pvt Ltd.<br>58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Sterile Water for injection 4ml |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5278 dated 14-02-2018 Rs. 20,000/- Dated 12-02-2018 |
| | Composition | Each ampoule contains:<br>Sterile Water for injection…4ml |
| | Pharmacological Group | Diluent |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Sterile water for injection MHRA approved. |
| | Me-too status | Water for Injection 4ml ampoule by M/s Healthtek (Reg#079940) |
| | GMP status | 11-10-2017 & 16-10-2017; Routine GMP Inspection<br>Firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 308. | Name and address of manufacturer / Applicant | M/s Brookes Pharma Pvt Ltd.<br>58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Sterile Water for injection 2ml |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5277 dated 14-02-2018 Rs. 20,000/- Dated 12-02-2018 |
| | Composition | Each ampoule contains:<br>Sterile Water for injection…2ml |
| | Pharmacological Group | Diluent |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Sterile water for injection MHRA approved |

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| | Me-too status | Water for Injection 2ml ampoule by M/s Healthtek (Reg#076466) |
| | GMP status | 11-10-2017 & 16-10-2017<br>Routine GMP Inspection<br>Firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 309. | Name and address of manufacturer / Applicant | M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Met-Cort Cream 2%w/w + 1% w/w |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5276 dated 14-02-2018 Rs. 20,000/- Dated 12-02-2018 |
| | Composition | Each gram Cream contains<br>Miconazole nitrate …20mg (2%w/w)<br>Hydrocortisone …10mg (1%w/w) |
| | Pharmacological Group | Antifungals for topical use (Imidazole and triazole derivative + Corticosteroid) |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Daktacort 2% / 1% w/w cream by M/s Janssen-Cilag Limited (MHRA Approved) |
| | Me-too status | Micasone Cream by M/s Leonine Pharma (Reg#013602) |
| | GMP status | 11-10-2017 & 16-10-2017; Routine GMP Inspection<br>Firm is operating at satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 310. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | QGEM 320mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5546 (15-02-2018) Rs. 20,000/- 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Gemifloxacin (as mesylate) …320mg |
| | Pharmacological Group | Fluoroquinolone |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 7's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Factive film-coated tablet 320mg by M/s Merus Labs International, Inc (USFDA Approved) |
| | Me-too status | Genflox 320mg Tablet by M/s High-Q Pharmaceuticals (Reg#055998) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 311. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Qmox 400mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5545 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Moxifloxacin (as hydrochloride) …400mg |
| | Pharmacological Group | Fluoroquinolone |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 5's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Avelox 400 mg film-coated tablets by M/s Bayer plc (MHRA Approved) |

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| | Me-too status | Moxiflox Tablets 400mg by M/s Mediceena Pharma (Reg#034453) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 312. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Lezin 5mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5552 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Levocetirizine dihydrochloride …5mg |
| | Pharmacological Group | Antihistamines for systemic use (Piperazine derivatives) |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Levocetirizine dihydrochloride 5mg film-coated tablets by M/s Manx Healthcare Ltd (MHRA Approved) |
| | Me-too status | Levrix Tablets 5mg by M/s AGP (Reg#034675) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 313. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Otron 8mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5551 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Ondansetron (as hydrochloride dihydrate). …8mg |
| | Pharmacological Group | Serotonin (5HT3) antagonists |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ondansetron 8 mg film-coated tablets by M/s Teva UK Limited (MHRA Approved) |
| | Me-too status | Welon Tablets 8mg by M/s Werrick (Reg#029561) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 314. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Deslor 5mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5550 (15-02-2018) Rs. 20,000/- 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Desloratadine …5mg |
| | Pharmacological Group | Other antihistamines for systemic use |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Desloratadine 5 mg film-coated tablets by M/s Bristol Laboratories Ltd (MHRA Approved) |
| | Me-too status | Aerius Film Coated Tablets 5mg by M/s ICI Pakistan LTD (Reg#031370) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |

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| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 315. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Captop 25mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5556 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each tablet contains:<br>Captopril …25mg |
| | Pharmacological Group | ACE inhibitors, plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Captopril 25mg Tablets by M/s Tillomed Laboratories Ltd (MHRA Approved) |
| | Me-too status | Capoten 25mg tablet by M/s Squibb Khi (Reg#006156) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 316. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Captop 50mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5557 dated 15-02-2018 Rs. 20,000/- Dated 15-02-201 |
| | Composition | Each tablet contains:<br>Captopril …50mg |
| | Pharmacological Group | ACE inhibitors, plain |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Captopril 50mg Tablets by M/s Tillomed Laboratories Ltd (MHRA Approved) |
| | Me-too status | Capoten 50mg tablet by M/s Squibb Khi (Reg#006157) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 317. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Oxalid 600mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5553 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Linezolid…600mg |
| | Pharmacological Group | Oxazolidinone antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 2x6's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox 600 mg film-coated tablets by M/s Pharmacia Limited, (MHRA approved.) |
| | Me-too status | Ecasil 600mg tablet by M/s Sami (Reg#066904) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |

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| 318. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Clar 250mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5551 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Clarithromycin …250mg |
| | Pharmacological Group | Macrolides |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x6's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Clarithromycin 250 mg Film-coated Tablets by M/s Teva UK Limited (MHRA Approved) |
| | Me-too status | Clara 250mg Tablet by M/s Saydon Pharma (Reg#023322) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 319. | Name and address of manufacturer / Applicant | M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab |
| | Brand Name +Dosage Form + Strength | Clar 500mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5555 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Clarithromycin …500mg |
| | Pharmacological Group | Macrolides |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x6's, 10x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Clarithromycin 500 mg Film-coated Tablets by M/s Teva UK Limited (MHRA Approved) |
| | Me-too status | Clara 500mg Tablet by M/s Saydon Pharma (Reg#023323) |
| | GMP status | Last GMP inspection is conducted on 26-05-17 & report concludes that firm was considered GMP compliant |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 320. | Name and address of manufacturer / Applicant | M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Galvecta Plus Tablet 50/500mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5516 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each Film Coated Tablet Contains:<br>Vildagliptin…50mg<br>Metformin Hydrochloride…500mg |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 2x7's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/500 film coated tablet by M/s Novartis Pharmaceuticals Australia Pty Ltd (TGA Approved) |
| | Me-too status | Galvus Met 50/500mg Tablets by M/s Novartis (Reg#078106) |
| | GMP status | GMP inspection conducted on 5th and 27th December 2017 with conclusive remarks that firm is compliant to good cGMP at the time of inspection. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications.** | |

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| 321. | Name and address of manufacturer / Applicant | M/s Novamed Pharmaceuticals (Pvt) Ltd.<br>28-km,Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Demant Tablet 10mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5515 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Memantine hydrochloride …10mg |
| | Pharmacological Group | Other anti-dementia drugs |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Memantine 10 mg film-coated tablets by M/s Aristo Pharma GmbH (MHRA Approved) |
| | Me-too status | Zexa Tablets 10mg by M/s Mass Pharma (Pvt) Ltd (Reg#040700) |
| | GMP status | GMP inspection conducted on 5th and 27th December 2017 with conclusive remarks that firm is compliant to good cGMP at the time of inspection. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 322. | Name and address of manufacturer / Applicant | M/s Bio Labs Pvt Ltd.<br>Plot # 145, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Tacrol 0.1%w/w Ointment |
| | Diary No. Date of R& I & fee | Form-5 Dy.#5513 (15-02-2018) Rs.20,000/- 15-02-2018 |
| | Composition | Each gram contains:<br>Tacrolimus (as monohydrate)…1mg (0.1%w/w) |
| | Pharmacological Group | Agents for dermatitis, excluding corticosteroids |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10g, 30g /As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Tacrolimus Accord 0.1 % ointment by M/s Accord Healthcare Limited (MHRA Approved) |
| | Me-too status | Limus 0.1% Ointment by M/s Nabiqasim (Reg#045215) |
| | GMP status | The firm was granted GMP certificate based on inspection conducted on 5th & 6th December 2017. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.**<br>**Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.** | |
| 323. | Name and address of manufacturer / Applicant | M/s Bio Labs Pvt Ltd.<br>Plot # 145, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Osteo-Cure 50mg Capsule |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5513 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each Capsule Contains:<br>Diacerein…50mg |
| | Pharmacological Group | Other antiinflammatory and antirheumatic agents, non-steroids |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 30's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | DIACEREIN BIOGARAN 50 mg hard capsule by M/s BIOGARAN (ANSM, France Approved) |
| | Me-too status | Dibro 50mg capsules by M/s Winbrain Research Laboratories (Reg#071639) |
| | GMP status | The firm was granted GMP certificate based on inspection conducted on 5th & 6th December 2017. |

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| | Remarks of the Evaluator. | Brand name resemblance. |
| | Decision: **Approved with change of brand name & with Innovators specifications** | |
| 324. | 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 | Pletanant-100mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5501 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each tablet contains:<br>Cilostazol …100mg |
| | Pharmacological Group | Platelet aggregation inhibitors excl. heparin |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 30's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cilostazol 100 mg tablets by M/s Generics [UK] Ltd t/a Mylan (MHRA Approved) |
| | Me-too status | Prigtal Tablets 100mg by M/s Getz (Reg#036229) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 325. | 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 | Lamital 300mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5507 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each film coated tablet contains:<br>Lamotrigine…300mg |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 60's, 150's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | LAMICTAL XR extended-release tablets 300mg by M/s GlaxoSmithKline (USFDA Approved) |
| | Me-too status | Not confirmed |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | • Me-too status not confirmed from available database.<br>• Firm has applied as film coated tablet whereas formulation approved in USFDA is extended-release tablet. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as approved formulation is extended-release tablet.**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 326. | 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 | Aspide 200mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5504 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each tablet contains:<br>Amisulpride…200mg |
| | Pharmacological Group | Antipsychotics (Benzamides) |

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| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 60's, / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Amisulpride 200mg Tablets by M/s Accord-UK Ltd (MHRA Approved) |
| | Me-too status | Amiride Tablet 200mg by M/s Shrooq Pharmaceuticals (Pvt) Ltd (Reg#063102) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 327. | 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 | Lamital 50mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5505 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each tablet contains:<br>Lamotrigine…50mg |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lamotrigine Actavis 50mg tablets by M/s Actavis UK Limited (MHRA Approved) |
| | Me-too status | Lamictal Tablets 50mg by M/s GSK (Reg#014919) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 328. | 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 | Lamital 100mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5506 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each tablet contains:<br>Lamotrigine…100mg |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lamotrigine Actavis 100mg tablets by M/s Actavis UK Limited (MHRA Approved) |
| | Me-too status | Lamictal Tablets 100mg by M/s GSK (Reg#014921) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 329. | 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 | Aspide 100mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5503 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |

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| | Composition | Each tablet contains:<br>Amisulpride…100mg |
| | Pharmacological Group | Antipsychotics (Benzamides) |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 60's, / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Amisulpride 100mg Tablets by M/s Accord-UK Ltd (MHRA Approved) |
| | Me-too status | Solium-100 Tablets by M/s Genome Pharmaceuticals (Pvt,) Ltd (Reg#074533) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 330. | 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 | Aspide 50mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5502 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each tablet contains:<br>Amisulpride…50mg |
| | Pharmacological Group | Antipsychotics (Benzamides) |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 60's, / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Amisulpride 50mg Tablets by M/s Accord-UK Ltd (MHRA Approved) |
| | Me-too status | Solium-50 Tablets by M/s Genome Pharmaceuticals (Pvt,) Ltd (Reg#064017) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 331. | 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 | Pletanant-50mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5500 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each tablet contains:<br>Cilostazol …50mg |
| | Pharmacological Group | Platelet aggregation inhibitors excl. heparin |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 60's, / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cilostazol 50 mg tablets by M/s Generics [UK] Ltd t/a Mylan (MHRA Approved) |
| | Me-too status | Prigtal Tablets 50mg by M/s Getz (Reg#036228) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |

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| 332. | 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 | Phloronal-80mg Tablets |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5499 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each sugar coated tablet contains:<br>Phloroglucinol dihydrate…80mg<br>Trimethylphloroglucinol…80mg |
| | Pharmacological Group | Other drugs for functional gastrointestinal disorders |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 30's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | SPASFON, coated tablet by M/s Teva Health (ANSM approved.) |
| | Me-too status | Anafortan Plus Tablet by M/s AGP Pharma (Reg#024504) |
| | GMP status | Last GMP inspection conducted on 20-11-2017 and the report concludes that the firm was considered to be operating at reasonably acceptable compliance with GMP guidelines as of today. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 333. | Name and address of manufacturer / Applicant | M/s Asian Continental Pvt Ltd.<br>Continental House, D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Prazo Tablet 1mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5318 dated 14-02-2018 Rs. 20,000/- Dated 14-02-2018 |
| | Composition | Each Tablet contains:<br>Alprazolam …1mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Alprazolam Mylan 1 mg, tablet by M/s Mylan Sas (ANSM France Approved) |
| | Me-too status | Alprazolam 1 mg Tablets by M/s Heal Pharmaceuticals (Reg.# 079392) |
| | GMP status | 19-09-2017; Routine GMP Inspection<br>Firm is operating at good level of GMP compliance. |
| | Remarks of the Evaluator. | • Approval of manufacturing facility for production of said formulation could not be confirmed |
| | **Decision: Deferred for confirmation of requisite section for the applied product** | |
| 334. | Name and address of manufacturer / Applicant | M/s CCL Pharmaceuticals (Pvt) Ltd.<br>62 Quaid e Azam Industrial Estate,Kot, Lakhpat,Lahore |
| | Brand Name +Dosage Form + Strength | Colitis ER Tablet 400mg |
| | Diary No. Date of R& I & fee | Duplicate dossier : duplicate fee challan of Rs. 20,000/- (06-07-2017) (Challan#0593963)<br>Dy.No 38004 dated 19-11-2018 |
| | Composition | Each enteric coated Tablet contains:<br>Mesalamine…400mg |
| | Pharmacological Group | Intestinal antiinflammatory agents (Aminosalicylic acid and similar agents) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 3x10's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ASACOL mesalazine 400 mg enteric coated by M/s Emerge Health Pty Ltd (TGA Approved) |
| | Me-too status | Mesacam 400mg EC Tablets by M/s Genome (Reg.# 084212) |

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| | GMP status | Firm has submitted copy of GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 335. | Name and address of manufacturer / Applicant | M/s CCL Pharmaceuticals (Pvt) Ltd.<br>62 Quaid e Azam Industrial Estate,Kot, Lakhpat,Lahore |
| | Brand Name +Dosage Form + Strength | Colitis ER Tablet 800mg |
| | Diary No. Date of R& I & fee | Duplicate dossier : duplicate fee challan of Rs. 20,000/- (06-07-2017) (Challan#0593963)<br>Dy.No 38005 dated 19-11-2018 |
| | Composition | Each enteric coated Tablet contains:<br>Mesalamine…800mg |
| | Pharmacological Group | Intestinal antiinflammatory agents (Aminosalicylic acid and similar agents) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 3x10's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ASACOL mesalazine 800 mg enteric coated by M/s Emerge Health Pty Ltd (TGA Approved) |
| | Me-too status | Mesal 800mg EC Tablets by M/s Highnoon (Reg.# 081380) |
| | GMP status | Firm has submitted copy of GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |

**Evaluator PEC-XIII**

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| 336. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals Pvt. Limited, Plot No. A- 248 & A- 256 to 259 H.I.T.E. Lasbella, Balochistan. |
| | Brand Name +Dosage Form + Strength | Desco tablet 5mg |
| | Composition | Each film-coated tablet contains:<br>Desloratadine ……..5mg |
| | Diary No. Date of R& I & fee | Dy. No.224; 02-01-2018; Rs.20,000/- (02-01-2018) |
| | Pharmacological Group | Antihistamine/ Anti-allergic |
| | Type of Form | Form -5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 1x 10's & As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Desloratadine film-coated tablet 5mg of M/s Lupin Healthcare (UK) Limited (MHRA Approved) |
| | Me-too status | Destina tablet 5mg of M/s Hilton Pharma (Reg. # 039364) |
| | GMP status | Last GMP inspection was conducted on 03-08-2017 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP inspection report.<br>• No official monograph is available in USP, BP, IP or JP. |
| | **Decision: Approved with innovator's specification.** | |
| 337. | Name and address of manufacturer / Applicant | M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi. |
| | Brand Name +Dosage Form + Strength | Water for injection 2ml |
| | Composition | Each 2ml ampoule contains:<br>Water for injection …...2ml |
| | Diary No. Date of R& I & fee | Dy. No.225; 02-01-2018; Rs.20,000/- (02-01-2018) |
| | Pharmacological Group | Diluent / Solvent for reconstitution |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 2ml ampoule x 5's ; 2ml ampoule x 10's & as per PRC |

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| | Approval status of product in Reference Regulatory Authorities | Sterile water for injection of M/s Pfizer Limited MHRA Approved) |
| | Me-too status | Water for injection of M/s Epoch Pharmaceuticals (Reg.#047128) |
| | GMP status | Last GMP inspection was conducted on 23-07-2018 and report concludes an acceptable level of GMP compliance. |
| | Remarks of the Evaluator | Firm has liquid injectable (vial, ampoule and infusion) section as mentioned in the section approval letter. |
| | **Decision:Approved** | |
| 338. | Name and address of manufacturer / Applicant | M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi. |
| | Brand Name +Dosage Form + Strength | Water for injection 4ml |
| | Composition | Each 4ml ampoule contains:<br>Water for injection …..4ml |
| | Diary No. Date of R& I & fee | Dy. No.226; 02-01-2018; Rs.20,000/- (02-01-2018) |
| | Pharmacological Group | Diluent / Solvent for reconstitution |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 4ml ampoule x 5's ; 4ml ampoule x 10's & as per PRC |
| | Approval status of product in Reference Regulatory Authorities | Sterile water for injection of M/s Pfizer Limited (MHRA Approved) |
| | Me-too status | Sterile water for injection 4ml of M/s Healthtek, Karachi (Reg. # 079940) |
| | GMP status | Last GMP inspection was conducted on 23-07-2018 and report concludes an acceptable level of GMP compliance. |
| | Remarks of the Evaluator | Firm has liquid injectable (vial, ampoule and infusion) section as mentioned in the section approval letter. |
| | **Decision:Approved** | |
| 339. | Name and address of manufacturer / Applicant | M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi. |
| | Brand Name +Dosage Form + Strength | Levarol inhalation solution 0.63mg |
| | Composition | Each ml contains:<br>Levalbuterol as HCl……0.63mg |
| | Diary No. Date of R& I & fee | Dy. No.229; 02-01-2018; Rs.20,000/- (02-01-2018) |
| | Pharmacological Group | Beta-2 Agonist |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | 3ml, 5ml, 10ml & as per PRC |
| | Approval status of product in Reference Regulatory Authorities | Xopenex inhalation solution 0.63mg, 0.021% (3ml) of M/s Oak Pharms Inc. (USFDA Approved) |
| | Me-too status | Could not be confirmed |
| | GMP status | Last GMP inspection was conducted on 23-07-2018 and report concludes an acceptable level of GMP compliance. |
| | Remarks of the Evaluator | • Firm has Inhaler section as mentioned in the section approval letter.<br>• Firm has applied three volumes i.e. 3ml, 5ml and 10ml while only 3ml is approved in USFDA.<br>• Stability is required for the applied formulation so firm needs to resubmit the application on Form-5D with submission of additional fees and stability studies data as per decision of 276th meeting. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of required manufacturing facility for applied formulation.**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith 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 278th meeting of Registration Board.**<br>• **Selection of one fill volume only.** | |

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| 340. | Name and address of manufacturer / Applicant | M/s Genix Pharma Pvt. Limited, 44, 45-B, Korangi Creek Road, Karachi. |
| | Brand Name +Dosage Form + Strength | Levarol inhalation solution 1.25mg |
| | Composition | Each ml contains:<br>Levalbuterol as HCl……1.25mg |
| | Diary No. Date of R& I & fee | Dy. No.228; 02-01-2018; Rs.20,000/- (02-01-2018) |
| | Pharmacological Group | Beta-2 Agonist |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | 3ml, 5ml, 10ml & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Xopenex inhalation solution 1.25mg, 0.042% (3ml) of M/s Oak Pharms Inc. (USFDA Approved) |
| | Me-too status | Could not be confirmed |
| | GMP status | Last GMP inspection was conducted on 23-07-2018 and the report concludes an acceptable level of GMP compliance. |
| | Remarks of the Evaluator | • Firm has Inhaler section as mentioned in the section approval letter.<br>• Firm has applied three volumes i.e. 3ml, 5ml and 10ml while only 3ml is approved in USFDA.<br>• Stability is required for the applied formulation so firm needs to resubmit the application on Form-5D with submission of additional fees and stability studies data as per decision of 276th meeting. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of required manufacturing facility for applied formulation.**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith 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 278th meeting of Registration Board.**<br>• **Selection of one fill volume of only.** | |
| 341. | Name and address of manufacturer / Applicant | M/s Unexolabs (Pvt.) Limited, 9.5 km Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Cefdrox capsule 500mg |
| | Composition | Each capsule contains:<br>Cefadroxil (as Monohydrate)…….500mg |
| | Diary No. Date of R& I & fee | Dy.No.454; 04-01-2018;Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | First Generation Cephalosporin |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 3x 4's & not claimed |
| | Approval status of product in Reference Regulatory Authorities | Cefadroxil 500mg capsules of M/s Sandoz Limited, UK (MHRA Approved) |
| | Me-too status | Duricef 500mg capsule of M/s Bristol Myer, Karachi (Reg.# 008013) |
| | GMP status | Last GMP inspection was conducted on 20-04-2016 and the report concludes:<br>"Firm has shown positive approach towards compliance of GMP and advices were given for further up-gradation." |
| | Remarks of the Evaluator [XIII] | • Firm has General Capsule section as mentioned in the GMP inspection report.<br>• The official monograph of the applied formulation is available in USP.<br>• Submitted GMP report does not show compliant status. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 342. | Name and address of manufacturer / Applicant | M/s Unexolabs (Pvt.) Limited, 9.5 km Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Pregalin capsule 50mg |

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| | Composition | Each capsule contains:<br>Pregabalin ……50mg |
| | Diary No. Date of R& I & fee | Dy.No.458; 04-01-2018;Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | Anti- epileptic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 14's & not claimed |
| | Approval status of product in Reference Regulatory Authorities | Axalid 50mg hard capsule of M/s Kent Pharmaceuticals, Limited (MHRA Approved) |
| | Me-too status | Gabica 50 mg capsule of M/s Getz Pharma, Karachi (Reg. # 048725) |
| | GMP status | Last GMP inspection was conducted on 20-04-2016 and the report concludes:<br>"Firm has shown positive approach towards compliance of GMP and advices were given for further up-gradation." |
| | Remarks of the Evaluator [XIII] | • Firm has General Capsule section as mentioned in the GMP inspection report.<br>• No official monograph of the applied formulation is available in USP, BP, IP or JP.<br>• Submitted GMP report does not show compliant status. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 343. | Name and address of manufacturer / Applicant | M/s Unexolabs (Pvt.) Limited, 9.5 km Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Pregalin-75 capsule |
| | Composition | Each capsule contains:<br>Pregabalin ……75mg |
| | Diary No. Date of R& I & fee | Dy.No.457; 04-01-2018;Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | Anti- epileptic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 14's & not claimed |
| | Approval status of product in Reference Regulatory Authorities | Axalid 75mg hard capsule of M/s Kent Pharmaceuticals, Limited (MHRA Approved) |
| | Me-too status | Gabica 75 mg capsule of M/s Getz Pharma, Karachi (Reg.#047365) |
| | GMP status | Last GMP inspection was conducted on 20-04-2016 and the report concludes:<br>"Firm has shown positive approach towards compliance of GMP and advices were given for further up-gradation." |
| | Remarks of the Evaluator [XIII] | • Firm has General Capsule section as mentioned in the GMP inspection report.<br>• No official monograph of the applied formulation is available in USP, BP, IP or JP.<br>• Submitted GMP report does not show compliant status. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 344. | Name and address of manufacturer / Applicant | M/s Unexolabs (Pvt.) Limited, 9.5 km Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Pregalin-100 capsule |
| | Composition | Each capsule contains:<br>Pregabalin ……100mg |
| | Diary No. Date of R& I & fee | Dy.No.456; 04-01-2018;Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | Anti- epileptic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 2x 7's & not claimed |

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| | Approval status of product in Reference Regulatory Authorities | Axalid 100mg hard capsule of M/s Kent Pharmaceuticals, Limited (MHRA Approved) |
| | Me-too status | Gabica 100 mg capsule of M/s Getz Pharma, Karachi (Reg. # 047366) |
| | GMP status | Last GMP inspection was conducted on 20-04-2016 and the report concludes:<br>"Firm has shown positive approach towards compliance of GMP and advices were given for further up-gradation." |
| | Remarks of the Evaluator [XIII] | • Firm has General Capsule section as mentioned in the GMP inspection report.<br>• No official monograph of the applied formulation is available in USP, BP, IP or JP.<br>• Submitted GMP report does not show compliant status. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 345. | Name and address of manufacturer / Applicant | M/s Unexolabs (Pvt.) Limited, 9.5 km Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Pregalin-150 capsule |
| | Composition | Each capsule contains:<br>Pregabalin ……150mg |
| | Diary No. Date of R& I & fee | Dy.No.459; 04-01-2018;Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | Anti- epileptic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 2x 7's & not claimed |
| | Approval status of product in Reference Regulatory Authorities | Axalid 150mg hard capsule of M/s Kent Pharmaceuticals, Limited (MHRA Approved) |
| | Me-too status | Gabica 150 mg capsule of M/s Getz Pharma, Karachi (Reg. # 048724) |
| | GMP status | Last GMP inspection was conducted on 20-04-2016 and the report concludes:<br>"Firm has shown positive approach towards compliance of GMP and advices were given for further up-gradation." |
| | Remarks of the Evaluator [XIII] | • Firm has General Capsule section as mentioned in the GMP inspection report.<br>• No official monograph of the applied formulation is available in USP, BP, IP or JP.<br>• Submitted GMP report does not show compliant status. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 346. | Name and address of manufacturer / Applicant | M/s Unexolabs (Pvt.) Limited, 9.5 km Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Torvastin-20 tablet (20mg) |
| | Composition | Each film-coated tablet contains:<br>Atorvastatin as Calcium Trihydrate ……..20mg |
| | Diary No. Date of R& I & fee | Dy.No.455; 04-01-2018; Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | HMG CoA Reductase Inhibitor |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 1x 10's & not claimed |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Atorlip 20mg tablet of M/s Pearl Pharma (Reg. # 034931 ) |
| | GMP status | Last GMP inspection was conducted on 20-04-2016 and the report concludes:<br>"Firm has shown positive approach towards compliance of GMP and advices were given for further up-gradation." |
| | Remarks of the Evaluator [XIII] | • Firm has General tablet section as mentioned in the GMP inspection report. |

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| | | • No official monograph of the applied formulation is available in USP, BP, IP or JP.<br>• Submitted GMP report does not show compliant status. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 347. | Name and address of manufacturer / Applicant | M/s Zaynoon Pharmaceuticals Pvt Limited.<br>27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Nafpol Drops 100mg/ml |
| | Composition | Each ml contains:<br>Paracetamol…….100mg |
| | Diary No. Date of R& I & fee | Dy. No 860; 05-01-2018; Rs.20,000/- (05-01-2018) |
| | Pharmacological Group | Analgesic / Antipyretic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 60ml & Rs. 20/- |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Chilpol drops 100mg/ml of M/s Alliance Pharma (Reg. # 068435) |
| | GMP status | Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • The international availability for the applied formulation could not be confirmed.<br>• Drops are applied in amber glass bottle.<br>• Firm has only one approved section i.e. "Oral liquid" as mentioned in the submitted GMP report. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 348. | Name and address of manufacturer / Applicant | M/s Zaynoon Pharmaceuticals Pvt. Limited,<br>27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Nafpol total suspension 120mg + 1mg/ 5ml |
| | Composition | Each 5ml contains:<br>Paracetamol (Micronised)……..120mg<br>Chlorpheniramine Maleate……1mg |
| | Diary No. Date of R& I & fee | Dy. No 859; 05-01-2018; Rs.20,000/- (05-01-2018) |
| | Pharmacological Group | Analgesic / Anti-pyretic/Anti-histamine |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 60ml & Rs. 35/- |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Pedrol Total suspension of M/s Stanley Pharma<br>(Reg. # 026268) |
| | GMP status | Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has only one approved section i.e. "Oral liquid" as mentioned in the submitted GMP report.<br>• Applied in amber glass bottle.<br>• The international availability for the applied formulation could not be confirmed. |
| | Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting | |
| 349. | Name and address of manufacturer / Applicant | M/s Zaynoon Pharmaceuticals Pvt. Limited,<br>27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Zaycon drops (Oral suspension) 40mg/ ml (30ml) |
| | Composition | Each ml contains:<br>Simethicone ……40mg |
| | Diary No. Date of R& I & fee | Dy. No 861; 05-01-2018; Rs.20,000/- (05-01-2018) |

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| | Pharmacological Group | Anti- flatulent |
| | Type of Form | Form-5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 120ml & Rs. 25/- |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Minicol 40mg/ml Oral Drops by M/s Libra (Reg. # 036627) |
| | GMP status | Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Applied in amber glass bottle.<br>• The official monograph for the applied formulation is available in USP.<br>• Firm has oral liquid section as mentioned in the GMP inspection report.<br>• The international availability for the applied formulation could not be confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 350. | Name and address of manufacturer / Applicant | M/s Zaynoon Pharmaceuticals Pvt. Limited,<br>27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | P- Barbit Elixir 20mg/ 5ml |
| | Composition | Each 5ml contains:<br>Phenobarbital ……...20mg |
| | Diary No. Date of R& I & fee | Dy. No 858; 05-01-2018; Rs.20,000/- (05-01-2018) |
| | Pharmacological Group | Anti- convulsant/ Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 60ml, 120ml & Rs. 24/- for 60ml ; Rs. 40/- for 120ml |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed in the applied strength (Available strengths are 15mg/ ml in MHRA and TGA, Australia) |
| | Me-too status | Debritone 20mg/ 5ml Elixir of M/s Xenon Pharma |
| | GMP status | Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • The official monograph for the applied formulation is not available in USP, BP, IP or JP.<br>• International reference could not be confirmed in the applied strength. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of required manufacturing facility i.e., "Oral Liquid section (Psychotropic)" from Central Licensing Board.**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 351. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt.) Limited, L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Nitox tablet 500mg |
| | Composition | Each film- coated tablet contains:<br>Nitazoxanide…….500mg |
| | Diary No. Date of R& I & fee | Dy.No.326;03-01-2018; Rs.20,000/- (20-11-2017) |
| | Pharmacological Group | Broad spectrum Anti-parasitic Thiazolide |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10's, 20's, 30's & Rs. 50/-per tablet |
| | Approval status of product in Reference Regulatory Authorities | Alinia 500mg film- coated tablet of M/s Romark Pharmaceuticals (USFDA Approved) |
| | Me-too status | Nitazide 500mg tablet of M/s Helix Pharma<br>(Reg. # 075908) |
| | GMP status | Last GMP inspection was conducted on 24-04-2018 and report concludes satisfactory level of GMP compliance. |

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| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• No official monograph is available in USP, BP, IP or JP for the applied formulation. |
| | **Decision: Approved with innovator's specification.** | |
| 352. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt.) Limited, L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Levit tablet 250mg |
| | Composition | Each film- coated tablet contains:<br>Levetiracetam ……..250mg |
| | Diary No. Date of R& I & fee | Dy.No.330;03-01-2018; Rs.20,000/- (06-12-2017) |
| | Pharmacological Group | Pyrrolidone derivative (Anti-epileptic) |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10's, 30's & Rs. 100/- per tablet |
| | Approval status of product in Reference Regulatory Authorities | Keppra 250mg film-coated tablet of M/s UCB Pharma Limited (MHRA Approved) |
| | Me-too status | Keppra tablet 250mg of M/s AGP Pharma (Reg. # 045684) |
| | GMP status | Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved with USP specification.** | |
| 353. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt.) Limited, L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Levit tablet 500mg |
| | Composition | Each film- coated tablet contains:<br>Levetiracetam ……..500mg |
| | Diary No. Date of R& I & fee | Dy.No.327;03-01-2018; Rs.20,000/- (06-12-2017) |
| | Pharmacological Group | Pyrrolidone derivative (Anti-epileptic) |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 10's, 30's & Rs. 100/- per tablet |
| | Approval status of product in Reference Regulatory Authorities | Keppra 500mg film-coated tablet of M/s UCB Pharma Limited (MHRA Approved) |
| | Me-too status | Keppra tablet 500mg of M/s AGP Pharma (Reg. # 045685) |
| | GMP status | Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved with USP specification.** | |
| 354. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt.) Limited, L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Levit tablet 750mg |
| | Composition | Each film- coated tablet contains:<br>Levetiracetam ……..750mg |
| | Diary No. Date of R& I & fee | Dy.No.328;03-01-2018; Rs.20,000/- (06-12-2017) |
| | Pharmacological Group | Pyrrolidone derivative (Anti-epileptic) |
| | Type of Form | Form- 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's & Rs. 100/- per tablet |
| | Approval status of product in Reference Regulatory Authorities | Keppra 750mg film-coated tablet of M/s UCB Pharma Limited (MHRA Approved) |
| | Me-too status | Lumark 750mg tablet of M/s Searle Pharma (Reg.# 069065) |

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| | GMP status | Last GMP inspection was conducted on 24-04-2018 and report concludes satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved.** | |
| 355. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt.) Limited, L-10-D Block-21 Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Levit oral solution 100mg/ ml |
| | Composition | Each ml contains:<br>Levetiracetam ……..…..100mg |
| | Diary No. Date of R& I & fee | Dy.No.329;03-01-2018; Rs.20,000/- (06-12-2017) |
| | Pharmacological Group | Pyrrolidone derivative (Anti-epileptic) |
| | Type of Form | Form- 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 30ml, 60ml, 90ml, 120ml & Rs. 200/-, Rs. 400/-Rs.550/-, Rs. 850/-per bottle respectively |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Tamlev 100mg/ ml oral solution of M/s Medisure (Reg. # 081613) |
| | GMP status | Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has Liquid Syrup section as mentioned in the submitted GMP report.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved.** | |
| 356. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Limited, 45 km, Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | Rismed tablet 1mg |
| | Composition | Each film-coated tablet contains:<br>Risperidone ……..…..1mg |
| | Diary No. Date of R& I & fee | Dy.No.25934;26-12-2017;Rs.20,000/-(21-12-2017) |
| | Pharmacological Group | Antipsychotic |
| | Type of Form | Form -5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10’s, 18’s, 20’s, 30’s, 50’s & As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Benzisox of M/s Highnoon Laboratories |
| | GMP status | Last GMP inspection was conducted on 10-10-2017 & report concludes renewal of DML and grant of additional sections. |
| | Remarks of the Evaluator [XIII] | Firm has General Tablet section as is mentioned in the GMP inspection report. |
| | **Decision: Approved.** | |
| 357. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Limited, 45 km, Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | C- Pine tablet 25mg |
| | Composition | Each film-coated tablet contains:<br>Clozapine……..…..25mg |
| | Diary No. Date of R& I & fee | Dy.No.25919;26-12-2017;Rs.20,000/-(21-12-2017) |
| | Pharmacological Group | Antipsychotic |
| | Type of Form | Form -5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14’s, 30’s, 50’s & as per DRAP policy |

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| | Approval status of product in Reference Regulatory Authorities | Approved as uncoated in USFDA and MHRA |
| | Me-too status | Clozaril tablet 25mg of M/s Novartis Pharma |
| | GMP status | Last GMP inspection was conducted on 10-10-2017 and the report concludes renewal of DML and grant of additional sections. |
| | Remarks of the Evaluator [XIII] | • Firm has applied the formulation as film-coated tablet while it is approved as uncoated in USFDA and MHRA.<br>• Firm has General Tablet section as is mentioned in the GMP inspection report. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug uncoaed tablet, while the applied drug is fim coated tablet** | |
| 358. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Limited, 45 km, Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | ET- Oxine capsule 50mg |
| | Composition | Each capsule contains:<br>Etifoxine HCl..……50mg |
| | Diary No. Date of R& I & fee | Dy.No.25919;26-12-2017;Rs.20,000/-(21-12-2017) |
| | Pharmacological Group | Anxiolytic |
| | Type of Form | Form -5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 12's, 24's & As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | ANSM (France) Approved |
| | Me-too status | Stresam capsule 50mg of M/s CCL Pharma (Reg# 024595) |
| | GMP status | Last GMP inspection was conducted on 10-10-2017 and the report concludes renewal of DML and grant of additional sections. |
| | Remarks of the Evaluator [XIII] | The official monograph for the applied formulation is not available in USP or BP. |
| | **Decision: Approved with innovator's specification.** | |
| 359. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Limited, 45 km, Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | V- Fexin 37.5mg capsule |
| | Composition | Each capsule contains:<br>SR pellets of Venlafaxine HCl eq. to Venlafaxine ……....37.5mg |
| | Diary No. Date of R& I & fee | Dy.No.25954;26-12-2017;Rs.20,000/-(21-12-2017) |
| | Pharmacological Group | Anti- depressant |
| | Type of Form | Form -5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 14's, 20's & As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Faxine SR 37.5mg capsule of M/s Semos (Reg. # 055879) |
| | GMP status | Last GMP inspection was conducted on 10-10-2017 and the report concludes renewal of DML and grant of additional sections. |
| | Remarks of the Evaluator [XIII] | • Source of pellets is M/s Vision Pharma.<br>• Firm has submitted data of pellets including stability data, CoA of manufacturer. |
| | **Decision:Approved** | |
| 360. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Limited, 45 km, Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | V- Fexin 75mg capsule |
| | Composition | Each capsule contains:<br>SR pellets of Venlafaxine HCl eq. to Venlafaxine …..75mg |
| | Diary No. Date of R& I & fee | Dy.No.25955;26-12-2017;Rs.20,000/-(21-12-2017) |

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| | Pharmacological Group | Anti- depressant |
| | Type of Form | Form -5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 14's, 20's & As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Faxine 75mg capsule of M/s Semos(Reg.# 055878) |
| | GMP status | Last GMP inspection was conducted on 10-10-2017 & report concludes renewal of DML and grant of additional sections. |
| | Remarks of the Evaluator [XIII] | • Source of pellets is M/s Vision Pharma.<br>• Firm has submitted data of pellets including stability data, CoA of manufacturer. |
| | **Decision:Approved** | |
| 361. | Name and address of manufacturer / Applicant | M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Low-lip 10mg tablet |
| | Composition | Each film-coated tablet contains:<br>Rosuvastatin as Calcium…10mg |
| | Diary No. Date of R& I & fee | Dy.No.26688; 29-12-2017;Rs.20,000/-(29-12-2017) |
| | Pharmacological Group | Selective competitive inhibitor of HMG-CoA reductase Inhibitor (Statins) |
| | Type of Form | Form- 5 |
| | Finished product Specification | Innovator's |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Rovista 10mg tablet of M/s Getz Pharma (Reg.# 044044) |
| | GMP status | Last GMP inspection was conducted on 30-09-2018 & 29-10-2018 and the report concludes that firm is GMP compliant with need of some improvements and the panel recommends grant of GMP certificate. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with change of brand name & with Innovators specifications** | |
| 362. | Name and address of manufacturer / Applicant | M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industioral Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Low- lip 20mg tablet |
| | Composition | Each film-coated tablet contains:<br>Rosuvastatin as Calcium…20mg |
| | Diary No. Date of R& I & fee | Dy.No.26689; 29-12-2017;Rs.20,000/-(28-12-2017) |
| | Pharmacological Group | Selective competitive inhibitor of HMG-CoA reductase Inhibitor (Statins) |
| | Type of Form | Form- 5 |
| | Finished product Specification | Innovator's |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Rovista 20mg tablet of M/s Getz Pharma (Reg.# 044045) |
| | GMP status | Last GMP inspection was conducted on 30-09-2018 & 29-10-2018 and the report concludes that firm is GMP compliant with need of some improvements and the panel recommends grant of GMP certificate. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with change of brand name & with Innovators specifications** | |
| 363. | Name and address of manufacturer / Applicant | M/s Star Laboratories (Pvt.) Ltd. 23 kilometer, Multan road, Lahore |
| | Brand Name +Dosage Form + Strength | Montel Paediatric Sachet 4mg |
| | Composition | Each sachet contains:<br>Montelukast as Sodium…4 mg |
| | Diary No. Date of R& I & fee | Dy. No. 463;27-01-2014; Rs.20,000/- (27-01-2014) |

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| | Pharmacological Group | Leukotriene Receptor Antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovators |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Montiwel 4mg Sachet of M/s Welwrd Pharmaceuticals (Reg. # 075518) |
| | GMP status | Last GMP inspection was conducted on 27-10-2016 and GMP certificate is provided for export purpose. |
| | Remarks of the Evaluator [XIII] | • Firm has Oral Dry Powder Sachet section as mentioned in the section approval letter.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved with USP specifications** | |
| 364. | Name and address of manufacturer / Applicant | M/s Ameer & Adnan Pharmaceuticals (Pvt.) Limited, Plot # 47, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Adcipro Infusion 500mg |
| | Composition | Each 100ml injectable solution contains:<br>Ciprofloxacin as Lactate……..200mg |
| | Diary No. Date of R& I & fee | Dy. No. 285;06-02-2017; Rs.20,000/- (06-02-2017) |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Cipgreen Infusion 200mg/ 100ml of M/s Evergreen Pharmaceuticals (Reg. # 062617) |
| | GMP status | Last GMP inspection was conducted on 05-01-2018 and the report concludes the firm to be GMP compliant. |
| | Remarks of the Evaluator [XIII] | • The case was previously deferred in 281st meeting wherein Board referred the case to Licensing Division for confirmation of manufacturing facility. Now the firm has submitted copy of letter (letter no. G.1-58/2004-Lic) dated 11-02-2014, wherein DML has been issued for various sections including "Liquid injectable general SVPs (a) Ampoule, (b) Vial/Infusion." |
| | **Decision: Approved.** | |
| 365. | Name and address of manufacturer / Applicant | M/s Inventor Pharma, Plot # K/196, S.I.T.E., (SHW) Phase – II, Karachi. |
| | Brand Name +Dosage Form + Strength | Lactol syrup 3.35gm/ 5ml |
| | Composition | Each 5ml contains:<br>Lactitol Monohydrate…….3.35gm |
| | Diary No. Date of R& I & fee | Dy. No. 25410; 21-12-2017; Rs.1,00,000/- (21-12-2017) |
| | Pharmacological Group | To treat constipation and chronic encephalopathy |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 120ml & As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | Lactitol Monohydrate by M/s Zambon Schweiz AG (Swiss Medica) Switzerland Approved |
| | Me-too status | Lacasil syrup 3.35gm/ 5ml of Sami Pharmaceuticals (Reg. # 070552) |
| | GMP status | Last GMP inspection was conducted on 05-07-2018 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator | • Evidence of availability of RI detector needs to be confirmed by the firm.<br>• Source of lactitol, along with stability studies data, GMP certificate of supplier needs to be submitted.<br>• Firm has oral Liquid General section.<br>• Letter was issued to the firm on 3rd Dec., 2018 but still |

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| | | no reply has been received. |
| | **Decision: Deferred for following:**<br>• **Evidence of availability of RI detector is needed**<br>• **Source of lactitol, along with stability studies data, GMP certificate of supplier needs to be submitted.** | |
| 366. | Name and address of manufacturer / Applicant | M/s Saibins Pharmaceuticals, Plot # 316, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Lonofast tablet 4mg |
| | Composition | Each film-coated tablet contains:<br>Lornoxicam…….....4mg |
| | Diary No. Date of R& I & fee | Dy.No.431;21-03-2016; Rs.20,000/- (18-03-2016) |
| | Pharmacological Group | NSAIDs |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 1x 10's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved) |
| | Me-too status | Nicam Tablets of M/s S.J & G Fazul Ellahie (Pvt.) Ltd, (Reg. # 061603) |
| | GMP status | Last GMP inspection was conducted on 26-07-2018 & 28-12-2018 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | • No USP or BP monograph is available for the applied formulation.<br>• Letter was issued to the firm on 29th Jan., 2019 but the firm has not replied yet.<br>• The formulation is applied as film-coated while film-coating is not mentioned in the master formulation.<br>• 3% overage is applied. |
| | **Decision: Deferred for revision of formulation and justification of overage.** | |
| 367. | Name and address of manufacturer / Applicant | M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura<br>**Contract Manufacturer:** M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Gezole injection I/V 40mg |
| | Composition | Each vial contains:<br>Omeprazole as Sodium (lyophilised)…….40mg |
| | Diary No. Date of R& I & fee | Dy. No.16472; 04-05-2018; Rs.50,000/- DUPLICATE (13-10-2014) |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 1's & Rs. 300/- per vial |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | OmepMine 40mg injection of M/s Lawari International (Reg. # 069704) |
| | GMP status | Applicant:<br>Grant of additional section dated 08-05-2018.<br>Manufacturer:<br>The firm was granted GMP certificate based on inspection dated 16-01-2018. |

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| | Remarks of the Evaluator [XIII] | • Firm showed yellow copy of fee- challan as an evidence of fees paid.<br>• Lyophilized injection section of manufacturer needs confirmation.<br>• Firm has 12 already registered drugs on Contract and 08 approved sections.<br>• No USP or BP monograph is available for the applied formulation. |
| | **Decision: The Board was apprised regarding the panel inspection report of M/s English Pharmaceutical Industries, Lahore conducted on 18-01-2019, in response to letter no. F.3-9/2018 Reg-II (M-286) (Misc.), for the purpose of assesment and confirmation of manufacturing capacity for contract manufacturing of Omeprazole dry powder Injection wherein the panel of inspectors has reported as under:**<br>• **As per record the firm has manufactured 16 batches of different products to a total number of 127,490 vials during year 2018 with an average production of 1499 vials per day. Hence utilized capacity of the firm was about 4%.**<br>• **Firm has provided necessary equipment for carrying out the required QC testing of the products.**<br>**Considering the aforementioned obseravtions the Board approved above product of M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura for contract manufacturing by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 368. | Name and address of manufacturer / Applicant | M/s Basel Pharmaceuticals, 227-Phase II, Multan Industrial Estate, Multan **Contract Manufacturer:** M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | B- zole injection I/V 40mg |
| | Composition | Each vial contains:<br>Omeprazole as Sodium (lyophilised)…….40mg |
| | Diary No. Date of R& I & fee | Dy. No.115; 09-09-2013; Rs.50,000/- (09-09-2013) |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 1x 1's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | OmepMine 40mg injection of M/s Lawari International (Reg. # 069704) |
| | GMP status | Applicant: 27-10-2016 and the status from QA shows "reply FID to send case to CLB".<br>Manufacturer: The firm was granted GMP certificate based on inspection dated 16-01-2018. |
| | Remarks of the Evaluator [XIII] | • Firm showed yellow copy of fee- challan as an evidence of fees paid.<br>• Lyophilized injection section of manufacturer needs confirmation.<br>• Already registered drugs on Contract and approved sections need to be confirmed by the firm.<br>• No USP or BP monograph is available for the applied formulation.<br>• GMP status of the applicant needs confirmation.<br>• Letter was issued to the firm on 30th January, 2019 but the firm has not replied yet. |
| | **Decision: The Board was apprised regarding the panel inspection report of M/s English Pharmaceutical Industries, Lahore conducted on 18-01-2019, in response to letter no. F.3-9/2018 Reg-II (M-286) (Misc.), for the purpose of assesment and confirmation of manufacturing capacity** | |

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| | **for contract manufacturing of Omeprazole dry powder Injection wherein the panel of inspectors has reported as under:**<br>• **As per record the firm has manufactured 16 batches of different products to a total number of 127,490 vials during year 2018 with an average production of 1499 vials per day. Hence utilized capacity of the firm was about 4%.**<br>• **Firm has provided necessary equipment for carrying out the required QC testing of the products.**<br>**Considering the aforementioned obseravtions the Board approved above product of M/s Basel Pharmaceuticals, 227-Phase II, Multan Industrial Estate, Multan for contract manufacturing by M/s English Pharmaceutical Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 369. | Name and address of manufacturer / Applicant | M/s Biolabs (Pvt.) Limited, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Emtil tablet 250mg |
| | Composition | Each film-coated tablet contains:<br>Mycophenolate Mofetil…250mg |
| | Diary No. Date of R& I & fee | Dy.No.1632;16-02-2017; Rs.20,000/- (15-02-2017) |
| | Pharmacological Group | Immuno-supressant |
| | Type of Form | Form- 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 40's, 50's & as per PRC (MOH) |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed in the applied strength (available strength is 500mg) |
| | Me-too status | Linfonex 250mg tablet of M/s CCL Pharma (Reg. # 053874) |
| | GMP status | GMP certificate was granted based on inspection conducted on 05 & 06.12.2017. |
| | Remarks of the Evaluator [XIII] | • For the applied formulation, Registration Board asks manufacturer to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.<br>• Firm has General Tablet section as mentioned in the submitted GMP report.<br>• Could not be confirmed internationally in the applied strength (available strength is 500mg). |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 370. | Name and address of manufacturer / Applicant | M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industioral Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Febux tablet 80mg |
| | Composition | Each film-coated tablet contains:<br>Febuxostat ……..…..80mg |
| | Diary No. Date of R& I & fee | Dy.No.475; 04-01-2018;Rs.20,000/-(04-01-2018) |
| | Pharmacological Group | Xanthine Oxidase Inhibitor |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Febuxin 80mg tablet of M/s AGP Pharma (Reg. # 081105) |
| | GMP status | Last GMP inspection was conducted on 30-09-2018 & 29-10-2018 and the report concludes that firm is GMP compliant with need of some improvements and the panel recommends grant of GMP certificate. |
| | Remarks of the Evaluator | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• No USP or BP monograph is available for the applied formulation. |

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| | **Decision: Approved with innovator's specification.** | |
| 371. | Name and address of manufacturer / Applicant | M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Rimeta tablet 35mg |
| | Composition | Each modified-release film- coated tablet contains:<br>Trimetazidine dihydrochloride ……..……35mg |
| | Diary No. Date of R& I & fee | Dy.No.474; 04-01-2018;Rs.20,000/-(04-01-2018) |
| | Pharmacological Group | Anti- anginal |
| | Type of Form | Form- 5 |
| | Finished product Specification | In- house |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Trimetazidine 35mg, modified release film-coated tablet (ANSM approved) |
| | Me-too status | Trikat MR 35mg of Next Pharma (Reg.# 064849) |
| | GMP status | Last GMP inspection was conducted on 30-09-2018 & 29-10-2018 and the report concludes that firm is GMP compliant with need of some improvements and the panel recommends grant of GMP certificate. |
| | Remarks of the Evaluator | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• The official monograph for the applied formulation is available in JP. |
| | **Decision: Approved with innovator's specification.** | |
| 372. | Name and address of manufacturer / Applicant | M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Colside tablet 4mg |
| | Composition | Each film- coated tablet contains:<br>Thiocolchicoside ……..4mg |
| | Diary No. Date of R& I & fee | Dy.No.473; 04-01-2018;Rs.20,000/-(04-01-2018) |
| | Pharmacological Group | Muscle Relaxant |
| | Type of Form | Form- 5 |
| | Finished product Specification | In- house |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in ANSM (France) as uncoated tablet |
| | Me-too status | Wodnik 4mg tablet of M/s Martin Dow (Reg. # 081138) |
| | GMP status | Last GMP inspection was conducted on 30-09-2018 & 29-10-2018 and the report concludes that firm is GMP compliant with need of some improvements and the panel recommends grant of GMP certificate. |
| | Remarks of the Evaluator | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• Approved in ANSM (France) as uncoated tablet while is applied as film-coated. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film coated tablet.** | |
| 373. | Name and address of manufacturer / Applicant | M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Etorwen tablet 60mg |
| | Composition | Each film- coated tablet contains:<br>Etoricoxib ……..…60mg |
| | Diary No. Date of R& I & fee | Dy.No.472; 04-01-2018;Rs.20,000/-(04-01-2018) |
| | Pharmacological Group | NSAID |
| | Type of Form | Form- 5 |
| | Finished product Specification | In- house |
| | Pack size & Demanded Price | As per SRO & as per SRO |

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| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Etoria 60mg Table of M/s Hygeia Pharmaceuticals, (Reg.# 080818) |
| | GMP status | Last GMP inspection was conducted on 30-09-2018 & 29-10-2018 and the report concludes that firm is GMP compliant with need of some improvements and the panel recommends grant of GMP certificate. |
| | Remarks of the Evaluator | • Firm has General Tablet section as mentioned in the submitted GMP report.<br>• No USP or BP monograph is available for the applied formulation. |
| | **Decision: Approved with innovator's specification** | |
| 374. | Name and address of manufacturer / Applicant | M/s Fedro Pharmaceutical Labs (Pvt.) Limited, 149 Industrial Estate, Hayatabad, Peshawar |
| | Brand Name +Dosage Form + Strength | Rofyl Plus Syrup 45mg+8mg/ 5ml |
| | Composition | Each 5ml contains:<br>Acefylline Piperazine…….……..45mg<br>Diphenhydramine Hydrochloride……..…8mg |
| | Diary No. Date of R& I & fee | Dy. No.471; 04-01-2018; 20,000/-(04-01-2018) |
| | Pharmacological Group | Xanthine /Anti-histaminic agent |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's |
| | Pack size & Demanded Price | 60ml, 90ml & 120ml & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Acefyl Cough Syrup of M/s Nabi Qasim (Reg.# 023394 ) |
| | GMP status | Last GMP inspection was conducted on 03-03-2017 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | • The firm has General liquid section as is mentioned in the section approval letter.<br>• The approval status of the applied formulation in the reference regulatory authorities could not be confirmed.<br>• No USP or BP monograph is available for the applied formulation. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 375. | Name and address of manufacturer / Applicant | M/s Asian Continental (Pvt.) Ltd., D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Predot tablet 10mg |
| | Composition | Each film- coated tablet contains:<br>Domperidone as Maleate ….....10mg |
| | Diary No. Date of R& I & fee | Dy.No.469;04-01-2018; Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | Anti- emetic/ Anti- vertigo |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 3x 10's, 5x 10's &As per PRC |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Dompro tablets 10mg of M/s Unison Chemical Works (Reg. # 050154) |
| | GMP status | Last GMP inspection was conducted on 19-09-2017 and the report concludes good compliance. |
| | Remarks of the Evaluator [XIII] | • General tablet section as is mentioned in the GMP inspection report.<br>• The official monograph for the applied formulation is available in BP. |
| | **Decision: Approved with innovator's specification.** | |

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| 376. | Name and address of manufacturer / Applicant | M/s Asian Continental (Pvt.) Ltd., D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Acbedol tablet 37.5mg/ 325mg |
| | Composition | Each film-coated tablet contains:<br>Tramadol HCl…….37.5mg<br>Paracetamol……..... 325mg |
| | Diary No. Date of R& I & fee | Dy.No.94;01-01-2018; Rs.20,000/- (01-01-2018) |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form- 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1x 10's & as per PRC |
| | Approval status of product in Reference Regulatory Authorities | Tramacet 37.5mg/ 325mg film-coated tablet of M/s Grunenthal Limited (MHRA Approved) |
| | Me-too status | Tonoflex-P of M/s Sami Pharmaceuticals (Reg.# 067163) |
| | GMP status | Last GMP inspection was conducted on 19-09-2017 and the report concludes good compliance. |
| | Remarks of the Evaluator [XIII] | • General tablet section as is mentioned in the GMP inspection report. |
| | **Decision: Approved** | |
| 377. | Name and address of manufacturer / Applicant | M/s Asian Continental (Pvt.) Ltd., D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Ac- tidal capsule 50mg |
| | Composition | Each capsule contains:<br>Tramadol HCl.....50mg |
| | Diary No. Date of R& I & fee | Dy.No.97;01-01-2018; Rs.20,000/- (01-01-2018) |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 1x 10's & as per PRC |
| | Approval status of product in Reference Regulatory Authorities | Tramadol 50 mg capsules, hard by M/s Milpharm Limited (MHRA Approved) |
| | Me-too status | Tramal capsule 50mg by Impex Plus Karachi (Reg. # 010170) |
| | GMP status | Last GMP inspection was conducted on 19-09-2017 and the report concludes good compliance. |
| | Remarks of the Evaluator [XIII] | • General capsule section as is mentioned in the GMP inspection report.<br>• The official monograph for the applied formulation is available in BP. |
| | **Decision: Approved with innovator's specification.** | |
| 378. | Name and address of manufacturer / Applicant | M/s Semos Pharmaceuticals Pvt. Limited, Plot # 11, Sector 12-A, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Semolax tablet 5mg |
| | Composition | Each enteric-coated tablet contains:<br>Bisacodyl ……....5mg |
| | Diary No. Date of R& I & fee | Dy.No.7569;28-02-2018; Rs.20,000/- (28-02-2018) |
| | Pharmacological Group | Laxative |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 20's, 60's, 100's, 500's, 1000's & as per PAC |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Bisacodyl tablet 5mg of M/s Ferozesons Pharma (Reg. # 002878) |
| | GMP status | Last GMP inspection was conducted on 04-07-2018 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the section approval letter. |

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| | | • The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved with innovator's specification.** | |
| 379. | Name and address of manufacturer / Applicant | M/s Semos Pharmaceuticals Pvt. Limited, Plot # 11, Sector 12-A, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Oxetine CR tablet 25mg |
| | Composition | Each enteric- coated controlled–release tablet contains: Paroxetine as Hydrochloride……25mg |
| | Diary No. Date of R& I & fee | Dy.No.7568;28-02-2018; Rs.20,000/- (28-02-2018) |
| | Pharmacological Group | SSRI |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10's, 15's, 20's, 30's & as per PAC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | Paroxin CR tablet 25mg of Shrooq Pharma (Reg.# 060470) |
| | GMP status | Last GMP inspection was conducted on 04-07-2018 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the section approval letter.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Deferred for revision of applied dosage form in as per reference product which is approved as "enteric, film-coated, controlled-release tablet", along with requisite fee for change of formulation.** | |
| 380. | Name and address of manufacturer / Applicant | M/s Semos Pharmaceuticals Pvt. Limited, Plot # 11, Sector 12-A, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Oxetine CR tablet 12.5mg |
| | Composition | Each enteric- coated controlled –release tablet contains: Paroxetine as Hydrochloride……12.5mg |
| | Diary No. Date of R& I & fee | Dy.No.7567;28-02-2018; Rs.20,000/- (28-02-2018) |
| | Pharmacological Group | SSRI |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10's, 15's, 20's, 30's & as per PAC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | Paroxin CR tablet 12.5mg of Shrooq Pharma (Reg. # 060471) |
| | GMP status | Last GMP inspection was conducted on 04-07-2018 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the section approval letter.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Deferred for revision of applied dosage form in as per reference product which is approved as "enteric, film-coated, controlled-release tablet", along with requisite fee for change of formulation.** | |
| 381. | Name and address of manufacturer / Applicant | M/s Semos Pharmaceuticals Pvt. Limited, Plot # 11, Sector 12-A, North Karachi Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Oxetine CR tablet 37.5mg |
| | Composition | Each enteric- coated controlled –release tablet contains: Paroxetine as Hydrochloride……37.5mg |
| | Diary No. Date of R& I & fee | Dy.No.7566;28-02-2018; Rs.20,000/- (28-02-2018) |
| | Pharmacological Group | SSRI |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10's, 20's, 30's & as per PAC |

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| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | Deroxat CR 37.5mg tablets of M/s Global Pharma (Reg. # 069948) |
| | GMP status | Last GMP inspection was conducted on 04-07-2018 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the section approval letter.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Deferred for revision of applied dosage form in as per reference product which is approved as "enteric, film-coated, controlled-release tablet", along with requisite fee for change of formulation.** | |
| 382. | Name and address of manufacturer / Applicant | M/s Wilson's Pharmaceuticals, 387- 388, I-9 Industrial Area, Islamabad. |
| | Brand Name +Dosage Form + Strength | Talergin EB Syrup |
| | Composition | Each ml contains:<br>Ebastine ….....5mg |
| | Diary No. Date of R& I & fee | Dy.No.2179;26-02-2018; Rs.20,000/- (26-02-2018) |
| | Pharmacological Group | Anti- histamine |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 30ml & 60ml / bottle & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Fystine Liquid Syrup of M/s Fynk Pharma<br>(Reg. # 077173) |
| | GMP status | Last GMP inspection was conducted on 24-01-2018 and the report concludes very good level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has Oral Liquid General Section as mentioned in the GMP inspection report.<br>• No USP, BP or JP monograph is available for the applied formulation.<br>• Internationally, applied formulation could not be confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 383. | Name and address of manufacturer / Applicant | M/s Asian Continental (Pvt.) Ltd., D/32, S.I.T.E. Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Lorin- P tablet |
| | Composition | Each extended- release tablet contains:<br>Loratadine……5mg<br>Pseudoephedrine Sulphate…...120mg |
| | Diary No. Date of R& I & fee | Dy.No.7390;27-02-2018; Rs.20,000/- (26-02-2018) |
| | Pharmacological Group | Anti- histamine/ Sympathomimetic (Nasal Decongestants) |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 1x 10's, 3x 10's & as per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | Could not be confirmed as extended- release tablet |
| | GMP status | Last GMP inspection was conducted on 19-09-2017 and the report concludes good compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General tablet section as mentioned in the GMP inspection report.<br>• No USP or BP monograph is available for applied formulation. |

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| | | • Me- too could not be confirmed as extended- release tablet. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 384. | Name and address of manufacturer / Applicant | M/s Aspin Pharma (Pvt.) Limited, Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Obglyza tablet 2.5mg |
| | Composition | Each film- coated tablet contains:<br>Saxagliptin as Hydrochloride …..2.5mg |
| | Diary No. Date of R& I & fee | Dy.No.7393;27-02-2018; Rs.20,000/- (27-02-2018) |
| | Pharmacological Group | Anti- diabetic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 7's, 10's, 14's, 30's & as per DPC |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Saxagen tablet 2.5mg of M/s Genix Pharma (Reg#076644) |
| | GMP status | Last GMP inspection was conducted on 18-08-2017 and the report concludes satisfactory compliance. |
| | Remarks of the Evaluator [XIII] | • No USP or BP monograph is available for the applied formulation.<br>• Firm has General Tablet Section as mentioned in the GMP inspection report. |
| | **Decision: Registration Board was apprised with reference to EMA Publis assessment report that Saxagliptin is prone to undergo an intra-molecular cyclisation reaction in solution & solid states to form a cyclic amidine. The tablet formulation was developed using active an active coating process to minimize this formation. Saxagliptin was embedded within a film coat of Opadry spray coated onto inert core tablets. During the coating process, Saxagliptin free base is converted in-situ into hydrochloride salt.**<br>**Considering the above facts Registration Board deferred the case for clarification to avoid cyclisation process.** | |
| 385. | Name and address of manufacturer / Applicant | M/s Aspin Pharma (Pvt.) Limited, Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Obglyza tablet 5mg |
| | Composition | Each film- coated tablet contains:<br>Saxagliptin as Hydrochloride …..5mg |
| | Diary No. Date of R& I & fee | Dy.No.7394;27-02-2018; Rs.20,000/- (27-02-2018) |
| | Pharmacological Group | Anti- diabetic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 7's, 10's, 14's, 30's & as per DPC |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Saxagen tablet 5mg of M/s Genix Pharma (Reg. # 076643) |
| | GMP status | Last GMP inspection was conducted on 18-08-2017 and the report concludes satisfactory compliance. |
| | Remarks of the Evaluator [XIII] | • No USP or BP monograph is available for the applied formulation.<br>• Firm has General Tablet Section as mentioned in the GMP inspection report. |
| | **Decision: Registration Board was apprised with reference to EMA Publis assessment report that Saxagliptin is prone to undergo an intra-molecular cyclisation reaction in solution & solid states to form a cyclic amidine. The tablet formulation was developed using active an active coating process to minimize this formation. Saxagliptin was embedded within a film coat of Opadry spray coated onto inert core tablets. During the coating process, Saxagliptin free base is converted in-situ into hydrochloride salt.** | |

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| | **Considering the above facts, Registration Board deferred the case for clarification to avoid cyclisation process.** | |
| 386. | Name and address of manufacturer / Applicant | M/s Neutro Pharma (Pvt.) Limited, 9.5 Km, Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Truace tablets 37.5mg/ 325mg |
| | Composition | Each film-coated tablet contains:<br>Tramadol ……37.5mg<br>Paracetamol……..325mg |
| | Diary No. Date of R& I & fee | Dy. No. 31372; 17-09-2018; Rs.8,000/- (30-11-2010)+ Rs.12,000/- (10-11-2017) DUPLICATE |
| | Pharmacological Group | Analgesic/ Opiate Analogue |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 2x 5's, 10's, 2x 10's, 10x 10's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Tramadoln Plus tablet 37.5mg/ 325mg of M/s Akson Pharma (Reg. # 085459) |
| | GMP status | Last GMP inspection was conducted on 21 & 23-08-2017 and the report concludes renewal of DML. |
| | Remarks of the Evaluator | • Firm has tablet General section as mentioned in the inspection report.<br>• Firm has shown its yellow copy as an evidence of fees paid.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved with USP specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 387. | Name and address of manufacturer / Applicant | M/s Neutro Pharma (Pvt.) Limited, 9.5 Km, Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Nuprofen SR tablet 800mg |
| | Composition | Each film-coated tablet contains:<br>Ibuprofen…….800mg |
| | Diary No. Date of R& I & fee | Dy. No. 31373; 17-09-2018; Rs.8,000/- (30-09-2010)+ Rs.12,000/- (10-11-2017) DUPLICATE |
| | Pharmacological Group | NSAID |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 30's, 60's, 24's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Brufen Retard tablet 800mg of M/s Mylan Products Limited (Approved in MHRA as sustained-release tablet) |
| | Me-too status | Could not be confirmed in the applied strength (available strengths are 200mg, 400mg & 600mg) |
| | GMP status | Last GMP inspection was conducted on 21 & 23-08-2017 and the report concludes renewal of DML. |
| | Remarks of the Evaluator | • The official monograph for the applied formulation is available in International Pharmacopoeia.<br>• Firm has tablet General section as mentioned in the inspection report.<br>• Firm has shown its yellow copy as an evidence of fees paid.<br>• Firm has applied the formulation as film-coated tablet while in reference regulatory authorities, it is approved as sustained-release tablet.<br>• Me- too product could not be confirmed in the applied strength. |
| | **Decision: Deferred for following:**<br>• **Clarification of manufacturing outline as in reference regulatory authorities the approved drug is sustained-release tablet, while the applied drug is film coated tablet.** | |

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| | • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 388. | Name and address of manufacturer / Applicant | M/s ARP (Pvt.) Limited, Plot # 12 & 12A, Street No. W-3, National Industrial Zone , Rawat |
| | Brand Name +Dosage Form + Strength | Infecnil tablet 250mg |
| | Composition | Each film- coated tablet contains:<br>Ciprofloxacin as HCl..…..250mg |
| | Diary No. Date of R& I & fee | Dy.No.7654;28-02-2018; Rs.20,000/- (28-02-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | 1x 10's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Novidat 250mg tablet of M/s Sami Pharma<br>(Reg. # 011836) |
| | GMP status | GMP certificate (valid up to 05-10-2018) was issued on the basis of inspection conducted on 06.10.2017. |
| | Remarks of the Evaluator [XIII] | • General Tablet Section is available in the firm as mentioned in the section approval letter. |
| | **Decision:Approved** | |
| 389. | Name and address of manufacturer / Applicant | M/s ARP (Pvt.) Limited, Plot # 12 & 12A, Street No. W-3, National Industrial Zone , Rawat |
| | Brand Name +Dosage Form + Strength | Infecnil tablets 750mg |
| | Composition | Each film- coated tablet contains:<br>Ciprofloxacin as HCl..…..750mg |
| | Diary No. Date of R& I & fee | Dy.No.7653;28-02-2018; Rs.20,000/- (28-02-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | 1x 10's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Novidat 250mg tablet of M/s Sami |
| | GMP status | GMP Certificate (valid up to 05-10-2018) was issued on the basis of inspection conducted on 06.10.2017. |
| | Remarks of the Evaluator [XIII] | • General Tablet Section is available in the firm as mentioned in the section approval letter. |
| | **Decision:Approved** | |
| 390. | Name and address of manufacturer / Applicant | M/s Fas Pharmaceuticals (Pvt.) Limited, Plot # F-748/ L S.I.T.E., Karachi |
| | Brand Name +Dosage Form + Strength | Fensedal CF tablet |
| | Composition | Each tablet contains:<br>Paracetamol ……..500mg<br>Pseudoephedrine HCl……..60mg<br>Chlorpheniramine Maleate ……...4mg |
| | Diary No. Date of R& I & fee | Dy.No.7565;28-02-2018; Rs.20,000/- (28-02-2018) |
| | Pharmacological Group | Anti-pyretic / Analgesic/ decongestant/ Anti- histamine |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10x 10's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Panafin-CF tablet of M/s Medipak (Reg. # 023954) |
| | GMP status | Last GMP inspection was conducted on 24-07-2017 and the report concludes satisfactory compliance. |
| | Remarks of the Evaluator [XIII] | • General Tablet Section is available in the firm as mentioned in the section approval letter. |

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| | | • The applied formulation could not be confirmed internationally.<br>• The official monograph for the applied formulation is not available in USP, BP or JP. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 391. | Name and address of manufacturer / Applicant | M/s Espoir Pharmaceutical , Laboratory Complex, University Road, Karachi |
| | Brand Name +Dosage Form + Strength | Vidogip tablets 50mg |
| | Composition | Each film- coated tablet contains:<br>Vildagliptin ……....50mg |
| | Diary No. Date of R& I & fee | Dy.No.7182;26-02-2018; Rs.20,000/- (23-02-2018) |
| | Pharmacological Group | Antidiabetic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 2x 14's & As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | GALVUS (Vildagliptin 50 mg tablets un-coated) by Novartis Pharmaceuticals Australia Pty Ltd. TGA approved |
| | Me-too status | V- Glip 50mg uncoated tablet of M/s Wellborne Pharma (Reg. # 080908) |
| | GMP status | Last GMP inspection was conducted on 28-09-2017 and the report concludes good GMP compliance with assurance of earlier compliance against the observations being observed during inspection. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP inspection report.<br>• Firm has applied as film- coated tablet while the formulation is approved in reference regulatory authority as uncoated tablet.<br>• No USP or BP monograph is available for the applied formulation. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film coated tablet.** | |
| 392. | Name and address of manufacturer / Applicant | M/s Espoir Pharmaceutical , Laboratory Complex, University Road, Karachi |
| | Brand Name +Dosage Form + Strength | Maxicam tablet 7.5mg |
| | Composition | Each film- coated tablet contains:<br>Meloxicam ……7.5mg |
| | Diary No. Date of R & I & fee | Dy.No.7180;26-02-2018; Rs.20,000/- (23-02-2018) |
| | Pharmacological Group | Anti- inflammatory/ Anti- rheumatic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 10's & as per brand leader |
| | Approval status of product in Reference Regulatory Authorities | Approved |
| | Me-too status | Artex un-coated tablet of M/s Pharmedic<br>(Reg. # 023939) |
| | GMP status | Last GMP inspection was conducted on 28-09-2017 and the report concludes good GMP compliance with assurance of earlier compliance against the observations being observed during inspection. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP inspection report.<br>• The applied formulation is approved as uncoated in USFDA and dispersible in MHRA while the firm has applied the formulation as film-coated tablet.<br>• No USP or BP monograph is available for the applied formulation. |

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| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| 393. | Name and address of manufacturer / Applicant | M/s Espoir Pharmaceutical , Laboratory Complex, University Road, Karachi |
| | Brand Name +Dosage Form + Strength | Maxicam tablet 15mg |
| | Composition | Each film- coated tablet contains:<br>Meloxicam ……15mg |
| | Diary No. Date of R& I & fee | Dy.No.7181;26-02-2018; Rs.20,000/- (23-02-2018) |
| | Pharmacological Group | Anti- inflammatory/ Anti- rheumatic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 10's & as per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | Artex un-coated tablet of M/s Pharmedic<br>(Reg. # 023940) |
| | GMP status | Last GMP inspection was conducted on 28-09-2017 and the report concludes good GMP compliance with assurance of earlier compliance against the observations being observed during inspection. |
| | Remarks of the Evaluator [XIII] | • Firm has General Tablet section as mentioned in the submitted GMP inspection report.<br>• The applied formulation is approved as uncoated in USFDA and dispersible in MHRA while the firm has applied the formulation as film-coated tablet.<br>• No USP or BP monograph is available for the applied formulation. |
| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| 394. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate Hattar |
| | Brand Name +Dosage Form + Strength | Welosamide 150mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Lacosamide……..…150mg |
| | Diary No. Date of R& I & fee | Dy. No.7189; 26-02-2018;Rs.20,000/-(23-02-2018) |
| | Pharmacological Group | Anti- epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vimpat film-coated tablets of M/s UCB Pharma, UK (MHRA Approved) |
| | Me-too status | Lacolep 150mg Tablets by Hilton Pharma<br>(Reg. # 073859) |
| | GMP status | Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | • Firm has General tablet section as mentioned in the GMP inspection report.<br>• Firm has applied USP specifications while no USP or BP monograph is available for the applied formulation. |
| | **Decision:Approved** | |
| 395. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate Hattar |
| | Brand Name +Dosage Form + Strength | Welosamide 200mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Lacosamide……..……...200mg |
| | Diary No. Date of R& I & fee | Dy. No.7190; 26-02-2018;Rs.20,000/-(23-02-2018) |
| | Pharmacological Group | Anti- epileptic |
| | Type of Form | Form-5 |

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| | Finished product Specification | USP |
| | Pack size & Demanded Price | 2x 7's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vimpat film-coated tablets of M/s UCB Pharma, (MHRA Approved) |
| | Me-too status | Lacolep 200mg Tablets by Hilton Pharma (Reg.# 073860) |
| | GMP status | Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | • Firm has General tablet section as mentioned in the GMP inspection report.<br>• Firm has applied USP specifications while no USP or BP monograph is available for the applied formulation. |
| | **Decision: Approved with innovator's specification** | |
| 396. | Name and address of manufacturer / Applicant | M/s Macter International Ltd., F-216, S.I.T.E, Karachi |
| | Brand Name +Dosage Form + Strength | Pen- V tablet 250mg |
| | Composition | Each film- coated tablet contains:<br>Penicillin-V (Phenoxymethyl Penicillin) as Potassium ……250mg |
| | Diary No. Date of R& I & fee | Dy. No.231;02-01-2018; Rs.20,000/- (02-01-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | Rs. 400/- for 50's & Rs. 760/- for 100's |
| | Approval status of product in Reference Regulatory Authorities | Penicillin VK tablets 250 mg of M/s Sandoz Limited (MHRA Approved) |
| | Me-too status | Penicillin-V tablet 250mg of M/s Lisko<br>(Reg. # 011959) |
| | GMP status | Last GMP inspection was conducted on 23-05-2018 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Registrationboard rejected the application since M/s Macter International Ltd., F-216, S.I.T.E, Karachi, does not have required manufacturing facility for "Tablet (Penicillin) section"** | |
| 397. | Name and address of manufacturer / Applicant | M/s Macter International Ltd., F-216, S.I.T.E, Karachi. |
| | Brand Name +Dosage Form + Strength | Pen- V tablet 500mg |
| | Composition | Each film- coated tablet contains:<br>Penicillin-V (Phenoxymethyl Penicillin) as Potassium ……500mg |
| | Diary No. Date of R& I & fee | Dy.No.230;02-01-2018; Rs.20,000/- (02-01-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | Rs. 600/- for 50's & Rs. 1140/- for 100's |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | Penicillin-V tablet 250mg of M/s Lisko<br>(Reg. # 011959) |
| | GMP status | Last GMP inspection was conducted on 23-05-2018 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Registrationboard rejected the application since M/s Macter International Ltd., F-216, S.I.T.E, Karachi, does not have required manufacturing facility for "Tablet (Penicillin) section"** | |
| 398. | Name and address of manufacturer / Applicant | M/s Zaynoon Pharmaceuticals Pvt. Limited,<br>27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Zayzine Syrup 5mg/ 5ml |
| | Composition | Each 5ml contains:<br>Cetirizine Di-hydrochloride……5mg |
| | Diary No. Date of R& I & fee | Dy. No 855; 05-01-2018; Rs.20,000/- (05-01-2018) |

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| | Pharmacological Group | Anti-histamine |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 60ml, 120ml & Rs. 30/-, Rs. 58/- |
| | Approval status of product in Reference Regulatory Authorities | *Benadryl Allergy Children's 1mg/ml Oral Solution of M/s McNeil Products Ltd (MHRA Approved)* |
| | Me-too status | Calzine Syrup of M/s Caliph Pharma (Reg. # 080402) |
| | GMP status | Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has relevant section i.e. "Oral liquid" as mentioned in the submitted GMP report.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision:Approved with USP specifications** | |
| 399. | Name and address of manufacturer / Applicant | M/s Zaynoon Pharmaceuticals Pvt. Limited, 27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Zayfyl Syrup 45mg/ 8ml |
| | Composition | Each 5ml contains:<br>Acefylline Piperazine…45mg<br>Diphenhydramine……8mg |
| | Diary No. Date of R& I & fee | Dy. No 856; 05-01-2018; Rs.20,000/- (05-01-2018) |
| | Pharmacological Group | Xanthine/ Anti-histamine |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 60ml, 120ml & Rs.43/-, Rs.22/- |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Acefyl cough syrup 45mg/ 8mg of M/s NabiQasim (Reg. # 023394) |
| | GMP status | Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has relevant section i.e. "Oral liquid" as mentioned in the submitted GMP report.<br>• No official monograph is avialable for the applied formulation.<br>• Approval in reference regulatory authorities could not be confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 400. | Name and address of manufacturer / Applicant | M/s. Zafa Pharmaceuticals Laboratories (Private) Limited, L-4/1, A & B Block 21, Federal-B Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Ibudex Tablet 200mg |
| | Composition | Each film- coated tablet contains:<br>Dexibuprofen ……...…200mg |
| | Diary No. Date of R& I & fee | Dy.No.7388;27-02-2018; Rs.20,000/- (26-02-2018) |
| | Pharmacological Group | Anti- rheumatic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 3x 10's & as per PRC |
| | Approval status of product in Reference Regulatory Authorities | Atriscal 200 mg - film-coated tablets of M/s Gebro Pharma GmbH, Approved in Austria |
| | Me-too status | Haltrin 200mg Tablet of M/s Brookes (Reg.#061068) |
| | GMP status | GMP certificate was issued on 15-05-2018 on the basis of inspection conducted on 25-01-2018. |
| | Remarks of the Evaluator [XIII] | • No official monograph is available for the applied formulation in USP, BP or JP. |
| | **Decision: Approved with innovator's specification** | |

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| 401. | Name and address of manufacturer / Applicant | M/s Zafa Pharmaceuticals Laboratories (Private) Limited, L-4/1, A & B Block 21, Federal-B Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Ibudex Tablets 400mg |
| | Composition | Each film- coated tablet contains:<br>Dexibuprofen ……...…400mg |
| | Diary No. Date of R& I & fee | Dy.No.7389;27-02-2018; Rs.20,000/- (26-02-2018) |
| | Pharmacological Group | Anti- rheumatic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 3x 10's & as per PRC |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Vanit 400mg tablet of M/s Getz Pharma (Reg. # 061487) |
| | GMP status | GMP certificate was issued on 15-05-2018 on the basis of inspection conducted on 25-01-2018. |
| | Remarks of the Evaluator [XIII] | • No official monograph is available for the applied formulation in USP, BP or JP. |
| | **Decision: Approved with innovator's specification** | |
| 402. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate Hattar |
| | Brand Name +Dosage Form + Strength | Weldrate 5mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Risedronate Sodium…….....5mg |
| | Diary No. Date of R& I & fee | Dy. No.7189; 26-02-2018;Rs.20,000/-(23-02-2018) |
| | Pharmacological Group | Bisphosphonate (to prevent bone reabsorption) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Actonel 5mg tablet of M/s Sanofi Aventis Pharma (Reg. # 027337) |
| | GMP status | Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | Firm has General tablet section as mentioned in the GMP inspection report. |
| | **Decision: Approved** | |
| 403. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate Hattar |
| | Brand Name +Dosage Form + Strength | Weldrate 35mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Risedronate as Sodium…..35mg |
| | Diary No. Date of R& I & fee | Dy. No.7187; 26-02-2018;Rs.20,000/-(23-02-2018) |
| | Pharmacological Group | Bisphosphonate (to prevent bone reabsorption) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specification |
| | Pack size & Demanded Price | 2x 7's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Actonel 35mg tablet of M/s Sanofi Aventis Pharma (Reg. # 031387) |
| | GMP status | Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | Firm has General tablet section as mentioned in the GMP inspection report. |
| | **Decision:Approved.** | |

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| 404. | Name and address of manufacturer / Applicant | M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate Hattar |
| | Brand Name +Dosage Form + Strength | Weldrate 150mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Risedronate Sodium…….150mg |
| | Diary No. Date of R& I & fee | Dy. No.7188; 26-02-2018;Rs.20,000/-(23-02-2018) |
| | Pharmacological Group | Bisphosphonate (to prevent bone reabsorption) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | Actonel 150mg tablets of M/s Sanofi Aventis Pharma (Reg. # 067727) |
| | GMP status | Last GMP inspection was conducted on 04-09-2018 & 26-09-2018 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | Firm has General tablet section as mentioned in the GMP inspection report. |
| | **Decision:Approved** | |
| 405. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi, KPK |
| | Brand Name +Dosage Form + Strength | Welfine tablet 125mg |
| | Composition | Each uncoated tablet contains:<br>Terbinafine as HCl…...125mg |
| | Diary No. Date of R& I & fee | Dy.No.4831;05-06-2017; Rs.20,000/- (05-06-2017) |
| | Pharmacological Group | Anti-fungal |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 7's, 14's, 28's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | TGA Australia Approved as uncoated tablet |
| | Me-too status | Afert tablet 125mg of M/s Genix (Reg. # 055856) |
| | GMP status | Last GMP inspection was conducted on 04-03-2017 and the report concludes renewal of DML. |
| | Remarks of the Evaluator [XIII] | • Film-coating is applied in the master formulation while the applied formulation is uncoated and approved in reference regulatory authority as uncoated as well.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film coated tablet.** | |
| 406. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi, KPK |
| | Brand Name +Dosage Form + Strength | NT-Wel tablet 500mg |
| | Composition | Each film-coated tablet contains:<br>Nitazoxanide ……...500mg |
| | Diary No. Date of R& I & fee | Dy.No.4833;05-06-2017; Rs.20,000/- (05-06-2017) |
| | Pharmacological Group | Anti- amoebic/ Anti- protozoal |
| | Type of Form | Form- 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 20's & As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Alinia Tablet USFDA Approved |
| | Me-too status | Izato 500mg tablet of M/s Sami Pharma<br>(Reg. # 076308) |
| | GMP status | Last GMP inspection was conducted on 04-03-2017 and the report concludes renewal of DML. |

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| | Remarks of the Evaluator [XIII] | Firm has claimed USP specifications while the applied formulation is non- pharmacopoeial. |
| | **Decision: Approved with innovator's specification.** | |
| 407. | Name and address of manufacturer / Applicant | M/s Revive Pharmakon, Adda Plot Sharaiz Avenue Jatti Umra, 10km Raiwind Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Revasol M- 20 I/V Infusion 500ml |
| | Composition | Each 100ml contains:<br>Mannitol ……..……..20g (20%) |
| | Diary No. Date of R& I & fee | Dy.No.506; 04-01-2018; Rs.20,000/- (04-01-2018) |
| | Pharmacological Group | Antiglaucoma , Diuretic |
| | Type of Form | Form- 5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 500ml & Rs. 119/- |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Mannitol solution 20% of M/s Imran & CO, Karachi (Reg. # 014021) |
| | GMP status | Last GMP inspection was conducted on 27-02-2017 and the report concludes the firm to be GMP compliant. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision:Approved** | |
| 408. | Name and address of manufacturer / Applicant | M/s Ipram International, Plot # 26, S.S 3, National Industrial Zone Rawat, Islamabad. |
| | Brand Name +Dosage Form + Strength | Iprolac 10mg/ 1ml I/V I/M Injection |
| | Composition | Each ml contains:<br>Ketorolac Tromethamol ……..10mg |
| | Diary No. Date of R& I & fee | Dy.No.8692;13-07-2017; Rs.20,000/- (13-07-2017) |
| | Pharmacological Group | NSAIDs |
| | Type of Form | Form- 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1ml x 5's ampoules & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Toradol Ketorolac Trometamol 10mg/1ml injection ampoule of M/s Atnahs Pharma Australia Pty Ltd (TGA Approved) |
| | Me-too status | Ketopan injection 10mg/ ml of M/s Welwrd (Reg. # 068349) |
| | GMP status | 16-02-2017 and grant of additional sections was granted in the report. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision:Approved** | |

**Evaluator PEC-XIV**

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| 409. | Name and address of manufacturer / Applicant | M/s Weatherfolds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Go-Peptic Suspension |
| | Composition | Each 5ml contains:<br>Sucralfate……1000mg |
| | Diary No. Date of R& I & fee | 1880, 18-01-2018, 20,000/-, 04-01-2018 |
| | Pharmacological Group | Cytoprotective agent |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 120ml; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Sucralate Oral Liquid suspension of M/s Regal Pharma (Reg.#081988) |
| | GMP status | GMP inspection conducted on 15-09-2017 concluded that overall the firm was GMP compliant as per DRAP guidelines |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification and change of brand name** | |

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| 410. | Name and address of manufacturer / Applicant | M/s Weatherfolds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | ALPHA-C 0.25mcg Tablet |
| | Composition | Each uncoated tablet contains:<br>Alfacalcidol……0.25mcg |
| | Diary No. Date of R& I & fee | 1881, 18-01-2018, 20,000/-, 04-01-2018 |
| | Pharmacological Group | Vitamin D3 analogue |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | As per SRO; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PMDA approved. |
| | Me-too status | Alfa-D Tablets 0.25mcg of Platinum (Reg#028124) |
| | GMP status | GMP inspection conducted on 15-09-2017 concluded that overall the firm was GMP compliant as per DRAP guidelines |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 411. | Name and address of manufacturer / Applicant | M/s Weatherfolds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Fusid 250mg Tablet |
| | Composition | Each film coated tablet contains:<br>Sodium Fusidate……250mg |
| | Diary No. Date of R& I & fee | 1882, 04-01-2018, 20,000/-, 04-01-2018 |
| | Pharmacological Group | Steroid Antibacterials;<br>ATC code: J01XC01 |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | As per SRO; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Fucidin Tablet of LEO Pharma |
| | GMP status | GMP inspection conducted on 15-09-2017 concluded that overall the firm was GMP compliant as per DRAP guidelines |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for submission of correct pharmacological group.** | |
| 412. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | McFAX 50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Venlafaxine as hydrochloride…….50 mg |
| | Diary No. Date of R& I & fee | 1802, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | SSNRI (Antidepressant) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Venlafaxine Hydrochloride 50mg tablets by M/s Teva Pharmaceuticals USA (USFDA Approved) |
| | Me-too status | Amfax 50mg Tablets by M/s Amson (Reg#029070) |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 413. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | McFAX 37.5mg Tablet |

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| | Composition | Each film coated tablet contains:<br>Venlafaxine as hydrochloride…….37.5 mg |
| | Diary No. Date of R& I & fee | 1801, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | SSNRI (Antidepressant) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | EFFEXOR of Pfizer (USFDA) |
| | Me-too status | EFEXOR of Pfizer |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 414. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Valmac 80 mg Tablet |
| | Composition | Each Film coated Tablet contains:<br>Valsartan……80mg |
| | Diary No. Date of R& I & fee | 1803, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Angiotensin II receptor Antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | DIOVAN tablets 80 by M/s Novartis Pharma (Reg#027346) |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 415. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Valmac 160 mg Tablet |
| | Composition | Each Film coated Tablet contains:<br>Valsartan……160mg |
| | Diary No. Date of R& I & fee | 1795, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Angiotensin II receptor Antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | DIOVAN tablets 160 by M/s Novartis Pharma Karachi (Reg.#027347) |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 416. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Co-Valmac 80/12.5 mg Tablet |

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| | Composition | Each Film coated Tablet contains:<br>Valsartan…….80mg<br>Hydrochlorothiazide……..12.5mg |
| | Diary No. Date of R& I & fee | 1796, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Antagonist and diuretic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 28's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Diovan HCT Tablet by Novartis<br>(USFDA Approved) |
| | Me-too status | Co-Diovan Tablets by Novartis |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 417. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Co-Valmac 160/12.5 mg Tablet |
| | Composition | Each Film coated Tablet contains:<br>Valsartan…….160mg<br>Hydrochlorothiazide……..12.5mg |
| | Diary No. Date of R& I & fee | 1797, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Antagonist and diuretic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Sofvasc-HCT Tablet of Wilson Pharma (Reg.# 077749) |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 418. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Co-Valmac 160/25 mg Tablet |
| | Composition | Each Film coated Tablet contains:<br>Valsartan…….160mg<br>Hydrochlorothiazide……..25mg |
| | Diary No. Date of R& I & fee | 1798, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Antagonist and diuretic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Sofvasc-HCT Tablet of Wilson Pharma (Reg.# 077753) |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

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| 419. | Name and address of manufacturer / Applicant | M/s McOlson Research Laboratories (Pvt.) Ltd. 26th KM Lahore- Sharikpur Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | M-SART 50 mg Tablets |
| | Composition | Each Film coated Tablet contains:<br>Losartan Potassium……..50mg |
| | Diary No. Date of R& I & fee | 1799, 12-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cozaar by MSD (MHRA Approved) |
| | Me-too status | Cozaar by OBS |
| | GMP status | GMP inspection conducted on 10-04-2017 & 24-04-2017 concluded that in overall consideration firm has fair compliance of GMP, however some advises are also given in the report to the firm for further up-gradations. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 420. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals (Pvt.) Ltd, plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan |
| | Brand Name +Dosage Form + Strength | ZIDAN 4mg TABLET |
| | Composition | Each tablet contains:<br>Tizanidine as hydrochloride…….4mg |
| | Diary No. Date of R& I & fee | 9478, 07-12-2018, 20,000/-, 30-01-2018 |
| | Pharmacological Group | Muscle relaxant |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | Musidin 4mg Tablet of M/s Martin Dow |
| | GMP status | The firm is granted GMP Certificate is issued based on inspection dated 15-03-2018. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 421. | Name and address of manufacturer / Applicant | M/s Akhai Pharmaceuticals (Pvt.) Ltd, plot # A-248 & A-256 to A-259, H.I.T.E. Lasbela Balochistan, Pakistan |
| | Brand Name +Dosage Form + Strength | ZIDAN 2mg TABLET |
| | Composition | Each tablet contains:<br>Tizanidine as hydrochloride…….2mg |
| | Diary No. Date of R& I & fee | 9477, 07-12-2018, 20,000/-, 30-01-2018 |
| | Pharmacological Group | Muscle relaxant |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | Tandolax 2mg Tablet M/s High-Q Pharmaceuticals |
| | GMP status | The firm is granted GMP Certificate is issued based on inspection dated 15-03-2018. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 422. | Name and address of manufacturer / Applicant | M/s EPHARM Laboratories, A-40, Road No. 1. S.I.T.E, Super Highway Industrial Area, north Karachi |
| | Brand Name +Dosage Form + Strength | TELTAN-80mg TABLETS |
| | Composition | Each tablet contains:<br>Telmisartan…….80mg |

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| | Diary No. Date of R& I & fee | 1786, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | Angiotensin II receptor antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1 × 10's; As per SRO<br>1 × 14's; As per SRO<br>2 × 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Tasmi 80mg tablet of M/s Getz Pharma (Reg. # 047483) |
| | GMP status | GMP inspection dated 27-04-2017 concluded that panel is of view to recommend the grant of GMP certificate of this site. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 423. | Name and address of manufacturer / Applicant | M/s EPHARM Laboratories, A-40, Road No. 1. S.I.T.E, Super Highway Industrial Area, north Karachi |
| | Brand Name +Dosage Form + Strength | TELTAN-40mg TABLETS |
| | Composition | Each tablet contains:<br>Telmisartan…….40mg |
| | Diary No. Date of R& I & fee | 1785, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | Angiotensin II receptor antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1 × 10's; As per SRO<br>1 × 14's; As per SRO<br>2 × 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Tasmi 40mg tablet of M/s Getz Pharma (Reg. # 047482) |
| | GMP status | GMP inspection dated 27-04-2017 concluded that panel is of view to recommend the grant of GMP certificate of this site. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 424. | Name and address of manufacturer / Applicant | M/s EPHARM Laboratories, A-40, Road No. 1. S.I.T.E, Super Highway Industrial Area, north Karachi |
| | Brand Name +Dosage Form + Strength | RUSTATIN-20mg TABLET |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin as calcium…….20mg |
| | Diary No. Date of R& I & fee | 1784, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specification | Firm has claimed in house specification |
| | Pack size & Demanded Price | 1x10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 20 mg film-coated tablets by AstraZeneca UK Limited (MHRA Approved) |
| | Me-too status | Rolip 20mg Tablets by Hilton Pharma (Reg# 042354) |
| | GMP status | GMP inspection dated 27-04-2017 concluded that panel is of view to recommend the grant of GMP certificate of this site. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 425. | Name and address of manufacturer / Applicant | M/s EPHARM Laboratories, A-40, Road No. 1. S.I.T.E, Super Highway Industrial Area, north Karachi |
| | Brand Name +Dosage Form + Strength | RUSTATIN-10mg TABLET |
| | Composition | Each film coated tablet contains:<br>Rosuvastatin as calcium…….10mg |
| | Diary No. Date of R& I & fee | 1783, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specification | Firm has claimed in house specification |

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| | Pack size & Demanded Price | 1x10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 10 mg film-coated tablets by AstraZeneca UK Limited (MHRA Approved) |
| | Me-too status | Rolip 10mg Tablets by Hilton Pharma (Reg# 042353) |
| | GMP status | GMP inspection dated 27-04-2017 concluded that panel is of view to recommend the grant of GMP certificate of this site. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 426. | Name and address of manufacturer / Applicant | M/s EPHARM Laboratories, A-40, Road No. 1. S.I.T.E, Super Highway Industrial Area, north Karachi |
| | Brand Name +Dosage Form + Strength | EPTRIL-20mg TABLETS |
| | Composition | Each tablet contains:<br>Lisinopril as dihydrate…….20mg |
| | Diary No. Date of R& I & fee | 1782, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | ACE inhibitor |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1x14's: As per SRO<br>2x10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Corace Tablet 20mg of M/s Bosch Pharmaceuticals |
| | GMP status | GMP inspection dated 27-04-2017 concluded that panel is of view to recommend the grant of GMP certificate of this site. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 427. | Name and address of manufacturer / Applicant | M/s EPHARM Laboratories, A-40, Road No. 1. S.I.T.E, Super Highway Industrial Area, north Karachi |
| | Brand Name +Dosage Form + Strength | EPTRIL-10mg TABLETS |
| | Composition | Each tablet contains:<br>Lisinopril as dihydrate…….10mg |
| | Diary No. Date of R& I & fee | 1781, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | ACE inhibitor |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1x14's: As per SRO<br>2x10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Corace Tablet 20mg of M/s Bosch Pharmaceuticals |
| | GMP status | GMP inspection dated 27-04-2017 concluded that panel is of view to recommend the grant of GMP certificate of this site. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 428. | Name and address of manufacturer / Applicant | M/s EPHARM Laboratories, A-40, Road No. 1. S.I.T.E, Super Highway Industrial Area, north Karachi |
| | Brand Name +Dosage Form + Strength | EPTRIL-5mg TABLETS |
| | Composition | Each tablet contains:<br>Lisinopril as dihydrate…….5mg |
| | Diary No. Date of R& I & fee | 1780, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | ACE inhibitor |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1x14's: As per SRO/ 2x10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Corace Tablet 5mg of M/s Bosch Pharma (Reg#027175) |
| | GMP status | GMP inspection dated 27-04-2017 concluded that panel is of view to recommend the grant of GMP certificate of this site. |

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| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 429. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Loroxi 8mg Tablet |
| | Composition | Each film coated tablet contains:<br>Lornoxicam……8mg |
| | Diary No. Date of R& I & fee | 1680, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 10's, 20's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Acabel 8 mg film-coated tablets by Grünenthal Pharma, S.A. (Spain Approved) |
| | Me-too status | Recam Tablet 8mg by M/s Regal Pharma (Reg.#081952) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 430. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Loroxi 4mg Tablet |
| | Composition | Each film coated tablet contains:<br>Lornoxicam……4mg |
| | Diary No. Date of R& I & fee | 1679, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 10's, 20's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved) |
| | Me-too status | Acabel 4mg Tablet by M/s Continental Pharma (Reg#061603) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 431. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Theramet 50/1000mg Tablet |
| | Composition | Each film coated tablet contains:<br>Sitagliptin as phosphate monohydrate……..50mg<br>Metformin HCl……..1000mg |
| | Diary No. Date of R& I & fee | 1674, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drugs<br>ATC code: A10BD07 |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 10's, 14's, 28's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Janumet 50/1000 mg film coated Tablet by Merck (USFDA Approved) |
| | Me-too status | Treviamet 50mg + 1000mg Tablet by Getz (Reg# 055444) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 432. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Fenid 60/120mg Tablet |

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|---|---|---|
| | Composition | Each film coated extended release tablet contains:<br>Fexofenadine HCl…….60mg<br>Pseudoephedrine HCl……..120mg |
| | Diary No. Date of R& I & fee | 1673, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | Sympathomimetic,<br>H1 receptor antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | ALLEGRA-D (Bi-layered tablet) NDA: 020786. \| Extended Release; Oral \| Over-The-Counter From Sanofi Aventis; Approved in USFDA. |
| | Me-too status | Fexet-D 60Mg/120Mg Tablets of Getz Pharma (Pvt.) Ltd, Karachi (Reg # 039099) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for following:**<br>• **Revision of formulation and label claim as per the USFDA approved reference product**<br>• **Evidence of availability of bi-layer machine.** | |
| 433. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Losar Plus 100/25mg Tablet |
| | Composition | Each film coated tablet contains:<br>Losartan Potassium ……..100mg<br>Hydrochlorothiazide……25mg |
| | Diary No. Date of R& I & fee | 1685, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | Anti-hypertensive (Angiotensin II Receptor Antagonist, Thiazide Diuretic) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Cozaar Comp 100mg/25mg ( MHRA Approved) |
| | Me-too status | Lotass Plus 100mg/25mg of M/S Getz pharma |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 434. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Itomed 50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Itopride hydrochloride……50m |
| | Diary No. Date of R& I & fee | 1670, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | Gastroprokinetic agent |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's Specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Ganaton of M/s Abbott Laboratories (PMDA approved) |
| | Me-too status | Itoguard Tablet of M/s Macter Int (Reg#055753) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 435. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Losar Plus 50/12.5mg Tablet |

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| | Composition | Each film coated tablet contains:<br>Losartan Potassium ……..50mg<br>Hydrochlorothiazide……12.5mg |
| | Diary No. Date of R& I & fee | 1684, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | Anti-hypertensive (Angiotensin II Receptor Antagonist, Thiazide Diuretic) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Cozaar Comp Tablet by MSD (MHRA Approved) |
| | Me-too status | Xavor DIU 50mg/12.5mg of M/s Ferozsons |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 436. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Losar 100 Tablet |
| | Composition | Each film coated tablet contains:<br>Losartan Potassium ……..100mg |
| | Diary No. Date of R& I & fee | 1683, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Cozaar tablets by MSD (MHRA Approved) |
| | Me-too status | Tansin DS by Pharmevo |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 437. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Losar 50 Tablet |
| | Composition | Each film coated tablet contains:<br>Losartan Potassium ……..50mg |
| | Diary No. Date of R& I & fee | 1682, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | COZAAR 50 mg tablet ,Merck Sharp & Dohme UK MHRA Approved. |
| | Me-too status | Xavor 50mg Tablet by Ferozsons pharma (Reg# 079743) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 438. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Losar 25mg Tablet |
| | Composition | Each film coated tablet contains:<br>Losartan Potassium ……..25mg |
| | Diary No. Date of R& I & fee | 1681, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | Angiotensin II receptor antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |

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| | Pack size & Demanded Price | 10's, 20's, 100's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | COZAAR 25 mg tablet ,Merck Sharp & Dohme UK MHRA Approved |
| | Me-too status | Xavor by Ferozsons pharma (Reg # 079742) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 439. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Theratin 40mg Tablet |
| | Composition | Each film coated tablet contains:<br>Atorvastatin as calcium trihydrate…….40mg |
| | Diary No. Date of R& I & fee | 1677, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | HMG-CoA reductase inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | JP specs |
| | Pack size & Demanded Price | 10's, 14's, 100's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Lipitor 40mg film coated Tablets by Pfizer (USFDA Approved) |
| | Me-too status | Lipitor 40mg Tablets by Pfizer (Reg# 023622) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 440. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Tiroxin 50mcg Tablet |
| | Composition | Each tablet contains :<br>Thyroxine Sodium……..50mcg |
| | Diary No. Date of R& I & fee | 1671, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | Thyroid hormone |
| | Type of Form | Form-5 |
| | Finished product Specification | BP (as Levothyroxine Tablets) |
| | Pack size & Demanded Price | 50's, 100's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Eltroxin 50mcg tablet (Levothyroxine) (MHRA Approved) |
| | Me-too status | Thyroxin50mcg of M/s GSK |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product.** | |
| 441. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Ofocin 200mg Tablet |
| | Composition | Each film coated tablet contains:<br>Ofloxacin…….200mg |
| | Diary No. Date of R& I & fee | 1675, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | A-Vid Tablets 200mg of M/s Alliance Pharma. (Reg.# 043768) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |

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| | **Decision:Approved** | |
| 442. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Theriptin 50mg Tablet |
| | Composition | Each tablet contains:<br>Sitagliptin as phosphate monohydrate……50mg |
| | Diary No. Date of R& I & fee | 1675, 11-01-2018, 20,000/-, 08-01-2018 |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Januvia tablets of (FDA approved) |
| | Me-too status | A-Glip Tablets of M/s Atco Labs |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 443. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Therazith 250mg Tablet |
| | Composition | Each film coated tablet contains:<br>Azithrmycin Dihydrate eq. to Azithromycin…...250mg |
| | Diary No. Date of R& I & fee | 1676, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | Macrolides |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 6's, 10's; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Azithromycin 250 mg film-coated tablets by Milpharm Limited (MHRA Approved) |
| | Me-too status | Zetro 250mg Tablet by Getz Pharma (Reg# 066913) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 444. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Acefenac 100mg Tablet |
| | Composition | Each film coated tablet contains:<br>Aceclofenac……..100mg |
| | Diary No. Date of R& I & fee | 1669, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's ; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Aclofen Tablets by M/s Alliance Pharma (Reg # 068419) |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 445. | Name and address of manufacturer / Applicant | M/s Theramed Pharmaceutical (Pvt.) Ltd. 45-Km, Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | T-Merz Syrup |
| | Composition | Each 5ml contains:<br>L-Ornithine L-Aspartate…….300mg<br>Nicotinamide……...…24mg<br>Riboflavin sodium Phosphate……..0.76mg |

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| | Diary No. Date of R& I & fee | 1672, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | Hepatic Encephalopathy |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 60ml, 120ml; As to be awarded by DRAP |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too status | Hepa-Merz by M/s Brookes |
| | GMP status | Panel inspection dated 10.10.2017 recommended renewal of DML and additional section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 446. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Calculix 250mg Capsule |
| | Composition | Each capsule contains:<br>Ursodeoxycholic acid……..250mg |
| | Diary No. Date of R& I & fee | 2156, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Cholagogues & hepatic preparations |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 1×10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ursogal capsule by Galen Ltd<br>(MHRA Approved) |
| | Me-too status | Urso capsule by AGP |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 447. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Calculix 500mg Capsule |
| | Composition | Each capsule contains:<br>Ursodeoxycholic acid……..500mg |
| | Diary No. Date of R& I & fee | 2157, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Bile acids and derivatives |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 1×10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ursochol 500 mg capsule, hard<br>By Orifarm Generics A/S (Sweden Approved) |
| | Me-too status | Urso capsule by AGP |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 448. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | F-REPA 0.5mg Tablet |
| | Composition | Each tablet contains:<br>Repaglinide…….0.5mg |
| | Diary No. Date of R& I & fee | 2163, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form-5 |

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| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1×10's, 1×30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Prandin 0.5mg Tablet by Gemini Labs LLC approved by USFDA |
| | Me-too status | Rapaglax Tablets 0.5mg by M/s Cirin Pharmaceuticals |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 449. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Histego 24mg Tablets |
| | Composition | Each tablet contains:<br>Betahistine Dihydrochloride……24mg |
| | Diary No. Date of R& I & fee | 2162, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anti-Vertigo |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 1×30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | Vertin 24mg tablets of M/s Libra pharmaceuticals |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 450. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Histego 16mg Tablets |
| | Composition | Each tablet contains:<br>Betahistine Dihydrochloride ……16mg |
| | Diary No. Date of R& I & fee | 2161, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anti-Vertigo |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 1×30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | Vertin 16mg tablets of M/s Remington Pharma (Reg#071250) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 451. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Histego 8mg Tablets |
| | Composition | Each tablet contains:<br>Betahistine Dihydrochloride ……8mg |
| | Diary No. Date of R& I & fee | 2160, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anti-Vertigo |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 1×30's; As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | VR-Tigo Tablets 8mg by Himont Pharmaceuticals (Pvt) Ltd. (Reg#079703) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| 452. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | IVANODE 5mg Tablets |
| | Composition | Each film coated tablet contains:<br>Ivabradine as hydrochloride……5mg |
| | Diary No. Date of R& I & fee | 2152, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anti-anginal |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 2×7's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Iva Tablet 5 mg of M/s CSH Pharma (Reg.# 081685) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 453. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | IVANODE 7.5mg Tablets |
| | Composition | Each film coated tablet contains:<br>Ivabradine as hydrochloride……7.5mg |
| | Diary No. Date of R& I & fee | 2153, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anti-anginal |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 2×7's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Ivatab Tablet 7.5 mg of M/s Nabiqasim (Reg # 076155) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 454. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | OMONIC 150mg Tablets |
| | Composition | Each film coated tablet contains:<br>Ibandronate sodium monohydrate eq. to Ibandronic acid……..150mg |
| | Diary No. Date of R& I & fee | 2147, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Bisphosphonates |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1×1's; As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | USFDA app |
| | Me-too status | Bionic Tablets 150mg by M/s S.J.&G. Fazul Ellahie (Reg.#058637) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 455. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Terbifaas 125mg Tablets |
| | Composition | Each Tablet contains:<br>Terbinafine as hydrochloride……125mg |
| | Diary No. Date of R& I & fee | 2144, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | TERBINAFINE 125 mg uncoated tablets Stada Arzneimittel AG (MHRA Approved) |
| | Me-too status | Lamisil 125mg Tablet by Sandoz (Reg# 013208) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 456. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Decoag 15mg Tablet |
| | Composition | Each film coated tablet contains:<br>Rivaroxaban……15mg |
| | Diary No. Date of R& I & fee | 2167, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anticoagulant |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 2×7's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Xarelto of M/s Bayer healthcare approved by EMA |
| | Me-too status | Xarelto 15mg Tablet by M/s. Bayer Pakistan (private) limited (Reg#072549) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 457. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Decoag 20mg Tablet |
| | Composition | Each film coated tablet contains:<br>Rivaroxaban……20mg |
| | Diary No. Date of R& I & fee | 2168, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Anticoagulant |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 2×7's; As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | Rivaroxaban 20 mg film-coated tablets by Milpharm Limited. MHRA approved |
| | Me-too status | Rivaxo 20mg film-coated Tablet by Getz Pharma Reg.#80791 |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 458. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | RIFAAS 550mg Tablet |
| | Composition | Each film coated tablet contains: Rifaximin……550mg |
| | Diary No. Date of R& I & fee | 2155, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 1×10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | REFERO 550 mg film-coated tablets by Alfasigma S.p.A (MHRA Approved) |
| | Me-too status | Xifaxa 550mg Tablet by Brookes Pharm (Reg#070438)- |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 459. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | RIFAAS 200mg Tablet |
| | Composition | Each film coated tablet contains: Rifaximin……200mg |
| | Diary No. Date of R& I & fee | 2154, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 1×10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Xifaxanta 200 mg film-coated tablets by Norgine Pharmaceuticals Limited (MHRA approved) |
| | Me-too status | Rifaxa 200mg Tablets by Ferozsons (Reg . No. 068205) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 460. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | RHEUMAX 4mg TABLET |
| | Composition | Each film coated tablet contains: Lornoxicam……4mg |
| | Diary No. Date of R& I & fee | 2158, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 1×10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved) |

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| | Me-too status | Acabel 4mg Tablet by M/s Continental Pharma (Reg#061603) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 461. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | RHEUMAX 8mg TABLET |
| | Composition | Each film coated tablet contains: Lornoxicam…….8mg |
| | Diary No. Date of R& I & fee | 2159, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 1×10's and 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Acabel 8 mg film-coated tablets by Grünenthal Pharma, S.A. (Spain Approved) |
| | Me-too status | Zafon 8mg Tablet by Getz Pharma (Reg# 058589) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 462. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Mucyst 200mg Sachet |
| | Composition | Each sachet contains: Acetylcysteine…….200mg |
| | Diary No. Date of R& I & fee | 2156, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Mucolytic agent |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 30's,; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Acetylcysteine 200 mg Powder for Oral Solution by M/s NTC S.r.l. (MHRA approved) |
| | Me-too status | Mucolator 200mg powders by M/s Abbott Laboratories. (Reg# 017693) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 463. | Name and address of manufacturer / Applicant | M/s FAAS Pharmaceuticals (Pvt.) Ltd., F-748, S.I.T.E, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Storiosis 2gm sachet |
| | Composition | Each sachet contains: Strontium Ranelate……..2gm |
| | Diary No. Date of R& I & fee | 2151, 16-01-2018, 20,000/-, 27-12-2017 |
| | Pharmacological Group | Bone metabolism modulator |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 1×7's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PROTOS strontium ranelate 2g granules for oral suspension sachet by Servier Laboratories (TGA Australia Approved) |

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| | Me-too status | Onita Sachet by PharmEvo (Reg # 057746) |
| | GMP status | Inspection dated 04-05-2018 concluded that the firm has complied/ improved according to the directions of the FID. Panel was satisfied for the improvements undertaken by the firm to comply with the observations. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 464. | Name and address of manufacturer / Applicant | M/s Treat Pharmaceutical industry (Pvt) Ltd., A-37, Small Industrial Estate, Township Kohat Road, Bannu |
| | Brand Name +Dosage Form + Strength | Tremgine INJECTION |
| | Composition | Each ampoule contains:<br>Methylergometrine as maleate……..0.2mg |
| | Diary No. Date of R& I & fee | 1614, 11-01-2018, 20,000/-, 09-01-2018 |
| | Pharmacological Group | Uterotonics<br>ATC Code: G02AB01 |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1ml ampoule; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Methylergonovine Maleate Injection 0.2mg/ml (1ml) by American Regent, Inc, USFDA |
| | Me-too status | Ergomin Injection 0.2 mg (1ml) Reg # 066614 |
| | GMP status | Routine GMP inspection dated 06-11-2018 concluded, the firm may be considered to be operating at satisfactory level of cGMP compliance. |
| | Remarks of the Evaluator. | The label claim is not as per Reference product. Revision of Form-5 is required. |
| | **Decision: Deferred for revision of formulation and label claim as per the USFDA approved reference product.** | |
| 465. | Name and address of manufacturer / Applicant | M/s The Searle Company Limited, F-319 SITE, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | HEMONSTIL 500mg/10ml INJECTION |
| | Composition | Each 10ml injection contains:<br>Iron as Ferric Carboxymaltose……..500mg |
| | Diary No. Date of R& I & fee | 1793, 12-01-2018, 20,000/-, 11-01-2018 |
| | Pharmacological Group | Haematinic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1's x 10ml / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Injectafer 750 mg iron / 15 mL single-use vial by M/s Luitpold Pharms Inc (USFDA Approved) |
| | Me-too status | Ferinject 50mg/ml Injectable Vial (10ml) by M/s R.G Pharmaceutica (Reg#072548) |
| | GMP status | Copy of GMP certificate valid upto 05-2019, issued by Additional Director, DRAP, Karachi has been submitted. |
| | Remarks of the Evaluator. | • Label claim does not clarify quantity of iron in applied formulation is not as per Reference product.<br>• Evidence of 10 ml pack size in Reference Regulatory Authorities is required to be submitted. |
| | **Decision: Deferred for revision of formulation and label claim as per the USFDA approved reference product and Evidence of 10 ml pack size in Reference Regulatory Authorities is required to be submitted.** | |
| 466. | Name and address of manufacturer / Applicant | M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Sita-Met 50/850 Tablet |
| | Composition | Each film coated tablet contains:<br>Sitagliptin as phosphate monohydrate…….50mg<br>Metformin hydrochloride…….850mg |
| | Diary No. Date of R& I & fee | 1757, 12-01-2018, 20,000/-, 02-01-2018 |
| | Pharmacological Group | Anti-diabetic ATC Code: A10BD07 |

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| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 2 x 7's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | JANUMET Tablet 50 mg/850 mg by M/s Merck Sharp & Dohme (Australia) Pty Limited (TGA approved) |
| | Me-too status | S-Gliptin Plus 50mg+850mg Tablet of M/s Barrett Hodgson (Reg#081619) |
| | GMP status | Firm has submitted copy of GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved with innovator's specification.** | |
| 467. | Name and address of manufacturer / Applicant | M/s ZAFA Pharmaceutical Laboratories (Private) Ltd, L1/B Block-22 Federal B Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Padrone Injection 30mg |
| | Composition | Each 10ml vial contains:<br>Pamidronate Disodium……30mg |
| | Diary No. Date of R& I & fee | 1778, 12-01-2018, 20,000/-, 26-12-2017 |
| | Pharmacological Group | Bisphosphonates<br>ATC Code: M05BA03 |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Pamisol 30mg/10ml Injection vial of Hospira Australia (TGA approved) |
| | Me-too status | Pamidria 30 Sterile Freeze Dried Powder of M/s CIPLA Ltd (Reg#066117) |
| | GMP status | GMP certificate issued on the basis of inspection dated 03.01.2018. |
| | Remarks of the Evaluator. | • |
| | **Decision: Deferred for confirmation of requisite section (vial general ) for the applied product** | |
| 468. | Name and address of manufacturer / Applicant | M/s ZAFA Pharmaceutical Laboratories (Private) Ltd, L1/B Block-22 Federal B Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Padrone Injection 60mg |
| | Composition | Each 10ml vial contains:<br>Pamidronate Disodium……60mg |
| | Diary No. Date of R& I & fee | 1777, 12-01-2018, 20,000/-, 26-12-2017 |
| | Pharmacological Group | Bisphosphonates<br>ATC Code: M05BA03 |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Pamisol 60mg/10ml Injection vial of Hospira Australia (TGA approved) |
| | Me-too status | Pamidria 60 Sterile Freeze Dried Powder of M/s CIPLA Ltd (Reg#066118) |
| | GMP status | GMP certificate issued on the basis of inspection dated 03.01.2018. |
| | Remarks of the Evaluator. | • |
| | **Decision: Deferred for confirmation of requisite section (vial general ) for the applied product** | |
| 469. | Name and address of manufacturer / Applicant | M/s ZAFA Pharmaceutical Laboratories (Private) Ltd, L1/B Block-22 Federal B Industrial Area, Karachi. |
| | Brand Name +Dosage Form + Strength | Padrone Injection 90mg |
| | Composition | Each 10ml vial contains:<br>Pamidronate Disodium……90mg |
| | Diary No. Date of R& I & fee | 1779, 12-01-2018, 20,000/-, 26-12-2017 |
| | Pharmacological Group | Bisphosphonates<br>ATC Code: M05BA03 |
| | Type of Form | Form 5 |

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| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Pamisol 90mg/10ml Injection vial of Hospira Australia (TGA approved) |
| | Me-too status | Pamidria 90 Sterile Freeze Dried Powder of M/s CIPLA Ltd (Reg#066119) |
| | GMP status | GMP certificate issued on the basis of inspection dated 03.01.2018. |
| | Remarks of the Evaluator. | • |
| | **Decision: Deferred for confirmation of requisite section (vial general ) for the applied product** | |
| 470. | Name and address of manufacturer / Applicant | M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Telscot HCT Tablet |
| | Composition | Each film coated tablet contains:<br>Telmisartan…….40mg<br>Hydrochlorothiazide…….12.5mg |
| | Diary No. Date of R& I & fee | 2143, 16-01-2018, 20,000/-, 12-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Blocker/Thiazide Diuretic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's, 28's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Micardis HCT (USFDA approved) |
| | Me-too status | Misar-H 40/12.5 Tablets of 'Highnoon Laboratories, Lahore (Reg # 065688) |
| | GMP status | The panel recommended for the grant of GMP certificate based on inspection dated 14-09-2017 & 21-09-2017. |
| | Remarks of the Evaluator. | • The formulation is approved as bilyered tablet in reference country while applied formulation is single tablet. Clarification is required. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.** | |
| 471. | Name and address of manufacturer / Applicant | M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Telscot HCT Tablet |
| | Composition | Each film coated tablet contains:<br>Telmisartan…….80mg<br>Hydrochlorothiazide…….12.5mg |
| | Diary No. Date of R& I & fee | 2141, 16-01-2018, 20,000/-, 12-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Blocker/Thiazide Diuretic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's, 28's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Micardis HCT (USFDA approved) |
| | Me-too status | Misar-H 80/12.5 Tablets of M/s Highnoon Laboratories, Lahore. (Reg # 065685) |
| | GMP status | The panel recommended for the grant of GMP certificate based on inspection dated 14-09-2017 & 21-09-2017. |
| | Remarks of the Evaluator. | • The formulation is approved as bilyered tablet in reference country while applied formulation is single tablet. Clarification is required. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.** | |
| 472. | Name and address of manufacturer / Applicant | M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad |
| | Brand Name +Dosage Form + Strength | Telscot HCT Tablet |

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| | Composition | Each film coated tablet contains:<br>Telmisartan…….80mg<br>Hydrochlorothiazide…….25mg |
| | Diary No. Date of R& I & fee | 2142, 16-01-2018, 20,000/-, 12-01-2018 |
| | Pharmacological Group | Angiotensin II Receptor Blocker/Thiazide Diuretic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's, 28's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Micardis HCT (USFDA approved) |
| | Me-too status | Misar-H 80/25 Tablets of M/s Highnoon Laboratories, Lahore. (Reg # 065685) |
| | GMP status | The panel recommended for the grant of GMP certificate based on inspection dated 14-09-2017 & 21-09-2017. |
| | Remarks of the Evaluator. | • The formulation is approved as bilyered tablet in reference country while applied formulation is single tablet. Clarification is required. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.** | |
| 473. | Name and address of manufacturer / Applicant | M/s Brookes Pharma (Private) Limited, 58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Misonil 75 Tablets |
| | Composition | Each tablet contains:<br>Diclofenac sodium……..75mg<br>Misoprostol (HPMC dispersion 1%)……..200mcg |
| | Diary No. Date of R& I & fee | 2142, 16-01-2018, 20,000/-, 12-01-2018 |
| | Pharmacological Group | NSAID with prostaglandin analogue |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 20's; As per brand leader price |
| | Approval status of product in Reference Regulatory Authorities. | Arthrotec 75 of GD Searle (USFDA approved) |
| | Me-too status | Cytopan-75 Tablets by Getz Pharma (Reg#024014) |
| | GMP status | GMP inspection dated 11-10-2017 and 16-10-2017 concluded that the firm is considered to be operating at satisfactory level of compliance. |
| | Remarks of the Evaluator. | • Master formulation shows that the tablet consists of an enteric coated core containing 75mg of diclofenac sodium surrounded by an outer mantle containing 200mcg misoprostol. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is multilayered tablet, while the applied drug is mono layered tablet and submission of double layer compression machine.** | |
| 474. | Name and address of manufacturer / Applicant | M/s Brookes Pharma (Private) Limited, 58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Glucomin SR 2mg/500mg Tablet |
| | Composition | Each bilayered tablet contains:<br>Glimepiride……..2 mg<br>Metformin hydrochloride (as sustained release)….500 mg |
| | Diary No. Date of R& I & fee | 1886, 13-01-2018, 20,000/-, 05-01-2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drug |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 3 × 10's; As per brand leader price |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Amaryl M SR tablet of Sanofi Aventis |

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| | GMP status | GMP inspection dated 11-10-2017 and 16-10-2017 concluded that the firm is considered to be operating at satisfactory level of compliance. |
| | Remarks of the Evaluator. | • Evidence of approval in reference regulatory authority could not be verified. |
| | **Decision: Deferred for following:**<br>**Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 475. | Name and address of manufacturer / Applicant | M/s Brookes Pharma (Private) Limited, 58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Glucomin SR 1mg/500mg Tablet |
| | Composition | Each bilayered tablet contains:<br>Glimepiride……..1 mg<br>Metformin hydrochloride (as sustained release)….500 mg |
| | Diary No. Date of R& I & fee | 1885, 13-01-2018, 20,000/-, 05-01-2018 |
| | Pharmacological Group | Combinations of oral blood glucose lowering drug |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 3 × 10's; As per brand leader price |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Amaryl M SR tablet of Sanofi Aventis |
| | GMP status | GMP inspection dated 11-10-2017 and 16-10-2017 concluded that the firm is considered to be operating at satisfactory level of compliance. |
| | Remarks of the Evaluator. | • Evidence of approval in reference regulatory authority could not be verified. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 476. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceutical Industries (Pvt.) Ltd, Plot # 108, R:2 Industrial Estate Gadoon Swabi, KPK |
| | Brand Name +Dosage Form + Strength | MONTIMED TABLET 5mg |
| | Composition | Each film coated tablet contains:<br>Montelukast sodium……5mg |
| | Diary No. Date of R& I & fee | 4832, 05-06-2017, 20,000/-, 31-05-2017 |
| | Pharmacological Group | Leukotriene receptor antagonist |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1 × 10's; As per DRAP policy |
| | Approval status of product in Reference Regulatory Authorities. | Montelukast Hexal 5mg Chewable Tablets (MHRA) |
| | Me-too status | Montekast 5mg tablet of M/s Global pharmaceutical |
| | GMP status | • Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator. | Master formulation shows film coating while reference product is chewable tablet. Clarification is required.\<br>Label claim is not as per reference product. |
| | **Decision: Deferred for clarification of manufacturing outline as in reference regulatory authorities the approved drug is chewable tablet, while the applied drug is film coated tablet.** | |
| 477. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceutical Industries (Pvt.) Ltd, Plot # 108, R:2 Industrial Estate Gadoon Swabi, KPK |
| | Brand Name +Dosage Form + Strength | WELFINE TABLET |
| | Composition | Each film coated tablet contains:<br>Terbinafine as Hydrochloride……250mg |

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| | Diary No. Date of R& I & fee | 4826, 05-06-2017, 20,000/-, 31-05-2017 |
| | Pharmacological Group | Allylamine antifungal |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1 × 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Neoterbin Tablets 250mg by M/s Neomedix (Reg# 081411) |
| | GMP status | • Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 478. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceutical Industries (Pvt.) Ltd, Plot # 108, R:2 Industrial Estate Gadoon Swabi, KPK |
| | Brand Name +Dosage Form + Strength | WELFENAC TABLET |
| | Composition | Each film coated tablet contains:<br>Aceclofenac……..100mg |
| | Diary No. Date of R& I & fee | 4835, 05-06-2017, 20,000/-, 02-06-2017 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1 × 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Aclofen Tablets by M/s Alliance Pharma, (Reg.# 068419) |
| | GMP status | • Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications.** | |
| 479. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceutical Industries (Pvt.) Ltd, Plot # 108, R:2 Industrial Estate Gadoon Swabi, KPK |
| | Brand Name +Dosage Form + Strength | Lormed 8mg Tablet |
| | Composition | Each film coated tablet contains:<br>Lornoxicam ……..8mg |
| | Diary No. Date of R& I & fee | 4827, 05-06-2017, 20,000/-, 31-05-2017 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1 × 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Acabel 8 mg film-coated tablets by Grünenthal Pharma, S.A. (Spanish agency of medicine and sanitary products) |
| | Me-too status | Zafon 8mg Tablet by Getz Pharma (Reg# 058589) |
| | GMP status | • Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |

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| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications.** | |
| 480. | Name and address of manufacturer / Applicant | M/s Paramount Pharmaceuticals, Plot no. 36, Industrial triangle, kahuta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | ALLERSAFE Tablet |
| | Composition | Each film coated tablet contains:<br>Montelukast sodium eq. to Montelukast ……..10mg<br>Ebastine……10mg |
| | Diary No. Date of R& I & fee | 1870, 15-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Leukotriene receptor antagonist<br>H1 Antihistamine |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 2 × 7's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Not confirmed. |
| | GMP status | Last GMP inspection was Conducted on 20-11-2018 with conclusive remarks as under:<br>"Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations since there is an immense need for revamping of unit/facility. The panel further advised to stop all production activity in the unit including in Cephalosporin area for at least one month for the purpose of CAPA with regards to above observations and submit a compliance report" |
| | Remarks of the Evaluator. | • Evidence of applied formulation already approved by DRAP/DCO is required to be submitted.<br>• Evidence of approval of applied formulation in reference regulatory authority is required to be submitted. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>• **Latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status.** | |
| 481. | Name and address of manufacturer / Applicant | M/s Paramount Pharmaceuticals, Plot no. 36, Industrial triangle, kahuta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | ALLER-D Tablet |
| | Composition | Each film coated tablet contains:<br>Montelukast sodium eq. to Montelukast……..10mg<br>Doxofylline……..400mg |
| | Diary No. Date of R& I & fee | 1871, 15-01-2018, 20,000/-, 10-01-2018 |
| | Pharmacological Group | Leukotriene receptor antagonist<br>Xanthine Derivative |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 1 × 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Not confirmed. |
| | GMP status | Last GMP inspection was Conducted on 20-11-2018 with conclusive remarks as under:<br>"Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above |

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| | | said observations since there is an immense need for revamping of unit/facility. The panel further advised to stop all production activity in the unit including in Cephalosporin area for at least one month for the purpose of CAPA with regards to above observations and submit a compliance report" |
| | Remarks of the Evaluator. | • Evidence of applied formulation already approved by DRAP/DCO is required to be submitted.<br>• Evidence of approval of applied formulation in reference regulatory authority is required to be submitted. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>• **Latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status.** | |
| 482. | Name and address of manufacturer / Applicant | M/s Paramount Pharmaceuticals, Plot no. 36, Industrial triangle, kahuta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Dolex Forte Tablets |
| | Composition | Each film coated tablet contains:<br>Paracetamol……650mg<br>Orphenadrine citrate…….50mg |
| | Diary No. Date of R& I & fee | 223, 14-11-2016, 20,000/-, 14-11-2016 |
| | Pharmacological Group | Analgesic muscle relaxant |
| | 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. | Pleren Plus Tablets of pharma lab , Peru |
| | Me-too status | Nuberol Forte tablets of M/s Searle |
| | GMP status | Last GMP inspection was Conducted on 20-11-2018 with conclusive remarks as under:<br>"Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations since there is an immense need for revamping of unit/facility. The panel further advised to stop all production activity in the unit including in Cephalosporin area for at least one month for the purpose of CAPA with regards to above observations and submit a compliance report" |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation in reference regulatory authority is required to be submitted. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Moreover firm was directed to submit latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status** | |
| 483. | Name and address of manufacturer / Applicant | M/s Paramount Pharmaceuticals, Plot no. 36, Industrial triangle, kahuta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Fibrate 67mg Capsules |
| | Composition | Each capsule contains:<br>Fenofibrate……67mg |
| | Diary No. Date of R& I & fee | 205, 14-11-2016, 20,000/-, 14-11-2016 |
| | Pharmacological Group | Lipid modifying agents<br>ATC code: C10AB05 |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | Fenofibrate 67 mg capsules by Actavis UK Limited. MHRA approved |
| | Me-too status | Lipidof 67 Capsule by ACME LABORATORIES PAKISTAN (PVT) LTD. (Reg. No. 33164) |
| | GMP status | Last GMP inspection was Conducted on 20-11-2018 with conclusive remarks as under:<br>"Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations since there is an immense need for revamping of unit/facility. The panel further advised to stop all production activity in the unit including in Cephalosporin area for at least one month for the purpose of CAPA with regards to above observations and submit a compliance report" |
| | Remarks of the Evaluator. | |
| | **Decision:Deferred for latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status** | |
| 484. | Name and address of manufacturer / Applicant | M/s Paramount Pharmaceuticals, Plot no. 36, Industrial triangle, kahuta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Fibrate 200mg Capsules |
| | Composition | Each capsule contains:<br>Fenofibrate……200mg |
| | Diary No. Date of R& I & fee | 226, 14-11-2016, 20,000/-, 14-11-2016 |
| | Pharmacological Group | Lipid modifying agents<br>ATC code: C10AB05 |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Fenofibrate 200mg capsules by Rhodes Pharms. US-FDA approved |
| | Me-too status | Felip 200mg Capsule by Bosch Pharmaceuticals (Pvt) Ltd. Reg. No. 55918 |
| | GMP status | Last GMP inspection was Conducted on 20-11-2018 with conclusive remarks as under:<br>"Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations since there is an immense need for revamping of unit/facility. The panel further advised to stop all production activity in the unit including in Cephalosporin area for at least one month for the purpose of CAPA with regards to above observations and submit a compliance report" |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status. Moreover firm was directed to submit latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status** | |
| 485. | Name and address of manufacturer / Applicant | M/s Paramount Pharmaceuticals, Plot no. 36, Industrial triangle, kahuta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Dutine 60mg Capsules |
| | Composition | Each capsule contains:<br>Duloxetine as Hydrochloride (EC pellets 20%)……..60mg |
| | Diary No. Date of R& I & fee | 222, 14-11-2016, 20,000/-, 14-11-2016 |
| | Pharmacological Group | Antidepressants ATC code: N06AX21 |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1 × 10's; As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Dulan (Duloxetine 60 mg capsule) by M/s Hilton Pharma.(Reg#055448) |
| | GMP status | Last GMP inspection was Conducted on 20-11-2018 with conclusive remarks as under:<br>"Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations since there is an immense need for revamping of unit/facility. The panel further advised to stop all production activity in the unit including in Cephalosporin area for at least one month for the purpose of CAPA with regards to above observations and submit a compliance report" |
| | Remarks of the Evaluator. | Source of pellets is required to be submitted. |
| | **Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. Moreover firm was directed to submit latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status** | |
| 486. | Name and address of manufacturer / Applicant | M/s Paramount Pharmaceuticals, Plot no. 36, Industrial triangle, kahuta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Dutine 30mg Capsules |
| | Composition | Each capsule contains:<br>Duloxetine as Hydrochloride (EC pellets) …….. 30mg |
| | Diary No. Date of R& I & fee | 224, 14-11-2016, 20,000/-, 14-11-2016 |
| | Pharmacological Group | Antidepressants<br>ATC code: N06AX21 |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1 × 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Dulan (Duloxetine 30mg capsule) by M/s Hilton Pharma. (Reg#055447) |
| | GMP status | Last GMP inspection was Conducted on 20-11-2018 with conclusive remarks as under:<br>"Keeping in view the observations noticed during inspection as narrated above, the panel is of the opinion not to recommend the GMP certificate till the rectification of above said observations since there is an immense need for revamping of unit/facility. The panel further advised to stop all production activity in the unit including in Cephalosporin area for at least one month for the purpose of CAPA with regards to above observations and submit a compliance report" |
| | Remarks of the Evaluator. | Source of pellets is required to be submitted. |
| | **Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. Moreover firm was directed to submit latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status.** | |
| 487. | Name and address of manufacturer / Applicant | M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post office Dahgal, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Medrogest Injectable Suspension |
| | Composition | Each 1ml contains:<br>Medroxyprogesterone Acetate……..150mg |
| | Diary No. Date of R& I & fee | 756, 02-09-2016, 20,000/-, 26-08-2016 |
| | Pharmacological Group | Depot Progestogen |
| | Type of Form | Form-5 |

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| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1ml vial ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Depo-Provera 150 mg/ml by Pfizer Limited (MHRA Approved) |
| | Me-too status | Medroxy Depo Injection by Global Pharma |
| | GMP status | Last GMP inspection was conducted on 14-12-2017 and the report concludes issuance of GMP certificate for export purpose. |
| | Remarks of the Evaluator. | The firm has provided Liquid injection ampoule (hormone) section.<br>Evidence of approval in vial section is required. |
| | **Decision: Deferred for confirmation of requisite section (Vial section) for the applied product** | |
| 488. | Name and address of manufacturer / Applicant | M/s Candid Pharmaceuticals Opposite pusrur sugar mills Sialkot Road, Pasrur |
| | Brand Name +Dosage Form + Strength | KALFEN TABLET 50mg |
| | Composition | Each film coated tablet contains:<br>Diclofenac potassium……50mg |
| | Diary No. Date of R& I & fee | 1904, 08-05-2017, 20,000/-, 24-04-2017 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 2 × 10's; Rs. 98.00/- |
| | Approval status of product in Reference Regulatory Authorities. | Diclofenac Potassium 50 mg Tablets (film-coated ) by Accord Healthcare Limited Dexcel®-Pharma Ltd. (MHRA approved) |
| | Me-too status | Arnil-P 50mg Tablet by Brookes Pharma, Karachi. (Reg # 82129) |
| | GMP status | Inspection Report dated 15-12-2016 which concludes that firm was found to be operating at a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division** | |
| 489. | Name and address of manufacturer / Applicant | M/s Aries Pharmaceuticals, 1-W, Industrial Estate, Hayatabad Peshawar, KPK |
| | Brand Name +Dosage Form + Strength | FLAGYZOLE Oral Suspension |
| | Composition | Each 5ml contains:<br>Metronidazole (as Benzoate)…….75mg<br>Furazolidone……25mg |
| | Diary No. Date of R& I & fee | 699, 26-04-2017, 20,000/-, 26-04-2017 |
| | Pharmacological Group | Amebicide |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 90ml; Rs. 34.00/- |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too status | Dependal-M suspension of M/s GSK Pharma |
| | GMP status | Firm has submitted GMP inspection report dated 4-6-2018 confirming satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 490. | Name and address of manufacturer / Applicant | M/s Tayyab laboratories Pvt. Ltd. Plot # 13-A, Street N-5, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | DOXIVA SYRUP |
| | Composition | Each 5ml contains:<br>Doxofylline……..100mg |
| | Diary No. Date of R& I & fee | 2984, 19-12-2016, 20,000/-, 15-12-2016 |
| | Pharmacological Group | Xanthines<br>ATC code: R03DA11 |
| | Type of Form | Form-5 |

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| | Finished product Specification | In-house |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in Italy |
| | Me-too status | Agolix 100mg/5ml syrup of Hiranis Pharmaceuticals(Reg No. 067129) |
| | GMP status | Routine GMP inspection conducted on 23-10-2017 concluded that overall GMP compliance is good. |
| | Remarks of the Evaluator. | |
| | **Decision: Defered for change in title and submission of fee with revised form 5 .** | |
| 491. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | Zareka 400mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Linezolid……400mg |
| | Diary No. Date of R& I & fee | Dy. No. 4013, 01-02-2018, Rs. 20,000/- 31-01-2018 |
| | Pharmacological Group | Other antibacterials |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox 400 mg film-coated tablets by Pharmacia Limited (USFDA Approved and discontinued but for reasons other than safety and efficacy as per USFDA website) |
| | Me-too status | Linzor 400mg Tablets by Hilton Pharma |
| | GMP status | GMP inspection conducted on 07-09-2017 concluded that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 492. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | Zareka 600mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Linezolid……..600mg |
| | Diary No. Date of R& I & fee | Dy. No. 4014, 01-02-2018, Rs. 20,000/- 31-01-2018 |
| | Pharmacological Group | Other Antibacterials |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox 600 mg film-coated tablets by Pharmacia Limited (MHRA Approved) |
| | Me-too status | Zyvox Tablets 600mg by Pharmacia (Reg# 028440) |
| | GMP status | GMP inspection conducted on 07-09-2017 concluded that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 493. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | Zareka 100mg/5ml Suspension |
| | Composition | Each 5ml Contains:<br>Linezolid……100mg |
| | Diary No. Date of R& I & fee | Dy. No. 4015, 01-02-2018, Rs. 20,000/- 31-01-2018 |
| | Pharmacological Group | Other antibacterials |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 60ml; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zyvox Dry Suspension by Pharmacia (USFDA Approved) |

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| | Me-too status | Nezolid 100mg Suspension by Searle (Reg# 050326) |
| | GMP status | GMP inspection conducted on 07-09-2017 concluded that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as reference product is as dry suspension.** | |
| 494. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | Teramic 100mg Capsule |
| | Composition | Each Capsule Contains:<br>Itraconazole……..100mg |
| | Diary No. Date of R& I & fee | Dy. No. 4010, 01-02-2018, Rs. 20,000/- 31-01-2018 |
| | Pharmacological Group | Anti-fungal |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Mukil Capsule 100mg of M/s. Dyson Research Laboratories (Pvt) Ltd (Reg.# 055356) |
| | GMP status | GMP inspection conducted on 07-09-2017 concluded that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator. | Source of pellets: M/s Vision Pharma |
| | **Decision: Approved with innovator's specification.** | |
| 495. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | Omiloc 20mg Capsule |
| | Composition | Each Capsule Contains:<br>Omeprazole (as enteric coated pellets)……..20mg |
| | Diary No. Date of R& I & fee | Dy. No. 4011, 01-02-2018, Rs. 20,000/- 31-01-2018 |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specification |
| | Pack size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Jumep -20 Capsule of M/s Jupiter Pharma |
| | GMP status | GMP inspection conducted on 07-09-2017 concluded that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator. | Source of pellets: M/s Vision Pharma |
| | **Decision: Approved.** | |
| 496. | Name and address of manufacturer / Applicant | M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi. |
| | Brand Name +Dosage Form + Strength | Omiloc 40mg Capsule |
| | Composition | Each Capsule Contains:<br>Omeprazole (as enteric coated pellets)……..40mg |
| | Diary No. Date of R& I & fee | Dy. No. 4012, 01-02-2018, Rs. 20,000/- 31-01-2018 |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Jumep-40 Capsule of M/s Jupiter Pharma |

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| | GMP status | GMP inspection conducted on 07-09-2017 concluded that the firm was considered to be operating at satisfactory compliance with GMP guideline |
| | Remarks of the Evaluator. | Source of pellets: M/s Vision Pharma |
| | **Decision:Approved** | |
| 497. | Name and address of manufacturer / Applicant | M/s Honig Pharmaceuticals Laboratories. 14-km, Adyala Road, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Procyl Tablets |
| | Composition | Each Tablet Contains:<br>Piroxicam Beta Cyclodextrin……..…20mg |
| | Diary No. Date of R& I & fee | Dy.No 4172, 02-02-2018, Rs. 20,000/-, 02-02-2018 |
| | Pharmacological Group | Oxicams |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | BREXIN 20 mg scored tablet by Pierre Fabre Medicament (ANSM Approved) |
| | Me-too status | Brexin Tablets 20mg by Chiesi (Reg#10637) |
| | GMP status | Inspection report 21-12-2017 The panel unanimously recommended for the renewal of DML. |
| | Remarks of the Evaluator. | The label claim is not as per Reference product. |
| | **Decision: Deferred for revision of formulation and label claim as per the reference regulatory authority approved reference product.** | |
| 498. | Name and address of manufacturer / Applicant | M/s Saturn Pharmaceuticals. 23-km Thokar Raiwind Road, Lahore contract manufactured by M/s Synchro Pharmaceuticals., 77-Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Satizime 250mg IM Injection |
| | Composition | Each vial Contains:<br>Ceftriaxone as Sodium……250mg |
| | Diary No. Date of R& I & fee | Dy.No. 4109, 01-02-2018, Rs. 50,000/-, 01-02-2018 |
| | Pharmacological Group | Third generation Cephalosporin |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 250mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved |
| | Me-too status | Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556 |
| | GMP status | Panel inspection of M/s Synchro Pharma dated 29-03-2016 recommended for renewal of DML.<br>M/s Synchro pharma has provided Dry Powder For Injectable Cephalosporin section.<br>Panel inspection of M/s Saturn pharma dated 16-02-2018 concluded that the firm now seems complied with cGMP at satisfactory level, hence the panel was of the opinion that the firm may be allowed for resumption of production. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Synchro Pharmaceuticals, Industrial Lahore by panel for further granting contract manufacturing permission.** | |
| 499. | Name and address of manufacturer / Applicant | M/s Saturn Pharmaceuticals. 23-km Thokar Raiwind Road, Lahore contract manufactured by M/s Synchro Pharmaceuticals., 77-Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Satizime 500mg IM Injection |
| | Composition | Each vial Contains:<br>Ceftriaxone as Sodium…500mg |
| | Diary No. Date of R& I & fee | Dy.No. 4110, 01-02-2018, Rs. 50,000/-, 01-02-2018 |
| | Pharmacological Group | Third generation Cephalosporin |
| | Type of Form | Form-5 |

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| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 500mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved |
| | Me-too status | Wincef 500 mg (Ceftriaxone sodium) IM injection by Wnsfeild Pharmaceuticals. Reg. No. 68371 |
| | GMP status | Panel inspection of M/s Synchro Pharma dated 29-03-2016 recommended for renewal of DML.<br>M/s Synchro pharma has provided Dry Powder For Injectable Cephalosporin section.<br>Panel inspection of M/s Saturn pharma dated 16-02-2018 concluded that the firm now seems complied with cGMP at satisfactory level, hence the panel was of the opinion that the firm may be allowed for resumption of production. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Synchro Pharmaceuticals, Industrial Lahore by panel for further granting contract manufacturing permission.** | |
| 500. | Name and address of manufacturer / Applicant | M/s Saturn Pharmaceuticals. 23-km Thokar Raiwind Road, Lahore contract manufactured by M/s Synchro Pharmaceuticals., 77-Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Satizime 1g IV Injection |
| | Composition | Each vial Contains:<br>Ceftriaxone as Sodium…1.0gm |
| | Diary No. Date of R& I & fee | Dy.No. 4111, 01-02-2018, Rs. 50,000/-, 01-02-2018 |
| | Pharmacological Group | Third generation Cephalosporin |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 1 g (IV) by Lupin Pharmaceuticals Inc. US-FDA approved |
| | Me-too status | Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection by Alkemy Pharma. Reg. No. 70663 |
| | GMP status | Panel inspection of M/s Synchro Pharma dated 29-03-2016 recommended for renewal of DML.<br>M/s Synchro pharma has provided Dry Powder For Injectable Cephalosporin section.<br>Panel inspection of M/s Saturn pharma dated 16-02-2018 concluded that the firm now seems complied with cGMP at satisfactory level, hence the panel was of the opinion that the firm may be allowed for resumption of production. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Synchro Pharmaceuticals, Industrial Lahore by panel for further granting contract manufacturing permission.** | |
| 501. | Name and address of manufacturer / Applicant | M/s Saturn Pharmaceuticals. 23-km Thokar Raiwind Road, Lahore contract manufactured by M/s Synchro Pharmaceuticals., 77-Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Satofer 100mg/5ml Suspension |
| | Composition | Each 5ml Contains:<br>Cefixime Trihydrate eq. to Cefixime……100mg |
| | Diary No. Date of R& I & fee | Dy.No. 4107, 01-02-2018, Rs. 50,000/-, 01-02-2018 |
| | Pharmacological Group | Third generation Cephalosporin |
| | Type of Form | Form-5 |
| | Finished product Specification | USP Specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Stlicef Dry Suspension 100mg/5ml of Treat Pharma |

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| | GMP status | Panel inspection of M/s Synchro Pharma dated 29-03-2016 recommended for renewal of DML.<br>M/s Synchro pharma has provided Dry Powder For Injectable Cephalosporin section.<br>Panel inspection of M/s Saturn pharma dated 16-02-2018 concluded that the firm now seems complied with cGMP at satisfactory level, hence the panel was of the opinion that the firm may be allowed for resumption of production. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Synchro Pharmaceuticals, Industrial Lahore by panel for further granting contract manufacturing permission.** | |
| 502. | Name and address of manufacturer / Applicant | M/s Saturn Pharmaceuticals. 23-km Thokar Raiwind Road, Lahore contract manufactured by M/s Synchro Pharmaceuticals., 77-Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Satofer 200mg/5ml Suspension |
| | Composition | Each 5ml Contains:<br>Cefixime Trihydrate eq. to Cefixime……200mg |
| | Diary No. Date of R& I & fee | Dy.No. 4108, 01-02-2018, Rs. 50,000/-, 01-02-2018 |
| | Pharmacological Group | Third generation Cephalosporin |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Stlicef Dry Suspension 200mg/5ml of Treat Pharma |
| | GMP status | Panel inspection of M/s Synchro Pharma dated 29-03-2016 recommended for renewal of DML.<br>M/s Synchro pharma has provided Dry Powder For Injectable Cephalosporin section.<br>Panel inspection of M/s Saturn pharma dated 16-02-2018 concluded that the firm now seems complied with cGMP at satisfactory level, hence the panel was of the opinion that the firm may be allowed for resumption of production. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Synchro Pharmaceuticals, Industrial Lahore by panel for further granting contract manufacturing permission.** | |
| 503. | Name and address of manufacturer / Applicant | M/s Saturn Pharmaceuticals. 23-km Thokar Raiwind Road, Lahore contract manufactured by M/s Synchro Pharmaceuticals., 77-Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Satocap 400mg Capsule |
| | Composition | Each Capusle Contains:<br>Cefixime as Trihydrate……..400mg |
| | Diary No. Date of R& I & fee | Dy.No. 4106, 01-02-2018, Rs. 50,000/-, 01-02-2018 |
| | Pharmacological Group | Third generation Cephalosporin |
| | Type of Form | Form-5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | SUPRAX 400mg capsules by M/s Lupin Pharma (USFDA Approved) |
| | Me-too status | Soxime Capsule 400 mg by Swat Pharmaceuticals (Reg#060128) |
| | GMP status | Panel inspection of M/s Synchro Pharma dated 29-03-2016 recommended for renewal of DML.<br>M/s Synchro pharma has provided Dry Powder For Injectable Cephalosporin section.<br>Panel inspection of M/s Saturn pharma dated 16-02-2018 concluded that the firm now seems complied with cGMP at |

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| | | satisfactory level, hence the panel was of the opinion that the firm may be allowed for resumption of production. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Synchro Pharmaceuticals, Industrial Lahore by panel for further granting contract manufacturing permission.** | |
| 504. | Name and address of manufacturer / Applicant | M/s Weatherfolds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Nitza 500mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Nitazoxanide……..…500mg |
| | Diary No. Date of R& I & fee | Dy.No 4178, 02-02-2018, Rs. 20,000/-, 02-02-2018 |
| | Pharmacological Group | Agents against amoebiasis and other protozoal diseases |
| | 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. | ALINIA® (nitazoxanide) film-coated tablets, for oral use by Romark L.C. US-FDA approved |
| | Me-too status | Trinide 500mg Tablet by Ferozsons Laboratories Ltd. Reg. No. 80594 |
| | GMP status | GMP inspection conducted on 15-09-2017 concluded that overall the firm was GMP compliant as per DRAP guidelines |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 505. | Name and address of manufacturer / Applicant | M/s Weatherfolds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Mebifold SR 200mg Capsule |
| | Composition | Each Modified Release Capsule Contains:<br>Mebeverine HCl……..200mg |
| | Diary No. Date of R& I & fee | Dy.No 4177, 02-02-2018, Rs. 20,000/-, 02-02-2018 |
| | Pharmacological Group | Anti-spasmodic |
| | 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. | Mebeverine 200 mg modified release capsules of Aspire pharma, UK (MHRA approved) |
| | Me-too status | Despas MR Capsule of S.J&G Fazul Ellahie, Karachi |
| | GMP status | GMP inspection conducted on 15-09-2017 concluded that overall the firm was GMP compliant as per DRAP guidelines |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** | |
| 506. | Name and address of manufacturer / Applicant | M/s Weatherfolds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Artham 30+180 mg/5ml Suspension |
| | Composition | Each 5ml Contains:<br>Artemether……30mg<br>Lumefantrine……..…180mg |
| | Diary No. Date of R& I & fee | Dy.No 4176, 02-02-2018, Rs. 20,000/-, 02-02-2018 |
| | Pharmacological Group | Anti-malarial |
| | 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. | Could not be confirmed |
| | Me-too status | Arceva-DS Dry Suspension by Sami Pharmaceuticals |
| | GMP status | GMP inspection conducted on 15-09-2017 concluded that overall the firm was GMP compliant as per DRAP guidelines |
| | Remarks of the Evaluator. | |

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| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 507. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Chicowin 4mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Thiocolchicoside…4mg |
| | Diary No. Date of R& I & fee | Dy.No 4183, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Skeletal muscle relaxant |
| | 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. | ANSM approved |
| | Me-too status | Myolax tablet of Reko Pharma (Reg#074170) |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | Applied formulation is Film coated while reference formulation is uncoated tablet. |
| | **Decision: Deferred for the clarification of manufacturing outline as in reference regulatory authorities the approved drug is uncoated tablet, while the applied drug is film coated tablet** | |
| 508. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Betawin 8mg Tablet |
| | Composition | Each Uncoated Tablet Contains:<br>Betahistine Dihydrochloride……8mg |
| | Diary No. Date of R& I & fee | Dy.No 4184, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Anti-Vertigo |
| | 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 | VR-Tigo Tablets 8mg by Himont Pharma (Reg#079703) |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 509. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Meb Plus 135mg/3.5g Sachet |
| | Composition | Each Sachet Contains:<br>Mebeverine HCl……135mg<br>Ispaghula Husk……3.5g |
| | Diary No. Date of R& I & fee | Dy.No 4185, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Antispasmodics/Laxatives |
| | 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. | Fybogel Mebeverine effervescent granules by M/s Reckitt Benckiser Healthcare (UK) Ltd. (MHRA approved) |
| | Me-too status | Colospas Fibro 135mg/3.5g powder by M/s Nabiqasim. (R#058672) |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 510. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |

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|---|---|---|
| | Brand Name +Dosage Form + Strength | Terbilet 250mg Tablet |
| | Composition | Each Uncoated Tablet Contains:<br>Terbinafine as Hydrochloride……250mg |
| | Diary No. Date of R& I & fee | Dy.No 4182, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Anti-fungal |
| | 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. | Approved by MHRA of UK |
| | Me-too status | Neoterbin Tablets 250mg by M/s Neomedix (Reg# 081411) |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 511. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Varox 15mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Rivaroxaban……15mg |
| | Diary No. Date of R& I & fee | Dy.No 4186, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Factor Xa inhibitor |
| | 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. | Rivaroxaban 15 mg film-coated tablets by Milpharm Limited. MHRA approved |
| | Me-too status | Rivaxo 15mg film-coated Tablet by Getz Pharma Reg.#80790 |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 512. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Varox 20mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Rivaroxaban……20mg |
| | Diary No. Date of R& I & fee | Dy.No 4187, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Factor Xa inhibitor |
| | 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. | Rivaroxaban 20 mg film-coated tablets by Milpharm Limited. MHRA approved |
| | Me-too status | Rivaxo 20mg film-coated Tablet by Getz Pharma Reg.#80791 |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 513. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Nebiwin 2.5mg Tablet |
| | Composition | Each Uncoated Tablet Contains:<br>Nebivolol as Hydrochloride……2.5mg |
| | Diary No. Date of R& I & fee | Dy.No 4188, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Beta blocking agents, selective<br>ATC Code: C07AB12 |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |

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| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Bystolic (uncoated)<br>USFDA Approved |
| | Me-too status | Nebix 2.5mg tablet by Highnoon |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 514. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Nebiwin 5mg Tablet |
| | Composition | Each Uncoated Tablet Contains:<br>Nebivolol as Hydrochloride……..5mg |
| | Diary No. Date of R& I & fee | Dy.No 4189, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Beta blocking agents, selective ATC Code: C07AB12 |
| | 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. | Approved by USFDA |
| | Me-too status | Nebix 5mg Tablets of M/s. Highnoon (Reg#062777) |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 515. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals., Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Nebiwin 10mg Tablet |
| | Composition | Each Uncoated Tablet Contains:<br>Nebivolol as Hydrochloride……..10mg |
| | Diary No. Date of R& I & fee | Dy.No 4190, 02-02-2018, Rs. 20,000/-, 30-01-2018 |
| | Pharmacological Group | Beta blocking agents, selective<br>ATC Code: C07AB12 |
| | 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. | Bystolic Of (USFDA Approved) |
| | Me-too status | Nabilox 10mg Tablet of M/s Nabiqasim |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 516. | Name and address of manufacturer / Applicant | M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | Doxowin 400mg Tablet |
| | Composition | Each uncoated tablet contains:<br>Doxofylline……..…400mg |
| | Diary No. Date of R& I & fee | Dy.No 4463, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Other Systemic Drugs for Obstructive Airway Diseases (Xanthines) |
| | 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. | DOXOFILLINA ABC 400mg tablet by M/s ABC FARMACEUTICI S.p.A (Italian Medicine Agency approved) |
| | Me-too status | Profylline Tablet 400mg by M/s Kaizen (Reg# 073744) |
| | GMP status | Last GMP Inspection conducted on 18-1-2018 in which panel recommended the renewal of DML. |

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| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 517. | Name and address of manufacturer / Applicant | M/s Usawa Pharmaceuticals.<br>146 S.I.Z. Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | U-Zolid 600mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Linezolid……..600mg |
| | Diary No. Date of R& I & fee | Dy.No 4306, 06-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Other antibacterials |
| | 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. | Zyvox 600 mg film-coated tablets by Pharmacia Limited (MHRA Approved) |
| | Me-too status | Zyvox Tablets 600mg by Pharmacia (Reg# 028440) |
| | GMP status | The firm was issued GMP certificate based on inspection conducted on 08-12-2017. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 518. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd., Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Cepmol Extra Tablet |
| | Composition | Each tablet Contains:<br>Paracetamol……500mg<br>Caffeine……..65mg |
| | Diary No. Date of R& I & fee | Dy.No 4302, 06-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Analgesic combination |
| | 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. | Paracetamol Extra Tablets of Wrafton Laboratories Limited, UK (MHRA approved) |
| | Me-too status | Acetofeb Extra Tablets of M/s Vision Pharmaceuticals (Reg.#038900) |
| | GMP status | Panel inspection dated 06-11-2018 recommended for renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 519. | Name and address of manufacturer / Applicant | M/s Brookes Pharma Pvt Ltd., 58 & 59, Sector 15, Korangi Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Pantopep 40mg Tablets |
| | Composition | Each Enteric Coated Tablet Contains:<br>Pantoprazoele Sodium Sesquihydrate eq. to Pantoprazole……...40mg |
| | Diary No. Date of R& I & fee | Dy.No 4305, 06-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PROTONIX (pantoprazole sodium) delayed-release tablets, for oral use by Wyeth Pharms. US-FDA approved |
| | Me-too status | Pantasa Tablets by Platinum Pharma (Reg.No.030205) |
| | GMP status | GMP inspection dated 11-10-2017 and 16-10-2017 concluded that the firm is considered to be operating at satisfactory level of compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

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| 520. | Name and address of manufacturer / Applicant | M/s Pakistan Pharmaceutical Products Pvt Ltd.<br>D-122, Sindh Industrial Trading Estate, Karachi |
| | Brand Name +Dosage Form + Strength | Vibe 2.5mg Tablet |
| | Composition | Each Tablet Contains:<br>Nebivolol Hydrochloride eq. to Nebivolol……..2.5mg |
| | Diary No. Date of R& I & fee | Dy.No 4300, 06-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Beta blocking agents, selective<br>ATC Code: C07AB12 |
| | 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. | Bystolic (uncoated)<br>USFDA Approved |
| | Me-too status | Nebix 2.5mg tablet by Highnoon |
| | GMP status | GMP inspection dated 05-06-2018 concluded that the firm is found to be complying at Good level of GMP compliance at the time of inspection. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 521. | Name and address of manufacturer / Applicant | M/s Pakistan Pharmaceutical Products Pvt Ltd.<br>D-122, Sindh Industrial Trading Estate, Karachi |
| | Brand Name +Dosage Form + Strength | Vibe 5mg Tablet |
| | Composition | Each Tablet Contains:<br>Nebivolol Hydrochloride eq. to Nebivolol……..5mg |
| | Diary No. Date of R& I & fee | Dy.No 4301, 06-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Beta blocking agents, selective<br>ATC Code: C07AB12 |
| | 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. | Bystolic (uncoated)<br>USFDA Approved |
| | Me-too status | Nebix 5mg tablet by Highnoon |
| | GMP status | GMP inspection dated 05-06-2018 concluded that the firm is found to be complying at Good level of GMP compliance at the time of inspection. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 522. | Name and address of manufacturer / Applicant | M/s. Genetics Pharmaceuticals Pvt. Ltd.<br>539-A, Sundar Industrial Estate,Raiwind,Lahore |
| | Brand Name +Dosage Form + Strength | Vergo 24mg Tablet |
| | Composition | Each tablet Contains:<br>Betahistine Dihydrochloride……24mg |
| | Diary No. Date of R& I & fee | Dy.No 4303, 06-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Anti-Vertigo |
| | 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 | Vertin 24mg tablets of M/s Libra pharmaceuticals |
| | GMP status | GMP dated 12-2-2018, the GMP compliance status of firm can't be verified because firm was not operational at the time of inspection however premises were found well maintained and at satisfactory level. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |

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| 523. | Name and address of manufacturer / Applicant | M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan |
| | Brand Name +Dosage Form + Strength | Fina 5mg Tablet |
| | Composition | Each Film Coated Tablet Contains:<br>Finasteride……..5mg |
| | Diary No. Date of R& I & fee | Dy.No 4315, 06-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Testosterone-5-alpha reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Proscar Tablet (USFDA Approved) |
| | Me-too status | Proscar Tablet of M/s Muller &Phipps (Reg#014068) |
| | GMP status | Last GMP inspection report dated 16-02-2018 concluding "satisfactory level of compliance with cGMP guidelines as of today. The management was also suggested to further strengthen stability and analytical sections." |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 524. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan Pvt Ltd., L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Co-Allset 300/25 mg Tablet |
| | Composition | Each tablet Contains:<br>Irbesartan……..300mg<br>Hydrochlorothiazide…….25mg |
| | Diary No. Date of R& I & fee | Dy.No 4464, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Angiotensin II antagonists and diuretics |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Irbesartan and Hydrochlorthiazide Tablets by Aurobindo Pharm (USFDA Approved) |
| | Me-too status | Irecon – H Tablet by Barret Hodgson |
| | GMP status | Last inspection report dated 24-4-2018 confirms satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 525. | Name and address of manufacturer / Applicant | M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Vilip-M Tablet 50/500mg |
| | Composition | Each film coated tablet contains:<br>Vildagliptin…….50mg<br>Metformin HCI…….500mg |
| | Diary No. Date of R& I & fee | Dy.No 4548, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Antidiabetic |
| | 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. | GALVUMET 50/500 film coated tablet by Novartis Pharmaceuticals (TGA Australia Approved) |
| | Me-too status | Galvus Met 50/500mg Tablets by Novartis (Reg# 078106) |
| | GMP status | Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 526. | Name and address of manufacturer / Applicant | M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Duranol 60mg Capsules |
| | Composition | Each capsule contains: |

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| | | Duloxetine……..…60mg |
| | Diary No. Date of R& I & fee | Dy.No 4547, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cymbalta (Duloxetine 60 mg capsule) by M/s Eli Lilly, USFDA |
| | Me-too status | Dulan (Duloxetine 60 mg capsule) by M/s Hilton Pharma.(Reg#055448) |
| | GMP status | Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for following:**<br>• **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.**<br>• **Revision of formulation and label claim as per the USFDA approved reference product.** | |
| 527. | Name and address of manufacturer / Applicant | M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Duranol 30mg Capsules |
| | Composition | Each capsule contains:<br>Duloxetine……..…30mg |
| | Diary No. Date of R& I & fee | Dy.No 4546, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cymbalta (Duloxetine 30 mg capsule) by M/s Eli Lilly, USFDA |
| | Me-too status | Dulan 30mg by M/s Hilton Pharma. (Reg#055447) |
| | GMP status | Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | Source of pellets |
| | **Decision: Deferred for following:**<br>• **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.**<br>• **Revision of formulation and label claim as per the USFDA approved reference product.** | |
| 528. | Name and address of manufacturer / Applicant | M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Duranol 20mg Capsules |
| | Composition | Each capsule contains:<br>Duloxetine……..…20mg |
| | Diary No. Date of R& I & fee | Dy.No 4545, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cymbalta (Duloxetine 20 mg capsule) by M/s Eli Lilly, USFDA |
| | Me-too status | Dulan 20mg by M/s Hilton Pharma.(Reg#055446) |
| | GMP status | Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | Source of pellets |
| | **Decision: Deferred for following:**<br>• **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.**<br>• **Revision of formulation and label claim as per the USFDA approved reference product.** | |

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| 529. | Name and address of manufacturer / Applicant | M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Resque 500mg Tablet |
| | Composition | Each tablet contains:<br>Azithromycin……500mg |
| | Diary No. Date of R& I & fee | Dy.No 4544, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Macrolides |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Azithromycin 500 mg Film-Coated Tablets by TEVA UK Limited (MHRA Approved) |
| | Me-too status | Zetro 500mg Tablet by Getz Pharma (Reg# 053120) |
| | GMP status | Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for revision of salt form of API as per reference product along with requisite fee for change of formulation.** | |
| 530. | Name and address of manufacturer / Applicant | M/s Semos Pharmaceuticals Pvt Ltd.<br>Plot No.11, Sector 12-A, North Karachi, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Sebast 20mg Tablet |
| | Composition | Each film coated tablet contains:<br>Ebastine……..…20mg |
| | Diary No. Date of R& I & fee | Dy.No 4466, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form-5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Kestine<br>Netherlands Approved |
| | Me-too status | Antine Tablets 20 mg of M/s Wise Pharma Reg#068792 |
| | GMP status | Last inspection conducted on 17-10-2017 with good GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 531. | Name and address of manufacturer / Applicant | M/s Semos Pharmaceuticals Pvt Ltd.<br>Plot No.11, Sector 12-A, North Karachi, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Sebast 10mg Tablet |
| | Composition | Each film coated tablet contains:<br>Ebastine……..…10mg |
| | Diary No. Date of R& I & fee | Dy.No 4465, 07-02-2018, Rs. 20,000/-, 17-01-2018 |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form-5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | EBASTINE ARROW 10 mg film-coated tablets<br>ANSM Approved |
| | Me-too status | Nosetine Tablets by Technovision Pharmaceuticals |
| | GMP status | Last inspection conducted on 17-10-2017 with good GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |

**b. Deferred cases**

**Evaluator PEC-II**

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| 532. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi. |
| | Brand Name +Dosage Form + Strength | G-Med tablet 320mg<br>Other proposed brand names:<br>Wel-Gem<br>Gemiwel |
| | Composition | Each film coated tablet contains:<br>Gemifloxacin as mesylate…. ……320mg |
| | Diary No. Date of R& I & fee | Dy. No.4836; 05-06-2017; Rs.20,000/- (05-06-2017) |
| | Pharmacological Group | Anti-biotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | G-Active tablet 320mg of M/s. Dyson Research Laboratories |
| | GMP status | Panel Inspection conducted on 04-03-2017 recommends renewal of DML |
| | Remarks of the Evaluator. | • Latest GMP inspection report conducted within the period of last one year.<br>• Clarification regarding quantity of API as salt and its equivalent weight as base.<br>• Original fee challan of Rs.20,000/- for Gemifloxacin 500mg tablets is attached instead of Gemifloxacin 320mg tablets.<br>Upon communication of above cited observations firm has submitted firm has submitted revised master formulation as under:<br>" Each film coated tablet contains:<br>Gemifloxacin as mesylate…. ……320mg"<br>• Firm has submitted an undertaking that in the deposit slip we have mentioned the strength as 500mg tablet instead of 320mg due to typing error. We will use the above mentioned deposit slip for G-Med 320mg tablet only.<br>• Firm has submitted fee of Rs. 20,000/- (Deposit slip#. 0765528) dated 14-09-2018 for the applied formulation of Gemifloxacin 320mg tablet. |
| | Previous Decision: | Registration Board in its 284th meeting deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. |
| | Evaluation by PEC: | • Firm has submitted copy of GMP inspection report conducted on 12-12-2018, concluding as under:<br>"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance." |
| | **Decision: Approved with innovator's specification** | |
| 533. | Name and address of manufacturer / Applicant | M/s Biocef (Pvt). Ltd., 517, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | CEFIA Capsule 200mg |
| | Composition | Each Capsule Contains:-<br>Cefixime (as trihydrate)…….200mg |
| | Diary No. Date of R& I & fee | Dy Rs.20,000/- (15-06-2017) |
| | Pharmacological Group | Third-generation cephalosporins |
| | Type of Form | Form-5 |

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| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 10's: Rs. 314.0 |
| | Approval status of product in Reference Regulatory Authorities. | Not verifiable |
| | Me-too status | Cefim Capsule 200mg of M/s Hilton Pharmaceuticals... Reg.034664 |
| | GMP status | New facility DML issued (DML No. 000864, Dated 14-06-2017) |
| | Remarks of the Evaluator. | • Evidence of approval for applied formulation by reference regulatory authority is required. |
| | Previous Decision: | Registration Board in its 272nd meeting deferred for submission of evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 249th meeting. |
| | Evaluation by PEC: | Following reference for applied formulation submitted by firm has been verified:<br>"Cefixime Normon 200 mg hard capsules EFG" of M/s Laboratorios Normon, SA Round of Valdecarrizo, 6 28760 Tres Cantos – Madrid Spain approved by AEMPS of Spain." https://cima.aemps.es/cima/publico/detalle.html (Accessed on 07-02-2019).<br>Moreover firm has submitted that at the time of application firm's name was Biocef which was changed by Central Licensing Board from Biocef to Curexa Health vide letter No. F.1-23/2006-Lic dated 09th October, 2017. Now the firm has submitted new application on Form with the applicant title as M/s Curexa Health (Pvt.) Ltd. Lahore details of which are as under |
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| | Name and address of manufacturer / Applicant | M/s Curexa Health (Pvt.) Ltd. Plot No. 517, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | CEFIA Capsule 200mg |
| | Composition | Each Capsule Contains:-<br>Cefixime (as trihydrate)…….200mg |
| | Diary No. Date of R& I & fee | Dy. No. 4659 dated 01-02-2019, Rs.20,000/- (01-02-2019) |
| | Pharmacological Group | Anti-biotic |
| | Type of Form | Form-5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | 5's & 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cefixime Normon 200 mg hard capsules EFG" of M/s Laboratorios Normon, SA Round of Valdecarrizo, 6 28760 Tres Cantos – Madrid Spain approved by AEMPS of Spain. |
| | Me-too status | Cefim Capsule 200mg of M/s Hilton Pharmaceuticals... Reg.034664 |
| | GMP status | Copy of GMP certificate issued by Additional Director, DRAP, Lahore issued on the basis of inspection conducted on 20-02-2018. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 534. | Name and address of manufacturer / Applicant | M/s. Farmigea Pakistan (Pvt) Ltd, Lahore |
| | Brand Name +Dosage Form + Strength | Ocupatol 0.2% Eye Drops |
| | Composition | Each ml contains:-<br>Olopatadine HCl equivalent to Olopatadine ……. 0.2% |
| | Diary No. Date of R& I & fee | Dairy No.8990 dated 15.07.2013 Rs:20,000/- |
| | Pharmacological Group | Anti-allergic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | Rs. 275; 5ml |

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| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Olopat DS Eye Drops by M/s Vega Pharmaceuticals, Lahore (Reg.# 069169) |
| | GMP status | Last inspection report conducted on 07-12-2016 with remarks of satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | Previous Decision: | Registration Board in its 264th meeting deferred for confirmation of container closure system whether as per innovator or otherwise |
| | Evaluation by PEC: | Firm has submitted that they will be using same container closure system as that of the reference product. |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 535. | Name and address of manufacturer / Applicant | M/s. Farmigea Pakistan (Pvt) Ltd, Lahore |
| | Brand Name +Dosage Form + Strength | Levoflox Eye Drop |
| | Composition | Each ml contains:-<br>Levofloxacin as hemihydrate …….0.5% w/v |
| | Diary No. Date of R& I & fee | Dairy No.8994 dated 15.07.2013 Rs:20,000/- |
| | Pharmacological Group | anti biotic/ floroquinolone |
| | Type of Form | Form-5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | Rs. 120; 10ml |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Xeflox Eye Drops 0.5% by M/s Helix Pharma, Karachi (Reg.# 042189) |
| | GMP status | Last inspection report conducted on 07-12-2016 with remarks of satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | Previous Decision: | Registration Board in its 264th meeting deferred for confirmation of container closure system whether as per innovator or otherwise |
| | Evaluation by PEC: | Firm has submitted that they will be using same container closure system as that of the reference product. |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 536. | Name and address of manufacturer / Applicant | M/s. Farmigea Pakistan (Pvt) Ltd, Lahore |
| | Brand Name +Dosage Form + Strength | Nepanac 0.1% Gel Eye Drops |
| | Composition | Each ml contains:-<br>Nepafenac…..0.1% |
| | Diary No. Date of R& I & fee | Dairy No. 9873 dated 21.08.2013 Rs:20,000/- |
| | Pharmacological Group | anti-inflammatory |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer Specifications |
| | Pack size & Demanded Price | Rs. 195; 5ml |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Venac 0.1% Eye Drops by M/s M/s Vega Pharmaceuticals (Pvt) Ltd, Lahore (Reg.# 069189) |
| | GMP status | Last inspection report conducted on 07-12-2016 with remarks of satisfactory level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | Previous Decision: | Registration Board in its 264th meeting deferred for following:<br>i. Confirmation of container closure system whether as per innovator or otherwise<br>ii. Clarification of dosage form as reference product is |

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| | | available as eye drops, suspension |
| | Evaluation by PEC: | Firm has submitted that they will be using same container closure system as that of the reference product.<br>Moreover firm has submitted that it is a typographical error mentioning it as a gel. The product is in Eye drop suspension form. |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 537. | Name and address of manufacturer / Applicant | "M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi" |
| | Brand Name +Dosage Form + Strength | Duzalta 40mg Capsule |
| | Composition | Each Delayed Release Capsule Contains:<br>Enteric Coated Pellets of Duloxetine HCL Eq. to Duloxetine……40mg |
| | Diary No. Date of R& I & fee | Dy. No 1637 dated 11-01-2018 Rs. 20,000 Dated 10-01-2018 |
| | Pharmacological Group | Anti-depressant |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Worth 40 mg Capsules of M/s Werrick pharmaceuticals. (Reg.# 068816) |
| | GMP status | Last GMP inspection report dated 23-02-2018 concluding acceptable level of compliance with GMP standards as today |
| | Remarks of the Evaluator. | Source of pellets from M/s Alphamed Formulations Pvt., Ltd., Sy. No. 225, Sampanabole (V) Sahmirpet (M), Ranga Reddy, Dist., 500 078, Telangana State. India<br>GMP certificate valid upto 13-12-2018 |
| | Previous Decision: | Registration Board in its 287th meeting deferred for differential fee for import of pellets |
| | Evaluation by PEC: | Firm has submitted following:<br>• Fee of Rs. 100,000/- vide deposit slip#0702567 dated 21-01-2019, for import of pellets.<br>• Stability data for three batches of duloxetine pellets for both long term & accelerated storage conditions as per Zone IV-A from M/s Alphamed Formulations Pvt., Ltd., India. |
| | **Decision: Approved** | |

**Evaluator PEC-III**

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| 538. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45 KM, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Setaxin Tablet 250mg |
| | Composition | Each film coated tablet contains:<br>Levofloxacin as hemihydrate eq to levofloxacin…..250mg |
| | Diary No. Date of R& I & fee | Dy No. 198: 09-12-2015 PKR 20,000/-: 08-12-2015 |
| | Pharmacological Group | Fluoroquinolone antibacterial |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Evoxil tablet by Beacon Pharmaceutical<br>(MHRA Approved) |
| | Me-too status | Lefoflox tablet by Bosch Pharma |
| | GMP status | GMP inspection report within 1 year is not available |
| | Remarks of the Evaluator[III]. | GMP inspection report within 1 year is not available |
| | Decision of 284th meeting of RB | Registration Board deferred the case for further deliberation. |
| | Evaluation by PEC | • Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP. |
| | **Decision: Approved** | |

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| 539. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45 KM, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Setaxin Tablet 500mg |
| | Composition | Each film coated tablet contains:<br>Levofloxacin as hemihydrate eq to levofloxacin…..500mg |
| | Diary No. Date of R& I & fee | Dy No. 199: 09-12-2015 PKR 20,000/-: 08-12-2015 |
| | Pharmacological Group | Fluoroquinolone antibacterial |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Evoxil tablet by Beacon Pharmaceutical<br>(MHRA Approved) |
| | Me-too status | Lefloxid tablet by Wnsfield Pharma |
| | GMP status | GMP inspection report within 1 year is not available |
| | Remarks of the Evaluator[III]. | GMP inspection report within 1 year is not available |
| | Decision of 284th meeting of RB | Registration Board deferred the case for further deliberation. |
| | Evaluation by PEC | Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP. |
| | **Decision: Approved** | |
| 540. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45 KM, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Egrol Sachet |
| | Composition | Each sachet contains:<br>Macrogol 3350……13.125g<br>Sodium Chloride…….0.3507g<br>Sodium Bicarbonate……..0.1785g<br>Potassium chloride……0.0466g |
| | Diary No. Date of R& I & fee | Dy No. 200: 09-12-2015 PKR 20,000/-: 08-12-2015 |
| | Pharmacological Group | Osmotically active laxative |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & Demanded Price | 10's: Rs. 225/-<br>14's: Rs. 315/-<br>28's: Rs. 630/- |
| | Approval status of product in Reference Regulatory Authorities. | Movicol 13.8g sachet by Norgine Limited<br>(MHRA Approved) |
| | Me-too status | Movopeg Sachet by Wnsfeild Pharmaceutical, |
| | GMP status | GMP inspection report within 1 year is not available |
| | Remarks of the Evaluator[III]. | GMP inspection report within 1 year is not available<br>Evidence of sachet section could not be confirmed |
| | Decision of 284th meeting of RB | Registration Board deferred the case for further deliberation. |
| | Evaluation by PEC | • Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP.<br>• Evidence of sachet section could **NOT** be confirmed |
| | **Decision: Deferred for confirmation of requisite section (sachet section) for the applied product** | |
| 541. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45 KM, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Grash Capsule |
| | Composition | Each capsule contains:<br>Orlistat…….60mg |
| | Diary No. Date of R& I & fee | Dy No. 170: 07-12-2015 PKR 20,000/-: 04-12-2015 |
| | Pharmacological Group | Antiobesity preparation |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 84's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Beacita Capsule by Actavis<br>(MHRA Approved) |
| | Me-too status | Orslim capsule by Pharmevo |

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| | GMP status | GMP inspection report within 1 year is not available |
| | Remarks of the Evaluator[III]. | GMP inspection report within 1 year is not available<br>Source of pellets including GMP of manufacturer, stability study data of pellets is not provided. |
| | Decision of 284th meeting of RB | Registration Board deferred the case for further deliberation. |
| | Evaluation by PEC | • Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP.<br>• Source of pellets including GMP of manufacturer, stability study data of pellets is not provided. |
| | **Decision: Deffered for following**<br>• **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.**<br>• **Submission of correct pharmacological group.** | |
| 542. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45 KM, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Grash Capsule |
| | Composition | Each capsule contains:<br>Orlistat…….120mg |
| | Diary No. Date of R& I & fee | Dy No. 169: 07-12-2015 PKR 20,000/-: 04-12-2015 |
| | Pharmacological Group | Antiobesity preparation |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 84's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Beacita Capsule by Actavis<br>(MHRA Approved) |
| | Me-too status | Orslim capsule by Pharmevo |
| | GMP status | GMP inspection report within 1 year is not available |
| | Remarks of the Evaluator[III]. | GMP inspection report within 1 year is not available<br>Source of pellets including GMP of manufacturer, stability study data of pellets is not provided. |
| | Decision of 284th meeting of RB | Registration Board deferred the case for further deliberation. |
| | Evaluation by PEC | • Firm has submitted latest GMP inspection report dated 25-10-2018 which specifies good compliance to GMP.<br>• Source of pellets including GMP of manufacturer, stability study data of pellets is not provided. |
| | **Decision: Deffered for following**<br>• **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.**<br>• **Submission of correct pharmacological group.** | |
| 543. | Name and address of manufacturer / Applicant | M/s Welmed Pharmaceutical Industries (Pvt) Ltd., Plot # 108, R.2, Industrial Estate Gadoon, Swabi, KPK. |
| | Brand Name +Dosage Form + Strength | Letpro 2.5mg Tablet |
| | Composition | Dy No. 15265: 24-4-2018 PKR 20,000/-: 23-4-2018 |
| | Diary No. Date of R& I & fee | Each film coated tablet contains:<br>Letrozole…….2.5mg |
| | Pharmacological Group | Non-Steroidal aromatase inhibitor |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 3x10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Femara Tablets by Novartis<br>(MHRA Approved) |
| | Me-too status | Femara Tablets by Novartis |
| | GMP status | Last GMP inspection dated 12-7-2018 concludes as *"All the observations were discussed with the firm management and technical persons. They committed to rectify all the observations. The firm may be considered to be operating in satisfactory level of cGMP compliance subject to fulfillment of observations mentioned in the inspection report"*<br>Recommendations: |

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| | | *The firm should rectify all the observations in the report in the shortest period of time and convey the same to QALT division.* |
| | Remarks of the Evaluator[III]. | |
| | Decision of 285th meeting of RB | Registration Board referred the case to QA&LT division for detailed evaluation of the GMP inspection report. |
| | Evaluation by PEC | • Firm has submitted Panel inspection report dated 12-12-2018 for verification of compliance of last routine GMP inspection, the report concluded as "The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their GMP compliance. The firm may be considered to be operating in satisfactory level of cGMP compliance". |
| | **Decision: RegistrationBoard was apprised that the application was considered out of queue as per decision of 257th meeting of Registration Board. Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.** | |
| 544. | Name and address of manufacturer / Applicant | M/s Ahad Pharmaceuticals Ltd., 13 KM, Gomal University, Multan Road, Dera Ismail Khan |
| | Brand Name +Dosage Form + Strength | Anmycin Injection |
| | Composition | Each 2ml ampoule contains:<br>Lincomycin as hydrochloride……..600mg |
| | Diary No. Date of R& I & fee | Dy No. 2607: 10-12-2015 PKR 20,000/-: 08-12-2015 |
| | Pharmacological Group | Lincosamide |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2ml x 5's ampoule packed in unit carton: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lincocin injection by Pharmacia Upjohn<br>(USFDA Approved) |
| | Me-too status | Lincomycin Injection by Abbott Pharma |
| | GMP status | Could not be confirmed |
| | Remarks of the Evaluator[III]. | • GMP inspection within last 1 year is required |
| | Decision of 284th meeting of RB | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | • Firm has submitted GMP inspection report dated 07-11-2018 which concludes as "The firm may be considered to be operating at satisfactory level of cGMP compliance" |
| | **Decision: Approved** | |
| 545. | Name and address of manufacturer / Applicant | M/s Welwrd Pharmaceuticals, Plot No. 03, Block –A, Phase-I, II, Industrial Estate, Hattar. |
| | Brand Name +Dosage Form + Strength | Wrdrop 150mg tablet |
| | Composition | Each prolonged release Tablet contains: -<br>Bupropion hydrochloride …150mg |
| | Diary No. Date of R& I & fee | Duplicate copy where these particulars couldn't be verified. |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zyban 150 mg prolonged release tablets by M/s GlaxoSmithKline UK (MHRA approved) |
| | Me-too status | Wellbutrin XL Tablets 150mg by M/s GSK (Reg#047527) |
| | GMP status | Last GMP inspection conducted on 14-06-2017 and the report concludes that overall the firm is GMP compliant. |
| | Remarks of the Evaluator[III]. | • Diary No. Date of R& I & fee:<br>Duplicate copy where these particulars couldn't be verified.<br>Firm has submitted complete fee PKR 20,000 dated 28-6-2018 |
| | Decision of 283rd meeting of RB | Deferred for verification of submission of application on 16-7-2014 in R&I DRAP. |

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| | Evaluation by PEC | Firm has submitted copy of receiving of their application "WRDROP 150mg Tablet" in DRAP R&I on 16-7-2014. |
| | **Decision: Registration Board deferred for confirmation from R&I section for date of submission of original dossier along with details of submitted fee.** | |
| 546. | Name and address of manufacturer / Applicant | NOA HEMIS Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area Karachi |
| | Brand Name +Dosage Form + Strength | Flexem 30mg Capsule |
| | Composition | Each capsule contains:<br>Cyclobenzaprine hydrochloride…..30mg |
| | Diary No. Date of R& I & fee | Dy. No. 190: 31-05-2010 PKR 8000/- (31-5-2010) +<br>PKR 12,000/- (13-5-2013) |
| | Pharmacological Group | (muscle relaxant) |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & Demanded Price | 7's, 14's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Amrix Capsule by Teva (**USFDA** Approved) |
| | Me-too status | Emrix-SR 30mg Capsule by Getz Pharma |
| | GMP status | |
| | Remarks of the Evaluator[III]. | Reminder: 17-5-2018<br>Letter: 10-04-2018<br>• Latest GMP inspection report (which should have been conducted within the period of last one year).<br>• Evidence of approval of manufacturing facility / section of the manufacturer by Licensing Division.<br>• Evidence of submission of 12,000/- fee chalan.<br>• Justify the formulation of cyclobenzaprine hydrochloride plain (immediate release) capsule, since the product approved by reference regulatory authorities and by DRAP is cyclobenzaprine hydrochloride extended release capsule.<br>• For cyclobenzaprine hydrochloride extended release pellets, provide<br>o Source of pellets<br>o GMP of manufacturer of pellets<br>o Certificate of Analysis of Pellets<br>o Stability study data of 3 batches of pellets<br>o Differential fee (if pellets are imported). |
| | Decision of 284th meeting of RB | Registration Board deferred the case for further deliberation. |
| | Evaluation by PEC | Firm has submitted the following documents:<br>• Section approval letter for capsule section<br>• Copy of fee chalan of 12,000/- dated 08-05-2013<br>• Last GMP inspection report dated 09-08-2018 confirming good compliance to GMP<br>• Revised formulation as follows<br>Each capsule contains:<br>Cyclobenzaprine HCl (as extended release pellets)….30mg<br>Firm has **not** yet submitted source of pellets. |
| | **Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.** | |
| 547. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road F.B Industrial Area Karachi. |
| | Brand Name +Dosage Form + Strength | Valsart Plus Tablet 10/160/25mg |
| | Diary No. Date of R& I & fee | Dy No. 13643: 28-8-2017 PKR 20,000/-: 25-8-2017 |
| | Composition | Each film coated tablet contains:<br>Amlodipine as besylate……10mg<br>Valsartan……160mg<br>Hydrochlorthiazide……25mg |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form 5 |

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| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's, 28's: |
| | Approval status of product in Reference Regulatory Authorities. | Exforge HCT tablet by Novartis<br>(USFDA Approved) |
| | Me-too status | Exforge HCT tablet by Novartis |
| | GMP status | Last inspection report dated 24-4-2018 confirms satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | Decision of 283rd meeting of RB | Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies. |
| | Evaluation by PEC | FID-V Karachi through its letter No. F.SAA.02-06/2018-FID-V (K) dated 30th August 2018 has confirmed that firm has purchased 2 stability chambers with capacity of 250 L (accelerated) and 800L (Real time). |
| | **Decision: Approved** | |
| 548. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road F.B Industrial Area Karachi. |
| | Brand Name +Dosage Form + Strength | Mypride 50mg Tablet |
| | Diary No. Date of R& I & fee | Dy No. 13649: 28-8-2017 PKR 20,000/-: 25-8-2017 |
| | Composition | Each film coated tablet contains:<br>Itopride hydrochloride…….....50mg |
| | Pharmacological Group | Antiemetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specifications |
| | Pack size & Demanded Price | 10's, 30's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | (PMDA approved) |
| | Me-too status | Ganaton 50 mg tablet by M/s Abbott. |
| | GMP status | Last inspection report dated 24-4-2018 confirms satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | Decision of 283rd meeting of RB | Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies. |
| | Evaluation by PEC | FID-V Karachi through its letter No. F.SAA.02-06/2018-FID-V (K) dated 30th August 2018 has confirmed that firm has purchased 2 stability chambers with capacity of 250 L (accelerated) and 800L (Real time). |
| | **Decision: Approved with innovator's specification.** | |
| 549. | Name and address of manufacturer / Applicant | M/s Lisko Pakistan (Pvt) Ltd., L-10-D, Block-21, Shaheed Rashid Minhas Road F.B Industrial Area Karachi. |
| | Brand Name +Dosage Form + Strength | Kufest Syrup |
| | Diary No. Date of R& I & fee | Dy No. 13652: 28-8-2017 PKR 20,000/-: 25-8-2017 |
| | Composition | Each 5ml contains:<br>Carbocisteine……250mg |
| | Pharmacological Group | Mucolytic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specifications |
| | Pack size & Demanded Price | 120ml Bottle: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Mucodyne Oral solution of M/s Sanofi Aventis<br>(**MHRA** Approved) |
| | Me-too status | Rhinathiol 5% for adults of M/s Sanofi Aventis |
| | GMP status | Last inspection report dated 24-4-2018 confirms satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | Decision of 283rd meeting of RB | Registration Board deferred the case as FID has reported for not having stability chamber for conducting Real time stability studies. |

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| | Evaluation by PEC | FID-V Karachi through its letter No. F.SAA.02-06/2018-FID-V (K) dated 30th August 2018 has confirmed that firm has purchased 2 stability chambers with capacity of 250 L (accelerated) and 800L (Real time). |
| | **Decision: Approved with innovator's specification.** | |
| 550. | Name and address of manufacturer / Applicant | M/s. Bryon Pharmaceuticals, Peshawar |
| | Brand Name +Dosage Form + Strength | Omeceph Oral Dry Suspension |
| | Diary No. Date of R& I & fee | 18-6-2010 : PKR 8,000 (18-6-2010) +<br>PKR 12,000/- (11-03-2013) (**Photocopy)** |
| | Composition | Each 5 ml contains:-<br>Cefixime trihydrate equivalent to Cefixime ……..100 mg |
| | Pharmacological Group | (Cephalosporin) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30 ml: Rs.284.0 |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Cefim suspension by Hilton |
| | GMP status | Last inspection report dated 15-02-2017 confirms Satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | Decision of 238th meeting of RB | Deferred till inspection by Licensing Section. |
| | Evaluation by PEC | Firm has submitted copy of section approval letter for dry suspension (cephalosporin) and capsule (cephalosporin) section dated 28-01-2019. |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 551. | Name and address of manufacturer / Applicant | M/s. Bryon Pharmaceuticals, Peshawar |
| | Brand Name +Dosage Form + Strength | Omeceph Oral DS Dry Suspension |
| | Diary No. Date of R& I & fee | 18-6-2010 : PKR 8,000 (18-6-2010) +<br>PKR 12,000/- (11-03-2013) (**Photocopy)** |
| | Composition | Each 5 ml contains:-<br>Cefixime trihydrate equivalent to Cefixime ……..200 mg |
| | Pharmacological Group | (Cephalosporin) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30 ml: Rs.345.0 |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Cefim suspension by Hilton |
| | GMP status | Last inspection report dated 15-02-2017 confirms satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | Decision of 238th meeting of RB | Deferred till inspection by Licensing Section. |
| | Evaluation by PEC | Firm has submitted copy of section approval letter for dry suspension (cephalosporin) and capsule (cephalosporin) section dated 28-01-2019. |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |

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| 552. | Name and address of manufacturer / Applicant | M/s. Bryon Pharmaceuticals, Peshawar |
| | Brand Name +Dosage Form + Strength | Omeceph 400 mg Capsules |
| | Diary No. Date of R& I & fee | 18-6-2010 : PKR 8,000 (18-6-2010) +<br>PKR 12,000/- (11-03-2013) (Photocopy) |
| | Composition | Each capsule contains:-<br>Cefixime trihydrate ≡ Cefixime ……..400 mg |
| | Pharmacological Group | (Cephalosporin) |
| | Type of Form | Form 5 |
| | Finished Product Specification | |
| | Pack size & Demanded Price | 5's : Rs.505 |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Cefim capsule by Hilton |
| | GMP status | Last inspection report dated 15-02-2017 confirms satisfactory compliance to GMP. |
| | Remarks of the Evaluator. | |
| | Decision of 238th meeting of RB | Deferred till inspection by Licensing Section. |
| | Evaluation by PEC | Firm has submitted copy of section approval letter for dry suspension (cephalosporin) and capsule (cephalosporin) section dated 28-01-2019. |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 553. | Name and address of manufacturer / Applicant | M/s Delta Pharma Pvt Ltd. Plot. No. 9, Nowshera Industrial Estate, Risalpur, Kpk, Pakistan |
| | Brand Name +Dosage Form + Strength | Ventodine 2mg/5ml Liquid Suspension |
| | Composition | Each 5ml of Suspension Contains:<br>Sulbutamol as Sulphate…2mg |
| | Diary No. Date of R& I & fee | Dy. No 39940: 04-12-2018 PKR 20,000/- : 04-12-2018 |
| | Pharmacological Group | Selective beta-2-adrenoreceptor agonists |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 60ml, 120ml: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ventolin Syrup by Glaxo Wellcome<br>(MHRA Approved) |
| | Me-too status | Ventolin Syrup by GSK |
| | GMP status | Firm is granted additional sections Oral liquid (general) and dry suspension (general) section on the basis of inspection dated 12-10-2018 |
| | Remarks of the Evaluator. | • Justify the formulation of liquid suspension, since the MHRA approved reference formulation is liquid solution / syrup. In case of revision of formulation fee (for revision of formulation) needs to be submitted. |
| | Decision of 287th meeting of RB | Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation |
| | Evaluation by PEC | • Firm has revised formulation as per reference product along with submission of 5,000 fee dated 07-02-2019. The revised formulation submitted by the firm is as:<br>Each 5ml of solution Contains:<br>Sulbutamol as Sulphate…2mg |
| | **Decision: Deferred for submission of fee for revision of dosage form.** | |
| 554. | Name and address of manufacturer / Applicant | M/s Delta Pharma Pvt Ltd. Plot. No. 9, Nowshera Industrial Estate, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Zindell 20mg/5ml Liquid Suspension |
| | Composition | Each 5ml Contains:<br>Zinc as Sulphate Monohydrate…20mg |
| | Diary No. Date of R& I & fee | Dy. No 39943: 04-12-2018 PKR 20,000/- : 04-12-2018 |

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| | Pharmacological Group | Zinc supplement |
| | Type of Form | Form-5 |
| | Finished Product Specification | International pharmacopoeia |
| | Pack size & Demanded Price | 60ml: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | WHO recommended formulation |
| | Me-too status | Zincat-OD Syrup by Atco Pharma |
| | GMP status | Firm is granted additional sections Oral liquid (general) and dry suspension (general) section on the basis of inspection dated 12-10-2018 |
| | Remarks of the Evaluator. | • Justify the formulation of liquid suspension, since the WHO recommended formulation is liquid solution / syrup. In case of revision of formulation fee (for revision of formulation) needs to be submitted. |
| | Decision of 287th meeting of RB | Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation |
| | Evaluation by PEC | • Firm has revised formulation as per reference product along with submission of 5,000 fee dated 07-02-2019. The revised formulation submitted by the firm is as:<br>Each 5ml of solution Contains:<br>Zinc as Sulphate Monohydrate…20mg |
| | **Decision: Deferred for submission of fee for revision of dosage form.** | |
| 555. | Name and address of manufacturer / Applicant | M/s Delta Pharma Pvt Ltd. Plot. No. 9, Nowshera Industrial Estate, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Excip 250mg/5ml Dry Powder Suspension |
| | Composition | Each 5ml Contains:<br>Ciprofloxacin as Ciprofloxacin HCL…250mg |
| | Diary No. Date of R& I & fee | Dy. No 39937: 04-12-2018 PKR 20,000/- : 04-12-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 60ml: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ciproxin 250mg/5ml granules and solvent for oral suspension by Bayer (**MHRA Approved)** |
| | Me-too status | Novidat Dry Powder for Suspension by Sami Pharma |
| | GMP status | Firm is granted additional sections Oral liquid (general) and dry suspension (general) section on the basis of inspection dated 12-10-2018 |
| | Remarks of the Evaluator. | • Justify the formulation containing ciprofloxacin as hydrochloride since the reference formulation approved by MHRA contains ciprofloxacin base.<br>• Provide source of granules of ciprofloxacin since granulation process is not mentioned in method of manufacturing. |
| | Decision of 287th meeting of RB | Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation |
| | Evaluation by PEC | • Source of pellets: Vision Pharmaceuticals<br>• Firm has revised formulation as per reference product along with submission of 5,000 fee dated 07-02-2019. The revised formulation submitted by the firm is as:<br>Each 5ml Contains:<br>Ciprofloxacin …250mg |
| | **Decision: Deferred for further deliberation upon the salt form of API, in view of reference product.** | |
| 556. | Name and address of manufacturer / Applicant | M/s Delta Pharma Pvt Ltd. Plot. No. 9, Nowshera Industrial Estate, Risalpur, Kpk, Pakistan |
| | Brand Name +Dosage Form + Strength | Excip 125mg/5ml Dry Powder |
| | Composition | Each 5ml Contains:<br>Ciprofloxacin as Ciprofloxacin HCL…125mg |

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| | Diary No. Date of R& I & fee | Dy. No 39934: 04-12-2018 PKR 20,000/- : 04-12-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 60ml: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by Registration Board based on quantitative composition mentioned in SmPC of 250mg dry suspension |
| | Me-too status | Nafcin 125mg Suspension by Global Pharma |
| | GMP status | Firm is granted additional sections Oral liquid (general) and dry suspension (general) section on the basis of inspection dated 12-10-2018 |
| | Remarks of the Evaluator. | • Justify the formulation containing ciprofloxacin as hydrochloride since the reference formulation approved by MHRA contains ciprofloxacin base.<br>• Provide source of granules of ciprofloxacin since granulation process is not mentioned in method of manufacturing. |
| | Decision of 287th meeting of RB | Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation |
| | Evaluation by PEC | • Source of pellets: Vision Pharmaceuticals<br>• Firm has revised formulation as per reference product along with submission of 5,000 fee dated 07-02-2019. The revised formulation submitted by the firm is as:<br>Each 5ml Contains:<br>Ciprofloxacin …125mg |
| | **Decision: Deferred for further deliberation upon the salt form of API, in view of reference product.** | |
| 557. | Name and address of manufacturer / Applicant | M/s Pharmedic Laboratories (Pvt) Ltd., 16-Km Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Prazem 0.25 Tablet |
| | Diary No. Date of R& I & fee | Dy. No. 136: 22-07-2015<br>PKR 20,000/-: 22-07-2015 |
| | Composition | Each tablet contains:<br>Alprazolam…….0.25mg |
| | Pharmacological Group | Benzodiazepines |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30's: Rs 136/30 tablets |
| | Approval status of product in Reference Regulatory Authorities. | Xanax by Pfizer<br>(**MHRA** Approved) |
| | Me-too status | Xanax by Pfizer |
| | GMP status | Last inspection report dated 31-08-2016 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | • |
| | Decision of 273rd meeting of RB | Deferred for confirmation of approved manufacturing facility/section by Central Licensing Board. |
| | Evaluation by PEC | Firm has submitted copy of approval of Tablet (psychotropic) section dated 6th September 2018. |
| | **Decision: Deferred for updated status of GMP of the firm from QA & LT division as latest cGMP panel inspection report does not conclude GMP compliant status.** | |
| 558. | Name and address of manufacturer / Applicant | M/s Pharmedic Laboratories (Pvt) Ltd., 16-Km Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Prazem 0.5mg Tablets |
| | Diary No. Date of R& I & fee | Dy. No. 137: 22-7-2015 PKR 20,000/-: 22-07-2015 |
| | Composition | Each tablet contains:<br>Alprazolam…….0.5mg |
| | Pharmacological Group | Benzodiazepines |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 30's: Rs 191/30 tablets |

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| | Approval status of product in Reference Regulatory Authorities. | Xanax by Pfizer<br>(**MHRA** Approved) |
| | Me-too status | Xanax by Pfizer |
| | GMP status | Last inspection report dated 31-08-2016 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | • |
| | Decision of 273rd meeting of RB | Deferred for confirmation of approved manufacturing facility/section by Central Licensing Board. |
| | Evaluation by PEC | Firm has submitted copy of approval of Tablet (psychotropic) section dated 6th September 2018. |
| | **Decision: Deferred for updated status of GMP of the firm from QA & LT division as latest cGMP panel inspection report does not conclude GMP compliant status.** | |
| 559. | Name and address of manufacturer / Applicant | M/s Care Pharmaceuticals, 8-km,Thokar, Raiwind Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Optilone Eye Drops |
| | Composition | Each ml contains:-<br>Prednisolone.....0.1%w/w |
| | Diary No. Date of R& I & fee | Dy.#7447 dated 20-7-2012 Rs.8000 & Rs.12,000/- 30-07-2013 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | Rs.30/10ml pack. |
| | Approval status of product in Reference Regulatory Authorities. | -- |
| | Me-too status | Solopred drops by M/s Jeans |
| | GMP status | Firm is GMP compliant as per inspection by area FID. |
| | Remarks of the Evaluator. | |
| | Decision of 257th meeting of RB | Deferred for the confirmation of approval status in reference drug Authorities and manufacturing facility |
| | Evaluation by PEC | • Following reference submitted by firm has been verified: "Pred Mild ophthalmic drop by M/s Allergen (approved by USFDA)"<br>• Firm has also submitted revised Form-5 with following composition as per reference product:<br>"Each ml contains:-<br>Prednisolone as acetate.....0.1%w/w"<br>• Fee of Rs. 5,000 has also been submitted vide deposit slip# 0792098 dated 06-02-2019 for revision of formulation.<br>• Moreover firm has referred to 248th meeting of Registration Board wherein Board has allowed manufacturing of steroidal ophthalmic preparation in general area. |
| | **Decision: Deferred for updated status of GMP of the firm from QA & LT division.** | |
| 560. | Name and address of manufacturer / Applicant | M/s Care Pharmaceuticals, 8-km,Thokar, Raiwind Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Occubetan Eye Drops |
| | Composition | Each ml contains:-<br>Neomycin as sulphate …..... 0.5%w/v<br>Betamethasone as Sodium Phosphate …. 0.1%w/v |
| | Diary No. Date of R& I & fee | Dy. No. 7444 dated 20-07-2012 Rs.8000 & Rs.12,000 dated 30-07-2013 |
| | Pharmacological Group | Antibiotic/Corticosteroid |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's Specifications. |
| | Pack size & Demanded Price | Rs.50/7.5ml. |
| | Approval status of product in Reference Regulatory Authorities. | -- |

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| | Me-too status | Betatek-N Drops by M/s Innvotek Pharma |
| | GMP status | Firm is GMP compliant as per inspection by area FID. |
| | Remarks of the Evaluator. | |
| | Decision of 257th meeting of RB | Deferred for the confirmation of approval status in reference of drug authorities |
| | Evaluation by PEC | • Following reference submitted by firm has been verified: **"Betnesol-N Eye, Ear and Nose Drops by M/s RPH Pharmaceuticals AB (approved by MHRA of UK)"** Web link (accessed on 08-02-2019): http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1542345155760.pdf |
| | **Decision: Deferred for updated status of GMP of the firm from QA & LT division.** | |
| 561. | Name and address of manufacturer / Applicant | M/s Care Pharmaceuticals, 8-km,Thokar, Raiwind Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Epitizo Syrup |
| | Composition | Each 5ml contains:- Pizotifen (as Hydrogen Maleate) …… 0.25mg |
| | Diary No. Date of R& I & fee | Dy. No. dated 01-06-10 |
| | Pharmacological Group | Appetite Stimulant/ Vitamin |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's Specifications. |
| | Pack size & Demanded Price | Rs.50/60ml. |
| | Approval status of product in Reference Regulatory Authorities. | -- |
| | Me-too status | Mosegor syrup by M/s Novartis Pharma |
| | GMP status | Firm is GMP compliant as per inspection by area FID. |
| | Remarks of the Evaluator. | |
| | Decision of 257th meeting of RB | Referred to the Review Committee |
| | Evaluation by PEC | Firm has submitted that applied formulation is approved by MHRA of UK i.e., Sanomigran 0.25mg/5ml. Moreover Registration Board in its recent meetings have approved the same formulation It is also submitted that previously pharmacological group was mistakenly mentioned so please correct it as Anti- Migraine according to international classification of this drug. |
| | **Decision: Deferred for updated status of GMP of the firm from QA & LT division.** | |

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| 562. | Name and Address of Manufacturer / Applicant | M/s Pacific Pharmaceuticals Ltd, 30-km, Multan Road, Lahore. |
| | Brand Name + Dosage Form + Strength | Oncamide/Oncomide Tablets 50mg |
| | Diary No. Date of R & I & fee | Diary No:12520, 05/04/2018, Rs. 20,000/- |
| | Composition | Each film coated tablet contains:<br>Bicalutamide… 50mg |
| | Pharmacological Group | Antineoplastic And Immunomodulating Agents<br>Anti-Androgens<br>ATC code L02BB03 |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 28's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | COSUDEX bicalutamide 50mg tablet film coated by AstraZeneca Pty Ltd (TGA Approved) |
| | Me-too Status | Casodex 50mg Tablet by ICI (Reg. No. 027380) |
| | GMP Status | 07-11-2017<br>Panel recommends grant of Additional sections |
| | Remarks of the Evaluator. | |
| | Previous Decision(M-283): | Deferred for clarification/justification for manufacturing of applied formulation in Tablet (Hormone) section. |
| | **Fresh Evaluation:**<br>Firm has submitted that said product is not a hormone and will be manufactured in General Tablet Manufacturing Facility by taking the safety and protective measures.<br>The said product is used to treat prostate cancer and as per DRAP policy Anticancer products will be given priority. | |
| | **Decision: Deferred for further deliberation upon required manufacturing facility for applied formulation in the light of decision of 282nd meeting of Registration Board.** | |
| 563. | Name and address of manufacturer / Applicant | M/s Medipak limited 132/1,Industrial Estate, Kot Lakhpat, Lahore |
| | Brand Name +Dosage Form + Strength | Medisol BES<br>Balanced Electrolyte Solution<br>Opthalmic Irrigation Solution. |
| | Diary No. Date of R& I & fee | Diary No:19938, 3/11/2017, Rs: 20,000/- Dated 2/11/2017 |
| | Composition | Each 100 mL containing<br>sodium chloride …. 0.64g<br>potassium chloride ..0.075g<br>calcium chloride dehydrate…0.048g<br>magnesium chloride hexahydrate 0.03g<br>sodium acetate trihydrate 0.39g<br>sodium citrate dehydrate…0.17g |
| | Pharmacological Group | Extraocular and intraocular irrigating solution |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. |
| | Pack size & Demanded Price | 500 ml LDPE, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | BSS*<br>Sterile Irrigating Solution (balanced salt solution) USFDA Approved |
| | Me-too status | 025684; Balanced Salt Solution 500ml M/s Alza Pharmaceuticals, Islamabad |
| | GMP status | 17-10-2017, Satisfactory. Management was keen to maintain and improve the compliance to highest level. |
| | Remarks of the Evaluator. | • Section is present.<br>• The international availability of the applied formulation is in polypropylene container whereas, firm has applied for LDPE container. |

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| | Previous Decision (M-285): | Deferred for the following reasons:<br>• Submission of evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.<br>• Submission of evidence of applied formulation in "LDPE container" as approved in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Fresh Evaluation:**<br>Firm has submitted that their product is already registered in 10 ml and 250 ml pack size with same formulation Registration No. 014778 and manufacturing since 1994. The only difference is pack size.<br>To strengthen the case firm has provided the following:<br>I. Packaging Design Compatibility with salts and Blow Fill seal Technology.<br>II. Leachability factor<br>III. Physical and Chemical Factors<br>IV. SGS Testing Report<br>**V.** Shelf Life Stability Report of 250 ml pack size. | |
| | **Decision: Deferred for confirmation from Medical Devices and Medicated Cosmetics Division, whether applied formulation falls into classification of Medical devices or not as per prevailing rules.** | |
| 564. | Name and address of manufacturer / Applicant | M/s. Reign Pharmaceuticals, TBIC Building –I, PCSIR Laboratories Complex, Shahrah-E-Dr. Salim uz Zaman Siddiqui Road, Off University Road, Karachi |
| | Brand Name +Dosage Form + Strength | Lesil Tablet 250mg |
| | Composition | Each film coated contains:<br>Levofloxacin as hemihydrate……250mg |
| | Diary No. Date of R& I & fee | 161, 8-11-16, Rs. 20,000/- |
| | Pharmacological Group | Quinolone Anti-bacterial<br>Fluoroquinolones<br>ATC code J01MA12 |
| | Type of Form | Form 5 |
| | Finished product Specifications | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Levaquin by Janssen Ortho LLC<br>(USFDA Approved) |
| | Me-too status | Registration Number: 023979<br>Brand Name: Levoflox Tablets 250mg<br>Manufacturer Name: Bosch Pharmaceuticals (Pvt) Ltd, 221, Bosch House Sector 23, Korangi Industrial Area Karachi |
| | GMP status | Last inspection report 08-11-2017 overall GMP compliance level is rated as good. |
| | Remarks of the Evaluator. | • Approved in USFDA with box warning.<br>• Overage has been added.<br>Firm provided the following justification<br>To adjust potency we add overage. We are applying wet granulation method/Drying in which potency is reduced. To adjust potency we add water content value.<br>Calculation<br>Strength of tablet factor x %LOD |
| | Previous Decision (M-282) | Deferred for clarification since the justification submitted for use of overage is irrational. |
| | **Evaluation by PEC:**<br>Firm has submitted that they will not use overage. | |
| | **Decision: Approved.** | |
| 565. | Name and Address of Manufacturer / Applicant | M/s Aulton Pharmaceuticals,<br>Plot#84/1, Block-A, Phase 5, Industrial Estate, Hattar. |
| | Brand Name + Dosage Form + Strength | Tazo Tablet 2 mg |
| | Diary No. Date of R & I & fee | Diary No:19823 ,02/11/2017, Rs: 20,000/- , 01/11/2017 |

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| | Composition | Each film coated tablet contains:-<br>Tizanidine as HCl……2mg |
| | Pharmacological Group | Skeletal Muscle relaxant<br>ATC Code: M03BX02 |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1 x 10's ; As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Tizanidine of MHRA approved |
| | Me-too Status | Tandolax 2mg Tablet M/s High-Q Pharmaceuticals |
| | GMP Status | Inspection dated 13-02-2018<br>"Overall the firm was in good working condition with proper documentation, adequate Equipments both in production and quality control and qualified staff for performing the manufacturing and analysis of the manufactured products in accordance with the CGMP guidelines. Some of the minor shortcomings as described above were identified to the firm for immediate rectification. Based on the premises inspected, the qualified staff met and documentation reviewed, it is concluded that M/s Aulton Pharma Industrial Estate Hatter operate at good level of compliance with CGMP guidelines". |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation as **"film coated tablets"** in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | Previous Decision(M-285) | Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Evaluation by PEC:**<br>Firm has revised their formulation from film coated to uncoated tablets with submission of Rs. 5000/- dated 17-12-2018. | |
| | **Decision: Approved** | |
| 566. | Name and Address of Manufacturer / Applicant | M/s Aulton Pharmaceuticals, Plot#84/1, Block-A, Phase 5, Industrial Estate, Hattar. |
| | Brand Name + Dosage Form + Strength | Tazo Tablet 4 mg |
| | Diary No. Date of R & I & fee | Diary No:19824 ,02/11/2017, Rs: 20,000/- , 01/11/2017 |
| | Composition | Each film coated tablet contains:-<br>Tizanidine as HCl……4mg |
| | Pharmacological Group | Skeletal Muscle relaxant<br>ATC Code: M03BX02 |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1 x 10's ; As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Tizanidine of MHRA approved (uncoated) |
| | Me-too Status | Tandolax 4mg Tablet M/s High-Q Pharmaceuticals |
| | GMP Status | Inspection dated 13-02-2018<br>"Overall the firm was in good working condition with proper documentation, adequate Equipments both in production and quality control and qualified staff for performing the manufacturing and analysis of the manufactured products in accordance with the CGMP guidelines. Some of the minor shortcomings as described above were identified to the firm for immediate rectification. Based on the premises inspected, the qualified staff met and documentation reviewed, it is concluded that M/s Aulton Pharma Industrial Estate Hatter operate at good level of compliance with CGMP guidelines" |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation as **"film coated tablets"** in reference regulatory authorities/agencies which |

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| | | were adopted by the Registration Board in its 275th meeting. |
| | Previous Decision(M-285) | Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | Evaluation by PEC:<br>Firm has revised their formulation from film coated to uncoated tablets with submission of Rs. 5000/- dated 17-12-2018. | |
| | **Decision: Approved** | |
| 567. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Micin Gel 1% |
| | Composition | Each g of gel contains:<br>Clindamycin as phosphate……1% |
| | Diary No. Date of R& I & fee | Duplicate, 22-12-2010, 8,000/-, (Photocopy attached), 22-12-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Anti-infectives for treatment of acne<br>ATC Code; D10AF01 |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 15g, 20g |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Uniclin Gel by M/s Kaizen Pharma, Karachi (Reg.#076304) |
| | GMP status | Inspection dated 30-08-2017 recommended for Renewal of DML. |
| | Remarks of the Evaluator. | Duplicate Dossier. |
| | **Previous Decision(M-285):**<br>Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year. | |
| | **Fresh Evaluation:**<br>Date of inspection: 07-06-2017, 30-08-2017. Recommendation of DML. | |
| | **Decision: Approved with change of brand name. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 568. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Isonon Plus Gel |
| | Composition | Each g contains:<br>Erythromycin…20mg<br>Isotretinoin…..0.5mg |
| | Diary No. Date of R& I & fee | Duplicate, 23-09-2010, 8,000/-, (Photocopy attached), 23-09-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Anti-acne preparations<br>ATC Code: D10AD54 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. |
| | Pack size & Demanded Price | 10g |
| | Approval status of product in Reference Regulatory Authorities. | Isotrexin® Gel (MHRA Approved) |
| | Me-too status | Tretocin by Derma tecno Pakistan |
| | GMP status | Inspection dated 30-08-2017 recommended for Renewal of DML. |
| | Remarks of the Evaluator. | Duplicate Dossier. |
| | **Previous Decision(M-285):**<br>Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year. | |
| | **Fresh Evaluation:** Date of inspection: 07-06-2017, 30-08-2017. Recommendation of Renewal DML. | |
| | **Decision: Approved with Innovator's specifications change of brand name. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |

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| 569. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Tacrus Ointment 0.03% |
| | Composition | Each gram contains:<br>Tacrolimus (as monohydrate)…0.3mg (0.03%w/w) |
| | Diary No. Date of R& I & fee | Duplicate, 22-12-2010, 8,000/-, (Photocopy attached), 22-12-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Agents for dermatitis, excluding corticosteroid<br>ATC Code: D11AH01 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. Specs. |
| | Pack size & Demanded Price | 10g |
| | Approval status of product in Reference Regulatory Authorities. | PROTOPIC (tacrolimus) Ointment 0.03%w/w by M/s LEO PHARMA AS (USFDA Approved) |
| | Me-too status | Tacroderm Ointment 0.03% by M/s Caraway Pharmaceuticals (Reg#069932) |
| | GMP status | Inspection dated 30-08-2017 recommended for Renewal of DML. |
| | Remarks of the Evaluator. | Duplicate Dossier. |
| | **Previous Decision(M-285):**<br>Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year. | |
| | **Fresh Evaluation:**<br>Date of inspection: 07-06-2017, 30-08-2017. Recommendation of Renewal DML. | |
| | **Decision: Approved with innovator's specification and change of brand name.**<br>**Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 570. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Myfate DS Tablet |
| | Composition | Each film coated tablet contains:<br>Sucralfate…1g |
| | Diary No. Date of R& I & fee | Duplicate, 23-09-2010, 8,000/-, (Photocopy attached), 23-09-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Anti-ulcer<br>ATC Code: A02BX02 |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 8's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved (Uncoated) |
| | Me-too status | Registration Number:011748<br>Brand Name: SUCFATE 1GM TAB Each tablet contains:-SUCRALFATE 1000mg<br>Manufacturer Name:SIZA |
| | GMP status | Inspection dated 30-08-2017 recommended for Renewal of DML. |
| | Remarks of the Evaluator. | Firm has revised their formulation from film coated to uncoated tablet without submission of fee. |
| | **Previous Decision(M-285):**<br>Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year. | |
| | **Fresh Evaluation:**<br>Date of inspection: 07-06-2017, 30-08-2017. Recommendation of Renewal DML. | |
| | **Decision: Approved with change of brand name. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |

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| 571. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Tenovir Tablet 300mg |
| | Composition | Each film coated tablet contains:<br>Tenofovir Disoproxil fumarate……300mg |
| | Diary No. Date of R& I & fee | Duplicate, 14-12-2009, 8,000/-, (Photocopy attached), 14-12-2009, |
| | Pharmacological Group | Nucleoside reverse transcriptase inhibitors<br>ATC Code: J05AF07 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. Specs |
| | Pack size & Demanded Price | 30's in PVC jar |
| | Approval status of product in Reference Regulatory Authorities. | Tenofovir by Teva Pharma<br>(USFDA Approved) |
| | Me-too status | Tenofo-B by Getz |
| | GMP status | Inspection dated 30-08-2017 recommended for Renewal of DML. |
| | Previous remarks of the Evaluator. | Approved with box warning in USFDA. |
| | **Previous Decision(M-285):**<br>Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year. | |
| | **Fresh Evaluation:**<br>Date of inspection: 07-06-2017, 30-08-2017. Recommendation of Renewal DML. | |
| | **Decision: Approved with Innovator's specifications change of brand name. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 572. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.<br>3 km, Murghzar Road,Saidu Sharif, Swat |
| | Brand Name+DosageForm+Strength | Dipam Tablet 5mg |
| | Composition | Each tablet contains:<br>Diazepam…5mg |
| | Diary No. Date of R&I & fee | Dy No.30435; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivative<br>ATC Code: N05BA01 |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | 065299; Dipam tablet<br>By Leads Pharma Pvt Ltd, |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Approved in USFDA with box warning.<br>Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 573. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.<br>3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Dipam Tablet 2mg |

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| | Composition | Each tablet contains:<br>Diazepam…2mg |
| | Diary No. Date of R&I & fee | Dy No.30434; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivative<br>ATC Code: N05BA01 |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | 064075; Anxosal 2mg Tablets<br>By Universal Pharmaceuticals (Pvt) Ltd. |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Approved in USFDA with box warning.<br>Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 574. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Dipam Tablet 10mg |
| | Composition | Each tablet contains:<br>Diazepam…10mg |
| | Diary No. Date of R&I & fee | Dy No.30436; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivative<br>ATC Code: N05BA01 |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | 065300; Dipam tablet<br>By Leads Pharma Pvt Ltd, |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Approved in USFDA with box warning.<br>Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018.<br>**Decision: Approved** | |

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| 575. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Zepam Tablet 6mg |
| | Composition | Each tablet contains:<br>Bromazepam…6mg |
| | Diary No. Date of R&I & fee | Dy No.30433; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivative<br>ATC Code: N05BA08 |
| | Type of Form | Form 5 |
| | Finished Product Specification | Inhouse |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | TGA Approved (uncoated) |
| | Me-too status | 079326; "Normeez 6mg Tablets<br>By Navegal Laboratories |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018.<br>**Decision: Approved with innovator's specification.** | |
| 576. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Zepam Tablet 1.5 mg |
| | Composition | Each tablet contains:<br>Bromazepam…1.5 mg |
| | Diary No. Date of R&I & fee | Dy No.30431; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivative<br>ATC Code: N05BA08 |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |
| | Pack Size & Demanded Price | 3x10's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed. |
| | Me-too status | 071219; Yazd 1.5mg Tablet<br>By M/s. Wilshire Laboratories (Pvt) Ltd; |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision(M-286):<br>Deferred for the following reasons:<br>• Submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets.<br>• Evidence of approval of applied formulation in reference regulatory authorities/agencies which | |

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| | were adopted by the Registration Board in its 275th meeting. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. Swissmedica Approved. | |
| | **Decision: Approved with innovator's specification.** | |
| 577. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Zepam Tablet 3mg |
| | Composition | Each tablet contains:<br>Bromazepam…3mg |
| | Diary No. Date of R&I & fee | Dy No.30432; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivative<br>ATC Code: N05BA08 |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |
| | Pack Size & Demanded Price | 3x10's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | TGA Approved |
| | Me-too status | 079327; "Normeez 6mg Tablets<br>By Navegal Laboratories |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved with innovator's specification.** | |
| 578. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Nazep Tablet 0.5mg |
| | Composition | Each tablet contains::<br>Clonazepam…0.5mg |
| | Diary No. Date of R&I & fee | Dy No.30440; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Antiepileptics<br>Benzodiazepine derivatives<br>ATC Code: N03AE01 |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | 068006; "Clonazil Tablet 0.5mg<br>By "M/s English Pharm, |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Approved in USFDA with box warning.<br>Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |

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| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 579. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Nazep Tablet 1mg |
| | Composition | Each tablet contains:<br>Clonazepam…1mg |
| | Diary No. Date of R&I & fee | Dy No.30441; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Antiepileptics<br>Benzodiazepine derivatives<br>ATC Code: N03AE01 |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | 065700; "Curo 1mg Tablets<br>"M/s. Wilshire Laboratories (Pvt) Ltd; |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Approved in USFDA with box warning.<br>Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 580. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Nazep Tablet 2mg |
| | Composition | Each tablet contains:<br>Clonazepam…2mg |
| | Diary No. Date of R&I & fee | Dy No.30442; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Antiepileptics<br>Benzodiazepine derivatives ATC Code: N03AE01 |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved |
| | Me-too status | 068001<br>"Clonazil Tablet 2mg<br>By "M/s English Pharm, |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |

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| | Remarks of Evaluator | Approved in USFDA with box warning.<br>Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 581. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Butone Tablet 30mg |
| | Composition | Each tablet contains:<br>Phenobarbitone…30mg |
| | Diary No. Date of R&I & fee | Dy No.30425; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Antiepileptics<br>Barbiturates and derivatives<br>ATC Code: N03AA02 |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 10x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved (uncoated) |
| | Me-too status | 065717; "Phenotone Tablets<br>by "M/s Rasco Pharma, |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 582. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Alpraz Tablet 2mg |
| | Composition | Each Tablet Contains:<br>Alprazolam…2mg |
| | Diary No. Date of R&I & fee | Dy No.30430; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivatives<br>ATC Code: N05BA12 |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved (uncoated) |
| | Me-too status | 065695; Lydia 2mg Tablets<br>by M/s. Wilshire Laboratories (Pvt) Ltd; |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone |

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| | | Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 583. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals. 3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Alpraz Tablet 1mg |
| | Composition | Each Tablet Contains:<br>Alprazolam…1mg |
| | Diary No. Date of R&I & fee | Dy No.30429; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivatives<br>ATC Code: N05BA12 |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved (uncoated) |
| | Me-too status | 065699<br>Lydia 1mg Tablets<br>by M/s. Wilshire Laboratories (Pvt) Ltd; |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 584. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.<br>3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Alpraz Tablet 0.25mg |
| | Composition | Each Tablet Contains:<br>Alprazolam…0.25mg |
| | Diary No. Date of R&I & fee | Dy No.30428; 10-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivatives<br>ATC Code: N05BA12 |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved (uncoated) |
| | Me-too status | 065697; Lydia 0.25mg Tablets<br>by M/s. Wilshire Laboratories (Pvt) Ltd; |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of |

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| | | following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 585. | Name and address of Manufacturer / Applicant | M/s Shaheen Pharmaceuticals.3 km, Murghzar Road,Saidu Sharif |
| | Brand Name+DosageForm+Strength | Alpraz Tablet 0.5mg |
| | Composition | Each Tablet Contains:<br>Alprazolam…0.5mg |
| | Diary No. Date of R&I & fee | Dy No.31900; 24-09-2018; Rs.20,000/- |
| | Pharmacological Group | Anxiolytics<br>Benzodiazepine derivatives<br>ATC Code: N05BA12 |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 3x10's, As per PRC |
| | Approval status of product in Reference Regulatory Authorities | USFDA Approved (uncoated) |
| | Me-too status | 065705<br>Lydia 0.25mg Tablets<br>by M/s. Wilshire Laboratories (Pvt) Ltd; |
| | GMP status | The Central Licensing Board in its 265th meeting held on 09th - 10th August, 2018 has considered and approved the grant of following one (01) additional section<br>1. Psychotropic Tablet Section in place of Quinolone Tablet section and shifting of Quinolone tablet section to tablet General Section. |
| | Remarks of Evaluator | Firm has revised their formulation from film coated to uncoated tablet without the submission of fee. |
| | Previous Decision (M-286):<br>Deferred for submission of fee of Rs. 5000/- as the formulation has been revised from film coated to uncoated tablets. | |
| | Fresh Evaluation:<br>Firm has submitted fee of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved** | |
| 586. | Name and address of manufacturer / Applicant | M/s. Fynk Pharmaceuticals, 19-Km, Ferozepur Road, G.T. Road, Kala shah Kaku, Lahore. |
| | Brand Name +Dosage Form + Strength | Neblol tablet 10mg |
| | Composition | Each film coated tablet contains:<br>Nebivolol HCl equivalent to Nebivolol … 10mg |
| | Diary No. Date of R& I & fee | Dy. No. 17526, 09-10-2017; Rs.20,000/- (09-10-2017) |
| | Pharmacological Group | Beta blocking agents, selective<br>ATC Code: C07AB12 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. Specs. |
| | Pack size & Demanded Price | 1x14's / Alu-Alu Blister |
| | Approval status of product in Reference Regulatory Authorities. | Bystolic (uncoated)<br>USFDA Approved |
| | Me-too status | Registration Number:061346<br>Brand Name:Nebil 10mg Tablet<br>Manufacturer Name:Getz |

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| | GMP status | 20-09-2017 Conclusion:<br>"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory." |
| | Remarks of the Evaluator.<br>AD PEC V | 1. The master formulation of the applied formulation does not mention the coating material.<br>2. Evidence of approval of applied formulation as **"film coated tablets"** in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Previous Decision(M-285):**<br>Deferred for the following reasons:<br>• Submission of latest GMP inspection report which should have been conducted within the period of last one year.<br>• Submission of the master formulation of the applied formulation mentioning the coating material.<br>• Submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. | |
| | **Fresh Evaluation:**<br>I. Firm has submitted that in 286th RB Meeting the GMP inspection conducted of any firm shall be considered valid for a period of 3 years. Hence, GMP inspection conducted in Sep 2017 should be considered as valid.<br>20-09-2017 Conclusion:"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."<br>**II.** Revision of formulation from film coated to uncoated tablets and submission of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved with Innovator's specifications** | |
| 587. | Name and address of manufacturer / Applicant | M/s. Fynk Pharmaceuticals, 19-Km, Ferozepur Road, G.T. Road, Kala shah Kaku, Lahore. |
| | Brand Name +Dosage Form + Strength | Neblol tablet 5mg |
| | Composition | Each film coated tablet contains:<br>Nebivolol HCl equivalent to Nebivolol … 5mg |
| | Diary No. Date of R& I & fee | Dy. No. 17525, 09-10-2017; Rs.20,000/- (09-10-2017) |
| | Pharmacological Group | Beta blocking agents, selective<br>ATC Code: C07AB12 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. Specs. |
| | Pack size & Demanded Price | 1x14's/ Alu-Alu Blister |
| | Approval status of product in Reference Regulatory Authorities. | Bystolic (uncoated)<br>USFDA Approved |
| | Me-too status | Registration Number:061345<br>Brand Name:Nebil 10mg Tablet<br>Manufacturer Name:Getz |
| | GMP status | 20-09-2017 Conclusion:<br>"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory." |
| | Remarks of the Evaluator.<br>AD PEC V | Evidence of approval of applied formulation as **"film coated tablets"** in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Previous Decision(M-285):**<br>Deferred for the following reasons:<br>• Submission of latest GMP inspection report which should have been conducted within the | |

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| | period of last one year.<br>• Submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. | |
| | **Fresh Evaluation:**<br>I. Firm has submitted that in 286th RB Meeting the GMP inspection conducted of any firm shall be considered valid for a period of 3 years. Hence, GMP inspection conducted in Sep 2017 should be considered as valid.<br>20-09-2017 Conclusion:"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."<br>**II.** Revision of formulation from film coated to uncoated tablets and submission of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved with innovator's specification.** | |
| 588. | Name and address of manufacturer / Applicant | M/s. Fynk Pharmaceuticals, 19-Km, Ferozepur Road, G.T. Road, Kala shah Kaku, Lahore. |
| | Brand Name +Dosage Form + Strength | Neblol tablet 2.5mg |
| | Composition | Each film coated tablet contains:<br>Nebivolol HCl equivalent to Nebivolol … 2.5mg |
| | Diary No. Date of R& I & fee | Dy. No. 17524, 09-10-2017; Rs.20,000/- (09-10-2017) |
| | Pharmacological Group | Beta blocking agents, selective<br>ATC Code: C07AB12 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. Specs. |
| | Pack size & Demanded Price | 1x14's / Alu-Alu Blister |
| | Approval status of product in Reference Regulatory Authorities. | Bystolic (uncoated)<br>USFDA Approved |
| | Me-too status | Registration Number:061344<br>Brand Name:Nebil 10mg Tablet<br>Manufacturer Name:Getz |
| | GMP status | 20-09-2017 Conclusion:<br>"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory." |
| | Remarks of the Evaluator.<br>AD PEC V | Evidence of approval of applied formulation as **"film coated tablets"** in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| | **Previous Decision(M-285):**<br>Deferred for the following reasons:<br>• Submission of latest GMP inspection report which should have been conducted within the period of last one year.<br>• Submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. | |
| | **Fresh Evaluation:**<br>I. Firm has submitted that in 286th RB Meeting the GMP inspection conducted of any firm shall be considered valid for a period of 3 years. Hence, GMP inspection conducted in Sep 2017 should be considered as valid.<br>20-09-2017 Conclusion:"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."<br>**II.** Revision of formulation from film coated to uncoated tablets and submission of Rs. 5000/- dated 27-12-2018. | |
| | **Decision: Approved with innovator's specification** | |
| 589. | Name and address of manufacturer / Applicant | M/s. Fynk Pharmaceuticals, 19-Km, Ferozepur Road, G.T. Road, Kala shah Kaku, Lahore. |
| | Brand Name +Dosage Form + Strength | Vildamin Tablets 50/850 |

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| | Composition | Each film coated tablet contains:-<br>Vildagliptin……50mg<br>Metformin HCl…..850mg |
| | Diary No. Date of R& I & fee | Dy. No. 17528, 09-10-2017; Rs.20,000/- (09-10-2017) |
| | Pharmacological Group | Anti-diabetic |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg. Specs |
| | Pack size & Demanded Price | 1*14's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50mg/ 850mg film-coated tablet by M/s Novartis Pharmaceuticals Australia Pty Limited |
| | Me-too status | Galvus Met 50/850mg Tablets by M/s Novartis (Reg#066106) |
| | GMP status | 20-09-2017 Conclusion:<br>"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory." |
| | Remarks of the Evaluator.<br>AD PEC V | |
| | **Previous Decision(M-285):**<br>Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year. | |
| | **Fresh Evaluation**<br>I. Firm has submitted that in 286th RB Meeting the GMP inspection conducted of any firm shall be considered valid for a period of 3 years. Hence, GMP inspection conducted in Sep 2017 should be considered as valid.<br>20-09-2017 Conclusion: "Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."<br>**Decision: Approved with innovator's specification** | |
| 590. | Name and address of manufacturer / Applicant | M/s. Fynk Pharmaceuticals, 19-Km, Ferozepur Road, G.T. Road, Kala shah Kaku, Lahore. |
| | Brand Name +Dosage Form + Strength | Zolic Tablets 600mg |
| | Composition | Each film-coated tablet contains:<br>Linezolid .....600mg |
| | Diary No. Date of R& I & fee | Dy. No. 17534, 09-10-2017; Rs.20,000/- (09-10-2017) |
| | Pharmacological Group | Antibacterial<br>ATC Code: J01XX08 |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1x10;s, 12's ,As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Ecasil tablet of M/s Sami Pharmaceuticals (Reg. # 066904) |
| | GMP status | 20-09-2017 Conclusion:<br>"Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory." |
| | Remarks of the Evaluator.<br>AD PEC V | |
| | **Previous Decision(M-285):**<br>Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year. | |
| | **Fresh Evaluation**<br>I. Firm has submitted that in 286th RB Meeting the GMP inspection conducted of any firm shall | |

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| | be considered valid for a period of 3 years. Hence, GMP inspection conducted in Sep 2017 should be considered as valid.<br>20-09-2017 Conclusion: "Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."<br>**Decision: Approved with innovator's specification** | |
| 591. | Name and address of manufacturer / Applicant | M/s Fynk Pharmaceuticals, 19 Km G.T. Road, Kalashah Kaku, Lahore. |
| | Brand Name +Dosage Form + Strength | E-Prazole Insta oral sachet<br>Source of granules: Vision pharmaceuticals |
| | Composition | Each sachet contains:<br>Esomeprazole (as magnesium trihydrate EC 22.5% granules)…….……20mg |
| | Diary No. Date of R& I & fee | Dy. No.917; 10-02-2017; Rs.20,000/- (10-02-2017) |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1x14's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Somezol 20mg sachet of M/s Bosch Karachi |
| | GMP status | Copy of GMP inspection on 20-09-2017 concluded that overall condition of the firm is satisfactory. |
| | Remarks of the Evaluator. | ● Firm has submitted the following scientific justification of addition of 5% excess of API: "Stability data of three batches of API has been provided for real time and accelerated, that shows that the potency of the API is reduced with the passage of time. So, 5% API of the labelled amount is justified with the assay limit 90% to 110% for the labelled amount." |
| | Previous Decision: | Registration Board in its 282nd meeting did not accede with firm's justification for overage and deferred the case for submission of master formulation without overage or with complete product development data to justify overages. |
| | Evaluation by PEC: | ●□Firm has submitted revised master formulation without overage. |
| | **Previous Decision(M-285):**<br>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. | |
| | **Fresh Evaluation**<br>I. Firm has submitted that in 286th RB Meeting the GMP inspection conducted of any firm shall be considered valid for a period of 3 years. Hence, GMP inspection conducted in Sep 2017 should be considered as valid.<br>20-09-2017 Conclusion: "Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory." | |
| | **Decision: Approved with innovator's specification** | |
| 592. | Name and address of manufacturer / Applicant | M/s Fynk Pharmaceuticals, 19 Km G.T. Road, Kalashah Kaku, Lahore. |
| | Brand Name +Dosage Form + Strength | E-Prazole Plus oral sachet<br>Source of granules:Vision pharmaceuticals |
| | Composition | Each sachet contains:<br>Esomeprazole (as magnesium trihydrate EC 22.5% granules) ……40mg |
| | Diary No. Date of R& I & fee | Dy. No.918; 10-02-2017; Rs.20,000/- (10-02-2017) |

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| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1x14's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Somezol 40mg sachet of M/s Bosch Karachi |
| | GMP status | Copy of GMP inspection on 20-09-2017 concluded that overall condition of the firm is satisfactory. |
| | Remarks of the Evaluator. | ● Firm has submitted the following scientific justification of addition of 5% excess of API: "Stability data of three batches of API has been provided for real time and accelerated, that shows that the potency of the API is reduced with the passage of time. So, 5% API of the labelled amount is justified with the assay limit 90% to 110% for the labelled amount." |
| | Previous Decision: | Registration Board in its 282nd meeting did not accede with firm's justification for overage and deferred the case for submission of master formulation without overage or with complete product development data to justify overages. |
| | Evaluation by PEC: | ●□Firm has submitted revised master formulation without overage. |
| | **Previous Decision(M-285):**<br>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. | |
| | **Fresh Evaluation**<br>I. Firm has submitted that in 286th RB Meeting the GMP inspection conducted of any firm shall be considered valid for a period of 3 years. Hence, GMP inspection conducted in Sep 2017 should be considered as valid.<br>20-09-2017 Conclusion: "Overall hygienic condition of firm is satisfactory and they advised to comply all advises/shortcomings which are mentioned above. They showed good intension to improve further. However overall condition of the firm is satisfactory."<br>**Decision: Approved with innovator's specification** | |
| 593. | 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 | Legend Plus Capsule 40mg+1100mg |
| | Composition | Each capsule contains:<br>Omeprazole…… 40mg<br>Sodium Bicarbonate……1100mg |
| | Diary No. Date of R& I & fee | Dy. No. 7978, 07-07-2017 , Rs.20,000/- (07-07-2017) |
| | Pharmacological Group | Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)<br>Proton pump inhibitors/Antacid<br>ATC code: A02BC01 |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 14's |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Registration Number: 070571<br>Brand Name: Zoltar Insta 40mg Capsule<br>Manufacturer Name: Pharmevo |
| | GMP status | Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Recommendations) |
| | Remarks of the Evaluator. | Previously, applied formulation contained omeprazole enteric coated pellets. Now the firm has replied Omeprazole has been mistakenly taken as enteric coated pellets and is in the form of powder. |

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| | **Previous Decision (M-283): Deferred for the following reasons:**<br>•Submission of Fee Rs.20,000/- for revision of formulation from enteric coated pellets of omeprazole to powder.<br>•Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID. | |
| | **Fresh Evaluation:**<br>I. Firm has submitted Fee Rs.5,000/- and 15,000/- dated 11-02-2019.<br>II. FID verified 2 stability chamber 1 for Accelerated stability studies and 1 for Real time stability studies. | |
| | **Decision: Approved with innovator's specification** | |
| 594. | 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 | Legend Plus Capsule 20mg+1100mg |
| | Composition | Each capsule contains:<br>Omeprazole…… 20mg<br>Sodium Bicarbonate……1100mg |
| | Diary No. Date of R& I & fee | Dy. No. 7979, 07-07-2017 , Rs.20,000/- (07-07-2017) |
| | Pharmacological Group | Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)<br>Proton pump inhibitors/Antacid<br>ATC code: A02BC01 |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 10's, 14's, 15's, 7's, 30's |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Registration Number: 070570<br>Brand Name: Zoltar Insta 20mg Capsule<br>Manufacturer Name: Pharmevo |
| | GMP status | Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance.(Recommendations) |
| | Remarks of the Evaluator. | Previously, applied formulation contained omeprazole enteric coated pellets. Now the firm has replied Omeprazole has been mistakenly taken as enteric coated pellets and is in the form of powder. |
| | **Previous Decision (M-283): Deferred for the following reasons:**<br>•Submission of Fee Rs.20, 000/- for revision of formulation from enteric coated pellets of omeprazole to powder.<br>•Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID. | |
| | **Fresh Evaluation:**<br>I. Firm has submitted Fee Rs.5,000/- and 15,000/- dated 11-02-2019.<br>**II.** FID verified 2 stability chamber 1 for Accelerated stability studies and 1 for Real time stability studies. | |
| | **Decision: Approved with innovator's specification** | |

**Evaluator PEC-IV**

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| 595. | Name and address of manufacturer / Applicant | M/s. FAAS Pharmaceuticals (Pvt) Ltd . Plot No. F/748-L., S.I.T.E., Karachi, Pakistan<br>Contract manufactured by; M/S Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi, Industrial Area, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Ulciloc 40mg IV Injection |
| | Composition | Each vial contains:<br>Omeprazole Sodium (U.S.P) equivalent to Omeprazole (Lyophilized powder)…….40mg |
| | Diary No. Date of R& I & fee | Dy.No. 17779; 14-05-2018; Duplicate dossier Rs.50,000/- (18-08-2017) |

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| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture's specification |
| | Pack size & Demanded Price | 1's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Omeprazol 40mg injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Fymezole Dry Powder Injection IV of M/s Fynk Pharmaceuticals |
| | GMP status | Routine GMP inspection of FAAS Pharmaceuticals conducted on 14-07-2017 concluded that the current level of compliance is rated satisfactory.<br>&<br>Last GMP of Nabi qasim Inspection conducted on 03-08-2018 and report concludes that firm is considered to be operating at an acceptable level of compliance of GMP requirments. |
| | Previous remarks of the Evaluator. | • Contract manufacturing agreement: attached<br>• Number of sections of applicant approved by Licensing Board:03<br>• Number of products already registered/approved on contract manufacturing in the name of applicant: Nil |
| | Previous decision(s) | Deferred for following reasons:<br>Deferred for clarification of applied dosage form whether lyophiloized powder or lyophilized cake. (M-285) |
| | Evaluation by PEC | Omeprazole sodium equivalent to omeprazole in the form of Lyophilizes cake. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 596. | Name and address of manufacturer / Applicant | M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan<br>Contract manufactured by: Previous: M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad.<br><br>Now: Winthrox Laboratories (Pvt) Ltd K-219-A, SITE highway, phase-II Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Welrose injection |
| | Composition | Each ml contains:<br>Iron sucrose complex eq. to emental Iron…….100mg |
| | Diary No. Date of R& I & fee | Dy.No.10649; 01-08-2017; Rs.50,000/- (01-08-2017) |
| | Pharmacological Group | Anti anaemics |
| | Type of Form | Form 5 |
| | Finished product Specifications | BP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Venofer Injection by Vifor (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Venofer injection by Gastrocare , |
| | GMP status | Last GMP inspection of Welwrd conducted on 12-07-2018 and the report concludes<br>All the observations in the inspection were discussed with the firm management and technical persons. They were committed to rectify all the observations. The firm may be considerd to be operating in satisfactory level of cGMP compliance subject to fulfillment of observations mentioned in the inspection report."<br>&<br>Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance |

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| | Previous remarks of the Evaluator. | • Number of sections of applicant approved by Licensing Board :06<br>• Number of products already registered/approved on contract manufacturing in the name of applicant: 12 |
| | Previous decision(s) | Deferred for following reasons:<br>Regsitration Board Board decided to defer all applied products of contract manufacturing from M/s Bio Labs (Pvt) Ltd. of Cephalosporin facility, Ampoule general section and infusion (Non-Antibiotic and Antibiotic) section till the finalization of inspection report for assessment and confirmation of manufacturing capacity of M/s Bio Labs (Pvt) Ltd (M-285) |
| | Evaluation by PEC | Change manufacturing facility from M/S Biolabs to M/S Winthrox. |
| | **Decision: Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm** | |
| 597. | Name and address of manufacturer / Applicant | M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan<br>Contract manufactured by<br>Previous: M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad.<br><br>Now: Winthrox Laboratories (Pvt) Ltd K-219-A, SITE highway, phase-II Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Welferol 5mg injection |
| | Composition | Each 1ml contains:<br>Cholecalciferol (Vitamin D3) …….5mg<br>(Eq to 200,000 IU of vitamin D) |
| | Diary No. Date of R& I & fee | Dy.No.10648; 01-08-2017; Rs.50,000/- (01-08-2017) |
| | Pharmacological Group | Vitamin D analogue |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1ml x 1's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of ( ANSM France approved) |
| | Me-too status (with strength and dosage form) | Calciferol Injection M/s Global Pharmaceuticals, |
| | GMP status | Last GMP inspection of Welwrd conducted on 12-07-2018 and the report concludes<br>" All the observations in the inspection were discussed with the firm management and technical persons. They were committed to rectify all the observations. The firm may be considerd to be operating in satisfactory level of cGMP compliance subject to fulfillment of observations mentioned in the inspection report."<br>&<br>Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance |
| | Previous remarks of the Evaluator. | • Number of sections of applicant approved by Licensing Board :06<br>• Number of products already registered/approved on contract manufacturing in the name of applicant: 12 |
| | Previous decision(s) | Deferred for following reasons:<br>Regsitration Board Board decided to defer all applied products of contract manufacturing from M/s Bio Labs (Pvt) Ltd. of Cephalosporin facility, Ampoule general section and infusion (Non-Antibiotic and Antibiotic) section till the finalization of inspection |

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| | | report for assessment and confirmation of manufacturing capacity of M/s Bio Labs (Pvt) Ltd (M-285) |
| | Evaluation by PEC | Change manufacturing facility from M/S Biolabs to M/S Winthrox. |
| | **Decision: Decision: Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm** | |
| 598. | Name and address of manufacturer / Applicant | M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan<br>Contract manufactured by<br>Previous:M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad.<br><br>Now: Winthrox Laboratories (Pvt) Ltd K-219-A, SITE highway, phase-II Karachi, Pakistan. |
| | Brand Name +Dosage Form + Strength | Mecowel 500mcg injection |
| | Composition | Each ml contains:<br>Mecobalamine…..500mcg |
| | Diary No. Date of R& I & fee | Dy.No.10651; 01-08-2017; Rs.50,000/- (01-08-2017) |
| | Pharmacological Group | Co-enzyme-type vitamin B12 |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacture's specification |
| | Pack size & Demanded Price | 5ml x 5's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | PMDA approved |
| | Me-too status (with strength and dosage form) | Wycomin 500 mcg Injection by Wnsfeild Pharmaceutical, |
| | GMP status | Last GMP inspection of Welwrd conducted on 12-07-2018 and the report concludes<br>" All the observations in the inspection were discussed with the firm management and technical persons. They were committed to rectify all the observations. The firm may be considerd to be operating in satisfactory level of cGMP compliance subject to fulfillment of observations mentioned in the inspection report."<br>&<br>Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance |
| | Previous remarks of the Evaluator. | • Number of sections of applicant approved by Licensing Board :06<br>• Number of products already registered/approved on contract manufacturing in the name of applicant: 12 |
| | Previous decision(s) | Deferred for following reasons:<br>Regsitration Board Board decided to defer all applied products of contract manufacturing from M/s Bio Labs (Pvt) Ltd. of Cephalosporin facility, Ampoule general section and infusion (Non-Antibiotic and Antibiotic) section till the finalization of inspection report for assessment and confirmation of manufacturing capacity of M/s Bio Labs (Pvt) Ltd (M-285) |
| | Evaluation by PEC | Change manufacturing facility from M/S Biolabs to M/S Winthrox. |
| | **Decision: Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm** | |
| 599. | Name and address of manufacturer / Applicant | M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan<br>Contract manufactured by<br>Previous:M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad. |

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| | | Now: Winthrox Laboratories (Pvt) Ltd K-219-A, SITE highway, phase-II Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Ketrol-T 30mg injection |
| | Composition | Each ml contains:<br>Ketorolac trometamol……..30mg |
| | Diary No. Date of R& I & fee | Dy.No.10650; 01-08-2017; Rs.50,000/- (01-08-2017) |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1ml x 5's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ketorolac of USFDA approved |
| | Me-too status (with strength and dosage form) | Tolek injection by Regal Pharmaceuticals |
| | GMP status | Last GMP inspection of Welwrd conducted on 12-07-2018 and the report concludes<br>" All the observations in the inspection were discussed with the firm management and technical persons. They were committed to rectify all the observations. The firm may be considerd to be operating in satisfactory level of cGMP compliance subject to fulfillment of observations mentioned in the inspection report."<br>&<br>Last inspection of Bio-Labs conducted on 05-12-2017 & 06-12-2017 and report concludes that firm is found at fair level of GMP compliance |
| | Previous remarks of the Evaluator. | • Number of sections of applicant approved by Licensing Board :06<br>• Number of products already registered/approved on contract manufacturing in the name of applicant: 12 |
| | Previous decision(s) | Deferred for following reasons:<br>Regsitration Board Board decided to defer all applied products of contract manufacturing from M/s Bio Labs (Pvt) Ltd. of Cephalosporin facility, Ampoule general section and infusion (Non-Antibiotic and Antibiotic) section till the finalization of inspection report for assessment and confirmation of manufacturing capacity of M/s Bio Labs (Pvt) Ltd (M-285) |
| | Evaluation by PEC | Change manufacturing facility from M/S Biolabs to M/S Winthrox. |
| | **Decision: Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm** | |
| 600. | Name and address of manufacturer / Applicant | M/s Helix Pharma Karachi |
| | Brand Name +Dosage Form + Strength | Cymanta Capsule 20mg |
| | Composition | Each capsule contains:<br>22.4 mg of Duloxetine……20mg |
| | Diary No. Date of R& I & fee | Dy.No.995; 30-12-2014; Rs.12,000/- Duplicate dossier |
| | Pharmacological Group | Serotonin and Noradrenalin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specifications | (USP Specs) |
| | Pack size & Demanded Price | 10's & 14's As per PRC |
| | Approval status of product in Reference Regulatory Authorities | Cymbalta of (USFDA approved)) |
| | Me-too status (with strength and dosage form) | Swenta 20mg Capsule by M/s Martin Dow |
| | GMP status | Last inspection conducted on 10-08-2017 and report concludes that firm is found at satisfactory level of GMP compliance |

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| | Previous remarks of the Evaluator. | • Source of pellets: M/s Pelltech Healthcare India<br>• Rs; 1,00,000 fee challan attached (15-11-2017)<br>• Copy Of GMP certificate No: NEW-WHO- |
| | Previous decision(s) | Deferred for following reasons:<br>Deferred for clarification of composition of applied formulation. (M-285) |
| | Evaluation by PEC | Each capsule contains:<br>22.4mg of Duloxetine HCl (Enteric coated pellets) equivalent to Duloxetine…….20mg |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |

**Evaluator-PEC-VI**

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| 601. | Name and address of manufacturer / Applicant | M/s Pacific Pharmaceuticals Ltd, 30-km, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Femme-Safe Tablets 1.5mg |
| | Composition | Each tablet contains:<br>Levonorgestrel … 1.5mg |
| | Diary No. Date of R& I & fee | Diary No:10935, 26/03/2018, Rs. 20,000/- |
| | Pharmacological Group | Hormonal contraceptives for systemic use (Progestogens) |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 1's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Levonorgestrel 1.5 mg tablet by M/s Gedeon Richter Plc. (MHRA Approved) |
| | Me-too status | Not confirmed |
| | GMP status | 07-11-2017<br>Panel recommends grant of Additional sections |
| | Remarks of the Evaluator. | Me-too Status not confirmed from available database.<br>Levonorgestrel: (Synthetic Progestogen) is a synthetic estrane steroid and a derivative of testosterone<br>G GENITO URINARY SYSTEM AND SEX HORMONES<br>G03 SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM<br>G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE<br>G03AC Progestogens<br>ATC Code : G03AC03 |
| | Previous Decision: | **Decision of 281st meeting:**<br>The Board deferred product and advised the firm to get approval from Licensing Division particularly for either Tablet (Steroidal Hormone) or Tablet (Non-steroidal Hormone) for further processing by Registration Board.<br>**Decision of 286th 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 by PEC: | Firm has provided me too as Emkit-DS tablet 1.5mg of Zafa Pharma Reg # 032543. |
| | **Decision: Approved with innovator's specification. The Board further advised the firms to get approval for "Tablet (steroidal hormone) section" from Licensing Division before issuance of Registration letter.** | |
| 602. | Name and address of manufacturer / Applicant | M/s Pacific Pharmaceuticals Ltd, 30-km, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Fina-Grow 1mg Tablets |
| | Composition | Each film-coated tablet contains:<br>Finasteride…25mg |

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| | Diary No. Date of R& I & fee | Diary No:10915, 26/03/2018, Rs. 20,000/- |
| | Pharmacological Group | Testosterone-5-alpha reductase inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 3 x 10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Finasteride 1 mg Film-coated Tablets by M/s TEVA UK Ltd (MHRA Approved) |
| | Me-too status | Hairfin Tablets 1mg by M/s Elko Organization (Reg#034771) |
| | GMP status | 07-11-2017<br>Panel recommends grant of Additional sections |
| | Remarks of the Evaluator. | Finasteride is a 5α-reductase inhibitor, and hence is an antiandrogen.<br>Finasteride is a synthetic 4-azasteroid.<br>G GENITO URINARY SYSTEM AND SEX HORMONES G04 UROLOGICALS G04C DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY<br>G04CB Testosterone-5-alpha reductase inhibitors<br>ATC Code: G04CB01 |
| | Previous Decision: | **Decision of 281st meeting:**<br>The Board deferred product and advised the firm to get approval from Licensing Division particularly for either Tablet (Steroidal Hormone) or Tablet (Non-steroidal Hormone) for further processing by Registration Board.<br>**Decision of 286th meeting:**<br>Clarification required whether the applied product is steroidal hormone or otherwise. |
| | Evaluation by PEC: | Firm has stated that applied formulation is a synthetic 4-azasteroid compound and is analogue of androgen steroid hormone. |
| | **Decision: Approved with innovator's specification. The Board further advised the firms to get approval for "Tablet (steroidal hormone) section from Licensing Division before issuance of Registration letter.** | |
| 603. | Name and address of manufacturer / Applicant | M/s Pacific Pharmaceuticals Ltd, 30-km, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Androstat Tablets 50mg |
| | Composition | Each tablet contains:<br>Cyproterone acetate … 50mg |
| | Diary No. Date of R& I & fee | Diary No:10939, 26/03/2018, Rs. 20,000/- |
| | Pharmacological Group | Antiandrogen |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 5 x 10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Androcur 50 mg tablets by M/s Bayer plc (MHRA Approved) |
| | Me-too status | Androcur 50 mg tablets by M/s ALI GOHAR & CO (Reg#010221) |
| | GMP status | 07-11-2017<br>Panel recommends grant of Additional sections |
| | Remarks of the Evaluator. | Cyproterone acetate: A synthetic steroidal antiandrogen.<br>CPA, also known as 1α,2α-methylene-6-chloro-17α-acetoxy-δ6-progesterone or as 1α,2α-methylene-6-chloro-17α-hydroxypregna-4,6-diene-3,20-dione acetate, is a synthetic pregnane steroid and an acetylated derivative of 17α-hydroxyprogesterone |
| | Previous Decision: | **Decision of 281st meeting:**<br>The Board deferred product and advised the firm to get approval from Licensing Division particularly for either Tablet (Steroidal Hormone) or Tablet (Non-steroidal |

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| | | Hormone) for further processing by Registration Board.<br>**Decision of 286th meeting:**<br>Deferred for further deliberation upon requirements of manufacturing facility for applied formulation. |
| | Evaluation by PEC: | The firm has stated the the applied formultaions are steroidal hormone and will be manufactured in steroidal hormone section. |
| | **Decision: Approved with innovator's specification. The Board further advised the firms to get approval for "Tablet (steroidal hormone) section from Licensing Division before issuance of Registration letter.** | |
| 604. | Name and address of manufacturer / Applicant | M/s Pacific Pharmaceuticals Ltd, 30-km, Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Allure Tablets 0.035/2mg |
| | Composition | Each film coated tablet contains:<br>Cyproterone acetate … 2mg<br>Ethinylestradiol… 0.035mg |
| | Diary No. Date of R& I & fee | Diary No:10931, 26/03/2018, Rs. 20,000/- |
| | Pharmacological Group | Antiandrogens and estrogens |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 5 x 10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Acnocin 2000/35 Tablets by M/s Sandoz Limited (MHRA Approved) |
| | Me-too status | DIANE-35 Tablets by M/s Ali Gohar & Co. (Reg#011467) |
| | GMP status | 07-11-2017<br>Panel recommends grant of Additional sections |
| | Remarks of the Evaluator. | Cyproterone acetate: A synthetic steroidal antiandrogen.<br>Ethinylestradiol: A Steroidal Sex hormone |
| | Previous Decision: | **Decision of 281st meeting:**<br>The Board deferred product and advised the firm to get approval from Licensing Division particularly for either Tablet (Steroidal Hormone) or Tablet (Non-steroidal Hormone) for further processing by Registration Board.<br>**Decision of 286th meeting:**<br>Deferred for further deliberation upon requirements of manufacturing facility for applied formulation. |
| | Evaluation by PEC: | The firm has stated the the applied formulations are steroidal hormone and will be manufactured in steroidal hormone section. |
| | **Decision: Approved with innovator's specification. The Board further advised the firms to get approval for "Tablet (steroidal hormone) section from Licensing Division before issuance of Registration letter.** | |
| 605. | Name and address of manufacturer / Applicant | M/s Genome Pharmaceuticals, Hattar |
| | Brand Name +Dosage Form + Strength | Everogen 3mg Dispersible tablets |
| | Composition | Each dispersible tablet contains:<br>Everolimus……3mg |
| | Diary No. Date of R& I & fee | Dy. No.1385; 15-02-2018; Rs.20,000/- (14-2-2018) |
| | Pharmacological Group | Anti-neoplastic agent |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specification |
| | Pack size & Demanded Price | As per SRO, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | AFINITOR DISPERZ TABLET FOR ORAL SUSPENSION. USFDA Approved |
| | Me-too status | Could not be confirmed |
| | GMP status | Panel Inspection on 14-01-2017, No observations as informed by QA. |
| | Remarks of the Evaluator. | Me-too status could not be confirmed. |

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| | Previous Decision: | **Decision of 281st meeting:**<br>Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | Evaluation by PEC: | The firm has stated the Afinitor 3mg Dispersible tablet (Everolimus…….3mg) has been approved in M.263. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, or else application on form-5D alongwith stability data and differential fee.** | |
| 606. | Name and address of manufacturer / Applicant | M/s Genome Pharmaceuticals, Hattar |
| | Brand Name +Dosage Form + Strength | Everogen 2mg Dispersible tablets |
| | Composition | Each dispersible tablet contains:<br>Everolimus……2mg |
| | Diary No. Date of R& I & fee | Dy. No.1386; 15-02-2018; Rs.20,000/- (14-2-2018) |
| | Pharmacological Group | Anti-neoplastic agent |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer‘s Specification |
| | Pack size & Demanded Price | As per SRO, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | AFINITOR DISPERZ TABLET FOR ORAL SUSPENSION. USFDA Approved |
| | Me-too status | Could not be confirmed |
| | GMP status | Panel Inspection on 14-01-2017, No observations as informed by QA. |
| | Remarks of the Evaluator. | Me-too status could not be confirmed. |
| | Previous Decision: | **Decision of 281st meeting:**<br>Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | Evaluation by PEC: | The firm has stated the Afinitor 2mg Dispersible tablet (Everolimus…….2mg) has been approved in M.262. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, or else application on form-5D alongwith stability data and differential fee.** | |

**Evaluator PEC-VII**

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| 607. | Name and address of manufacturer / Applicant | M/s. News Pharma,42 Sunder industrial estate, Raiwind road, Lahore |
| | Brand Name +Dosage Form + Strength | Newcocin 600mg/2ml Injection |
| | Diary No. Date of R& I & fee | Dy.No. 762, 30-3-2015, Rs.20,000/- |
| | Composition | Each 2ml contains:-<br>Lincomycin as HCl…..600mg |
| | Pharmacological Group | H-1-Antagonist |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | Rs.450.00/5x2ml ampoules (IM/IV) |
| | Approval Status of Product in Reference Regulatory Authorities. | Lincocin by Pharmacia (USFDA) |
| | Me-too Status | Lincococin by Pfizer |
| | GMP status | Last GMP Inspection of News Pharma Conducted on 26-4-2018. GMP certificate is provided |
| | Remarks of the Evaluator. | inspection report is not within the past one year |
| | **Decision of 273:**<br>Deferred for latest GMP inspection report conducted within past one year.<br>**Remarks of evaluator [VII]:**<br>Last GMP Inspection of News Pharma Conducted on 26-4-2018. GMP certificate is provided | |
| | **Decision: Approved.** | |

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| 608. | Name and address of manufacturer / Applicant | M/s. News Pharma,42 Sunder industrial estate, Raiwind road, Lahore |
| | Brand Name +Dosage Form + Strength | Newcin Injection 80mg/2ml |
| | Diary No. Date of R& I & fee | Dy.No. 762, 30-3-2015, Rs.20,000/- |
| | Composition | Each 2ml contains:-<br>Gentamicin (as sulphate)…….80mg<br>Water for injection q.s to….2ml |
| | Pharmacological Group | H-1-Antagonist |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | Rs.250.00/5x2ml ampoules<br>Rs.1125.00/25x2ml ampoules |
| | Approval Status of Product in Reference Regulatory Authorities. | Garamycin by Schering (USFDA) |
| | Me-too Status | Cidomycin by Sanofi aventis |
| | GMP status | Last GMP Inspection of News Pharma Conducted on 6-4-2016 with conclusive remarks of cGMP Compliance. |
| | Remarks of the Evaluator. | Inspection report is not within the past one year |
| | **Decision of 273:**<br>Deferred for latest GMP inspection report conducted within past one year.<br>**Remarks of evaluator [VII]:**<br>Last GMP Inspection of News Pharma Conducted on 26-4-2018. GMP certificate is provided | |
| | **Decision:Approved** | |
| 609. | Name and address of Manufacturer / Applicant | M/s Winlet Pharma 30 Km, Laksian Lahore road. Sargodha |
| | Brand Name+ Dosage Form+ Strength | Lorades 0.5 mg/5ml syrup |
| | Composition | Each 5 ml contains:<br>Desloratadine …0.5 mg |
| | Diary No. Date of R&I & fee | Dy No. 3414 ; 13-04-2018; Rs.20,000/- |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | NA |
| | Me-too status | Deltafast of Schaazoo |
| | GMP status | New DML granted Inspection Date 05/12/2017 |
| | Remarks of Evaluator | |
| | **Decision of 282:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.<br>**Remarks of evaluator [VII]:**<br>Each 5 ml contains:<br>Desloratadine …2.5 mg<br>International: (Clarinex syrup by Schering, USFDA Approved)<br>Me-too status: (Neo-antial syrup by Sami Pharma)<br>Fee of 5000/-, challan # 0814955, dated: 31/12/2018 was submitted | |
| | **Decision: Deferred for submission of 20,000/- fee for revision of applied strength..** | |
| 610. | Name and address of Manufacturer / Applicant | M/s Winlet Pharma 30 Km, Laksian Lahore road. Sargodha |
| | Brand Name+ Dosage Form+ Strength | Famole 10 mg/5ml susp |
| | Composition | Each 5 ml contains:<br>Famotidine .....10 mg |
| | Diary No. Date of R&I & fee | Dy No. 3417 ; 13-04-2018; Rs.20,000/- |
| | Pharmacological Group | Anti-histamine |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |

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| | Approval status of product in Reference Regulatory Authorities | NA |
| | Me-too status | Apsin of saffron |
| | GMP status | New DML granted Inspection Date 05/12/2017 |
| | Remarks of Evaluator | Not approved by reference drug regulatory agencies. Internationally available formulation is dry powder for suspension in the strength of 40 mg/ 5 ml.(Ref: US FDA) |
| | **Decision of 282:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.<br>**Remarks of evaluator VII:**<br>Each 5 ml contains:<br>Famotidine .....40 mg<br>International: (Pepcid 40 mg/5 ml of Salix Pharma Inc., USA (USFDA)<br>Me-too status: (Pepnex 40mg/5ml Dry Powder Suspension of M/s Nexus Pharma)<br>Fee of 5000/-, challan # 0814954, dated: 31/12/2018 was submitted. | |
| | **Decision: Deferred for submission of 20,000/- fee for revision of dosage form.** | |
| 611. | Name and address of Manufacturer / Applicant | M/s Winlet Pharma 30 Km, Laksian Lahore road. Sargodha |
| | Brand Name+ Dosage Form+ Strength | Fosfo 250 mg/5 ml DS |
| | Composition | Each 5ml(when reconstituted)contains:<br>Fosfomycin …250 mg |
| | Diary No. Date of R&I & fee | Dy No. 3377 ; 13-04-2018; Rs.20,000/- |
| | Pharmacological Group | Antibiotic / antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovators |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Not provided |
| | Me-too status | Fosomin by CCL |
| | GMP status | New DML granted Inspection Date 05/12/2017 |
| | Remarks of Evaluator | Dry powder suspension is not available in any reference authority |
| | **Decision of 282:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.<br>**Remarks of evaluator VII:**<br><u>International:</u> FOSFOCINA Suspension 250mg/5ml by Spain<br><u>Me-too status:</u> Fosfonex 250mg/5ml Suspension of M/s Nexus Pharma | |
| | **Decision: Approved with innovator's specification.** | |
| 612. | Name and address of Manufacturer / Applicant | M/s Winlet Pharma 30 Km, Laksian Lahore road. Sargodha |
| | Brand Name+ Dosage Form+ Strength | Paradol Elixir 160 mg/ 5ml drops |
| | Composition | Each 5 ml contains:<br>Paracetamol……..160 mg |
| | Diary No. Date of R&I & fee | Dy No. 3428 ; 13-04-2018; Rs.20,000/- |
| | Pharmacological Group | Iron Supplement/Hematinic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | NA |
| | Me-too status | NA |
| | GMP status | New DML granted Inspection Date 05/12/2017 |
| | Remarks of Evaluator | • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith |

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| | | registration number, brand name and name of firm |
| | **Decision of 282:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.<br>**Remarks of evaluator VII:**<br>Provided reference of health Canada "acetaminophen 160 child elixir" can't be confirmed | |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 613. | Name and address of manufacturer / Applicant | M/s Cibex Pvt. Ltd. Factory # 405, SITE, Karachi. |
| | Brand Name +Dosage Form + Strength | Balin chewable tablet |
| | Composition | Each chewable tablets contains:-<br>Mecobalamin…… 500 mcg |
| | Diary No. Date of R& I & fee | Dy. No. 224; 3-1-2017; Rs. 20,000/- |
| | Pharmacological Group | Co-enzyme Vit B12 |
| | Type of Form | Form-5 |
| | Finished product Specifications | Innovator specs |
| | Pack size & Demanded Price | 30's<br>As per SRO |
| | Approval status of product in Reference Regulatory Authorities | NA (Approved in PMDA as sugar coated) |
| | Me-too status | Mecomed 500mcg by Global Pharma (Reg. No. 041670) in sugar coating |
| | GMP status | Last GMP Inspection of Cibex Pvt. Ltd conducted on 29-8-17 with conclusive remarks of satisfactory level of cGMP compliance. |
| | Remarks of Evaluator | |
| | **Decision of 282:**<br>Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting and me too reference.<br>**Remarks of evaluator VII:**<br>Provided reference of health Canada "Natural life nutrition product: natural one vitamin B-12. Reg#: 80035585" can't be confirmed<br>Me too: Himont pharma, hicobal chewable tablet, Reg # 032320 can't be confirmed.<br>• | |
| | **Decision:Deferred for following:**<br>**Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>**Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 614. | Name and address of manufacturer / Applicant | M/s Elite Pharma Pvt Ltd., P.D.H. Street 9.5 km Sheikhupura Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Betavel ointment 5 gm Tube |
| | Composition | Each 5 gm ointment Contains:<br>Betamethasone as valerate……..0.1% |
| | Diary No. Date of R& I & fee | Dy.No. 11922, 15-8-2017, Rs.20,000/= |
| | Pharmacological Group | Corticosteroids |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 5 gm<br>As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | BETA-VAL 0.1% ointment (USFDA) |
| | Me-too status | Betacin of Geofman Pharmaceuticals |
| | GMP status | Last GMP inspection was conducted on 31-01-2018 and the report concludes: |

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| | | "It is advised to overcome the shortcomings and submit the compliance report to the competent authorities so that the inspection could be conducted accordingly." |
| | Remarks of Evaluator | |
| | **Decision of 283:**<br>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority and licensing division for licensing status.<br>**Remarks of evaluator [VII]:**<br>Last GMP inspection conducted on 4-6-2018 and 16-7-2018, concludes:<br>"Keep in view that most of the observations are rectified by the management so maintaining satisfactory GMP compliance." | |
| | **Decision:Approved** | |
| 615. | Name and address of manufacturer / Applicant | M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Demnac 75/200mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 26421 dated 28-12-2017 Rs. 20,000<br>Dated 28-12-2017 |
| | Composition | Each Tablet Contains:<br>Diclofenac Sodium…75mg<br>Misoprostol…200Ug |
| | Pharmacological Group | (Cytoprotactant/NSAID) |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1x12's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | NA (Arthrotec 75 modified-release tablets (MHRA) but as gastro resistant) |
| | Me-too Status | ARTHO PLUS of Shaigan |
| | GMP status | Last GMP Inspection of Conducted on 23/2/2018, 26/2/2018 and report shows satisfactory cGMP level. |
| | Remarks of the Evaluator. | Each tablet consists of a gastro-resistant core containing 75 mg diclofenac sodium surrounded by an outer mantle containing 200 micrograms misoprostol But firm applied as film coated tablet |
| | **Decision of 286:**<br>Deferred for revision of formulation and label claim as per the USFDA approved<br>Reference product.<br>**Remarks of evaluator [VII]**<br>Revised Form 5, and formulation as gestro resistant core containing 75 mg diclofenac sodium surrounding by an outer mantle of 200 microgram of misoprostol along with the fee of 5000/-( Deposit slip # 0820236, dated:31-1-2019) is submitted. | |
| | **Decision: Deferred for confirmation of avaialbility of double compression machine.** | |
| 616. | Name and address of manufacturer / Applicant | M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Demzoflex 2mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 26432 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017 |
| | Composition | Each Film coated Tablet Contains:<br>Tinzanidine as Hydrochloride…2mg |
| | Pharmacological Group | Muscle Relaxant |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1x10's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | NA<br>Tizanidine 2mg uncoated Tablets Actavis UK Ltd (MHRA) |
| | Me-too Status | Analar by AGP |
| | GMP status | Last GMP Inspection of Conducted on 23/2/2018, 26/2/2018 and report shows satisfactory cGMP level. |
| | Remarks of the Evaluator. | Tablet is approved as uncoated tablet in reference regulatory authority. |

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| | **Decision of 286:**<br>Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.<br>**Remarks of evaluator [VII]**<br>Revised Form 5, and master formulation as uncoated tablet i.e.<br>Each uncoated Tablet Contains:<br>Tinzanidine as Hydrochloride…2mg<br>along with the fee of 5000/-( Deposit slip # 0820237, dated:31-1-2019) is submitted. | |
| | **Decision: Approved** | |
| 617. | Name and address of manufacturer / Applicant | M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Demzoflex 4mg Tablet |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 26433 dated 28-12-2017 Rs. 20,000 Dated 28-12-2017 |
| | Composition | Each Film Coated Tablet Contains:<br>Tinzanidine as Hydrochloride…4mg |
| | Pharmacological Group | Skeletal Muscle relaxant |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1x10's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Tizanidine of MHRA approved |
| | Me-too Status | Musidin of M/s Martin Dow |
| | GMP status | Last GMP Inspection of Conducted on 23/2/2018, 26/2/2018 and report shows satisfactory cGMP level. |
| | Remarks of the Evaluator. | Tablet is approved as uncoated tablet in reference regulatory authority. |
| | **Decision of 286:**<br>Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.<br>**Remarks of evaluator [VII]**<br>Revised Form 5, and master formulation as uncoated tablet i.e.<br>Each uncoated Tablet Contains:<br>Tinzanidine as Hydrochloride…2mg<br>along with the fee of 5000/-( Deposit slip # 0820238, dated:31-1-2019) is submitted. | |
| | **Decision:Approved** | |
| 618. | Name and address of manufacturer / Applicant | M/s. Rakaposhi Pharmaceuticals, 97-K Industrial Estate, Hayatabad, Peshawar |
| | Brand Name +Dosage Form + Strength | Gesteron 10 mg tablet |
| | Composition | Each Film coated tablet contains:-<br>Dydrogesteron……10 mg |
| | Diary No. Date of R& I & fee | Dy. No.1046; 10-1-2017; Rs. 20,000/- |
| | Pharmacological Group | Progestogen |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Duphaston by BGP Products<br>(Swissmedic Approved) |
| | Me-too status | Duphaston by Abbott |
| | GMP status | Last GMP Inspection dated …. with conclusive remarks of good cGMP compliance. |
| | Remarks of Evaluator | Letter was issued to the firm ;<br>• Approval of section/manufacturing facility by the Central Licensing Board for hormonal products. However, you may submit panel inspection report for |

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| | | renewal of DML verifying the section/manufacturing facility<br>• Latest GMP inspection report (which should have been conducted within the period of last one year).<br>• As Firm don't have approved section so they switch to contract manufacturing by Aries Pharmaceuticals and revised fee and dossier is received. |
| | **Details are as under** | |
| 619. | Name and address of manufacturer / Applicant | M/s. Rakaposhi Pharmaceuticals, 97-K Industrial Estate, Hayatabad, Peshawar contract manufacturing by M/s. Aries Pharmaceuticals (Pvt) Ltd. 1-W, Industrial Estate, Hayatabad Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Gesteron 10 mg tablet |
| | Composition | Each Film coated tablet contains:-<br>Dydrogesteron……10 mg |
| | Diary No. Date of R& I & fee | Dy. No.8122, 5-3-1-2018; Rs. 20,000/- +30000/- |
| | Pharmacological Group | Progestogen |
| | | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 20's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Duphaston by BGP Products<br>(Swissmedic Approved) |
| | Me-too status | Duphaston by Abbott |
| | GMP status | Last GMP inspection of Aries pharma was conducted on 4-June-2018 with satisfactory GMP compliance |
| | Remarks of evaluator | Rakaposhi is already contract manufacturing 1 product. |
| | **Decision 283:**<br>Defered for further delebration on cis/trans isomers of Dydrogesteron<br>**Remarks of evaluator [VII]**<br>The firm claims that aries already has been given registration of this product for their company. But this can't be verified from our database. | |
| | **Decision: Approved for contract manufacturing by M/s Aries Pharmaceutical, Peshawar. The Board further advised the manufacturer to get approval for steroidal hormone section from Licensing Division before issuance of Registration letter.** | |

**Evaluator PEC-VIII**

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| 620. | Name and address of Manufacturer / Applicant | M/s Rock Pharmaceuticals Laboratories (Pvt) Ltd. 134-B & 135-B Nowshera Industrial Estate, Risalpur. |
| | Brand Name +Dosage Form +Strength | Xocip 750mg tablets |
| | Composition | Each film coated tablet contains:<br>Ciprofloxacin (as hydrochloride monohydrate)…750mg |
| | Diary No. Date of R&I & fee | DyNo.3545; 22-05-2017; Rs. 20,000/- |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Ciprobid tablet 750mg of Nova pharmaceuticals |
| | GMP status | GMP inspection conducted on 07-12-2017 does not have conclusive remarks. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 281st meeting referred the case to QA &LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | Firm has submitted GMP Inspection Report dated 18th of July, 2018 with conclusive remarks that firm is complying cGMP. |
| | **Decision:Approved** | |

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| 621. | Name and address of Manufacturer / Applicant | M/s Rock Pharmaceuticals Laboratories (Pvt) Ltd. 134-B & 135-B Nowshera Industrial Estate, Risalpur. |
| | Brand Name +Dosage Form +Strength | Tiglit-M tablet 50/500 |
| | Composition | Each film coated tablet contains:<br>Sitagliptin(as phosphate monohydrate)…50mg<br>Metformin hydrochloride…..500mg |
| | Diary No. Date of R&I & fee | DyNo.3546; 12-05-2017; Rs. 20,000/- |
| | Pharmacological Group | Dipeptidyl peptidase-4 inhibitor/Biguanide |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Glusimet 50mg/500mg Tablet of Opal Lab. Karachi. |
| | GMP status | GMP inspection conducted on 07-12-2017 does not have conclusive remarks. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 281st meeting referred the case to QA &LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | Firm has submitted GMP Inspection Report dated 18th of July, 2018 with conclusive remarks that firm is complying cGMP. |
| | **Decision:Approved** | |
| 622. | Name and address of Manufacturer / Applicant | M/s Rock Pharmaceuticals Laboratories (Pvt) Ltd. 134-B & 135-B Nowshera Industrial Estate, Risalpur. |
| | Brand Name +Dosage Form +Strength | Tiglit-M tablet 50/1000 |
| | Composition | Each film coated tablet contains:<br>Sitagliptin(as phosphate monohydrate)…50mg<br>Metformin hydrochloride…..1000mg |
| | Diary No. Date of R&I & fee | DyNo.3547; 12-05-2017; Rs. 20,000/- |
| | Pharmacological Group | Dipeptidyl peptidase-4 inhibitor/Biguanide |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Glusimet 50mg/1000mg Tablet of Opal Lab. Karachi. |
| | GMP status | GMP inspection conducted on 07-12-2017 does not have conclusive remarks. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 281st meeting referred the case to QA &LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | Firm has submitted GMP Inspection Report dated 18th of July, 2018 with conclusive remarks that firm is complying cGMP. |
| | **Decision:Approved** | |
| 623. | Name and address of Manufacturer / Applicant | M/s Rock Pharmaceuticals Laboratories (Pvt) Ltd. 134-B & 135-B Nowshera Industrial Estate, Risalpur. |
| | Brand Name +Dosage Form +Strength | Robifen tablet 100mg |
| | Composition | Each film coated tablet contains:<br>Flurbiprofen…100mg |
| | Diary No. Date of R&I & fee | DyNo.5029; 07-06-2017; Rs. 20,000/- |
| | Pharmacological Group | Dipeptidyl peptidase-4 inhibitor/Biguanide |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 6×5's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in ANSM |
| | Me-too status | Biofen 100mg Tablet of Mission Pharma |
| | GMP status | GMP inspection conducted on 07-12-2017 does not have conclusive remarks. |

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| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 281st meeting referred the case to QA &LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | Firm has submitted GMP Inspection Report dated 18th of July, 2018 with conclusive remarks that firm is complying cGMP. |
| | **Decision:Approved** | |
| 624. | Name and address of Manufacturer / Applicant | M/s Rock Pharmaceuticals Laboratories (Pvt) Ltd. 134-B & 135-B Nowshera Industrial Estate, Risalpur. |
| | Brand Name +Dosage Form +Strength | Robecide 200mg/5ml suspension |
| | Composition | Each 5ml contains:<br>Metronidazole(as benzoate)…200mg |
| | Diary No. Date of R&I & fee | DyNo.5030or 5630; 07-06-2017; Rs. 20,000/- |
| | Pharmacological Group | Amoebicide |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 1's (60ml); As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Mogel 200mg Suspension of M/s Metro Pharma |
| | GMP status | GMP inspection conducted on 07-12-2017 does not have conclusive remarks. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 281st meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | Firm has submitted GMP Inspection Report dated 18th of July, 2018 with conclusive remarks that firm is complying cGMP. |
| | **Decision:Approved** | |

**Evaluator PEC-IX**

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| 625. | Name and address of manufacturer / Applicant | Berlex Lab. International, 10 Km Nangshah Chowk Karachi Road, Multan |
| | Brand Name +Dosage Form + Strength | Bercocin Capsule 500mg |
| | Composition | Each capsule contains:<br>Lincomycin as HCl monohydrate……. 500mg |
| | Diary No. Date of R& I & fee | Dy No. 4054: 21.04.2017<br>PKR 20,000/-: 21.04.2017 |
| | Pharmacological Group | Lincosamides |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x6's; Rs. 97/- |
| | Approval status of product in Reference Regulatory Authorities. | Lincocine 500 mg capsule (Lincomycin as HCl hydrate) by Pfizer Holding France. Approved by ANSM France |
| | Me-too status | Linnco 500mg Capsule (Lincomycin as HCl) by Mafins Pharmaceuticals (Pvt) Ltd., Karachi. Reg. No. 79898 |
| | GMP status | The firm was last inspected on 05.07.2018, wherein the panel recommended renewal of DML |
| | Remarks of the Evaluator. | • The USP has specified Raman spectroscopy for dissolution study of Lincomycin capsules. However, upon clarification, the firm did not provide proof of provision of Raman spectrophotometer.<br>• The firm revised the formulation to Lincomycin as HCl monohydrate (in Master Formula) from Lincomycin HCl without submission of fee. However, Form 5 still has Lincomycin HCl. |
| | Previous decision | • The Board in its 286th meeting deferred the case for provision of Raman spectrophotometer and correction of Form 5. |

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| | Evaluation by PEC | • The firm submitted revised Form 5 and requested for BP specifications instead of USP specifications. |
| | **Decision: Approved with BP specifications**. | |

**AD PEC- XIII**

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| 626. | Name and address of manufacturer / Applicant | M/s Amarant Pharmaceuticals, 158 D. Tore, Gadap Road, Superhighway Karachi |
| | Brand Name +Dosage Form + Strength | Telmipine Tablet 80/5mg |
| | Composition | Each tablet contains:<br>Telmisartan…….....80mg<br>Amlodipine……5mg |
| | Diary No. Date of R& I & fee | Dy. No. 314, 15-03-2017; Rs.20,000/- (15-03-2017) |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form- 5 |
| | Finished product Specification | Innovator's Specs |
| | Pack size & Demanded Price | 10's,14's/As per SRO |
| | Approval status of product in Reference Regulatory Authorities | USFDA approved |
| | Me-too status | Amtas Tablet by M/s Getz Pharma Karachi |
| | GMP status | Not provided |
| | Previous remarks of the Evaluator | GMP inspection needs to be conducted. |
| | Previous decision | In 279th meeting, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | • Firm has now submitted its latest GMP inspection report Dated: 24-07-2018 and the report concludes good level of GMP compliance. |
| | **Decision: Deferred for confirmation of availability of bi-layer compression machine.** | |
| 627. | Name and address of manufacturer / Applicant | M/s Amarant Pharmaceuticals, 158 D. Tore, Gadap Road, Superhighway Karachi |
| | Brand Name +Dosage Form + Strength | Telmipine Tablet 80/10mg |
| | Composition | Each tablet contains:<br>Telmisartan……..80mg<br>Amlodipine……10mg |
| | Diary No. Date of R& I & fee | Dy. No. 315, 15-03-2017; Rs.20,000/- (15-03-2017) |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form- 5 |
| | Finished product Specification | Innovator's Specs |
| | Pack size & Demanded Price | 10's,14's/As per SRO |
| | Approval status of product in Reference Regulatory Authorities | USFDA approved |
| | Me-too status | Amtas Tablet by M/s Getz Pharma Karachi |
| | GMP status | Not provided |
| | Previous remarks of the Evaluator | GMP inspection needs to be conducted. |
| | Previous decision | In 279th meeting, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | • Firm has now submitted its latest GMP inspection report Dated: 24-07-2018 and the report concludes good level of GMP compliance. |
| | **Decision: Deferred for confirmation of availability of bi-layer compression machine.** | |
| 628. | Name and address of manufacturer / Applicant | M/s Amarant Pharmaceuticals, 158 D. Tore, Gadap Road, Superhighway Karachi |
| | Brand Name +Dosage Form + Strength | Telmipine Tablet 40/5mg |
| | Composition | Each tablet contains:<br>Telmisartan…….....40mg<br>Amlodipine……5mg |
| | Diary No. Date of R& I & fee | Dy. No. 312, 15-03-2017; Rs.20,000/- (15-03-2017) |

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| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form- 5 |
| | Finished product Specification | Innovator's Specs |
| | Pack size & Demanded Price | 10's,14's/As per SRO |
| | Approval status of product in Reference Regulatory Authorities | USFDA approved |
| | Me-too status | Amtas Tablet by M/s Getz Pharma Karachi |
| | GMP status | **Not provided** |
| | Previous remarks of the Evaluator | GMP inspection needs to be conducted. |
| | Previous decision | In 279th meeting, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | • Firm has now submitted its latest GMP inspection report Dated: 24-07-2018 and the report concludes good level of GMP compliance. |
| | **Decision: Deferred for confirmation of availability of bi-layer compression machine.** | |
| 629. | Name and address of manufacturer / Applicant | M/s Amarant Pharmaceuticals, 158 D. Tore, Gadap Road, Superhighway Karachi |
| | Brand Name +Dosage Form + Strength | Telmipine Tablet 40/10mg |
| | Composition | Each tablet contains:<br>Telmisartan…….....40mg<br>Amlodipine……..…10mg |
| | Diary No. Date of R& I & fee | Dy. No. 313, 15-03-2017; Rs.20,000/- (15-03-2017) |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form- 5 |
| | Finished product Specification | Innovator's Specs |
| | Pack size & Demanded Price | 10's,14's/As per SRO |
| | Approval status of product in Reference Regulatory Authorities | USFDA approved |
| | Me-too status | Amtas Tablet by M/s Getz Pharma Karachi |
| | GMP status | Not provided |
| | Previous remarks of the Evaluator | GMP inspection needs to be conducted. |
| | Previous decision | In 279th meeting, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. |
| | Evaluation by PEC | • Firm has now submitted its latest GMP inspection report Dated: 24-07-2018 and the report concludes good level of GMP compliance. |
| | **Decision: Deferred for confirmation of availability of bi-layer compression machine.** | |
| 630. | Name and address of manufacturer / Applicant | M/s Avant Pharmaceuticals, M- 028 H.I.T.E., Lasbela, Balochistan |
| | Brand Name +Dosage Form + Strength | Cetofast tablet 20mg |
| | Composition | Each film-coated tablet contains:<br>Escitalopram as Oxalate ……20mg |
| | Diary No. Date of R& I & fee | Dy.No.22906; 04-12-2017; Rs.20,000(21-11-2017) |
| | Pharmacological Group | Anti-psychotic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | CIPRALEX 20 mg film-coated tablets (MHRA) |
| | Me-too status | Repram 20mg tablet of M/s Regal Pharma<br>(Reg. # 081963) |
| | GMP status | Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance. |
| | Previous remarks of the Evaluator | The firm has applied Anti-psychotic while in WHO ATC index it is Antidepressant (SSRI). |

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| | Previous decision | Deferred for applied pharmacological group as the firm has applied Anti-psychotic while in WHO ATC index it is Antidepressant (SSRI). |
| | Evaluation by PEC[XIII] | • Firm has submitted its correct pharmacological group as SSRI (Anti- depressant). |
| | **Decision:Approved** | |
| 631. | Name and address of manufacturer / Applicant | M/s Avant Pharmaceuticals, M-028 H.I.T.E., Lasbela, Balochistan |
| | Brand Name +Dosage Form + Strength | Lemowin tablet 25mg |
| | Composition | Each film-coated tablet contains:<br>Lamotrigine ……..25mg |
| | Diary No. Date of R& I & fee | Dy.No.22915; 04-12-2017; Rs.20,000(04-12-2017) |
| | Pharmacological Group | Anti- epileptic/ Anti- convulsant |
| | Type of Form | Form-5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Lamictal 25mg tablet of M/s GSK (Reg. # 014918) |
| | GMP status | Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance. |
| | Previous remarks of the Evaluator | Firm has applied as film-coated tablet while applied formulation is approved in MHRA as uncoated. |
| | Previous decision | Deferred for submission of evidence of approval of applied formulation as "film-coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee. |
| | Evaluation by PEC[XIII] | • Firm has submitted Rs. 5000/- for change of formulation from film-coated to uncoated tablet<br>• Firm has revised its label claim as,<br>" Each **uncoated** tablet contains:"<br>• Firm has also revised its master formulation as un-coated tablet. |
| | **Decision:Approved** | |
| 632. | Name and address of manufacturer / Applicant | M/s Avant Pharmaceuticals, M-028 H.I.T.E., Lasbela, Balochistan |
| | Brand Name +Dosage Form + Strength | Lemowin tablet 50mg |
| | Composition | Each film-coated tablet contains:<br>Lamotrigine ……..50mg |
| | Diary No. Date of R& I & fee | Dy.No.22916; 04-12-2017; Rs.20,000(04-12-2017) |
| | Pharmacological Group | Anti-epileptic/ Anti-convulsant |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Lamotrin 50mg tablet of M/s Swan Pharma<br>(Reg. # 083016) |
| | GMP status | Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance. |
| | Previous remarks of the Evaluator | Firm has applied for film-coated while applied formulation is approved in MHRA as uncoated. |
| | Previous decision | Deferred for submission of evidence of approval of applied formulation as "film-coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be |

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| | | revised in accordance with reference product along with submission of requisite fee. |
| | Evaluation by PEC[XIII] | • Firm has submitted Rs. 5000/- for change of formulation from film-coated to uncoated tablet<br>• Firm has revised its label claim as,<br>" Each **uncoated** tablet contains:"<br>• Firm has also revised its master formulation as un-coated tablet. |
| | **Decision:Approved** | |
| 633. | Name and address of manufacturer / Applicant | M/s Avant Pharmaceuticals, M-028 H.I.T.E., Lasbela, Balochistan |
| | Brand Name +Dosage Form + Strength | Avemate 25mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Topiramate ……....25mg |
| | Diary No. Date of R& I & fee | Dy.No.22917;04-12-2017;Rs.20,000 (04-12-2017) |
| | Pharmacological Group | Anti- psychotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Tritop 25mg tablet of M/s Semos Pharma (Reg. # 075818) |
| | GMP status | Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance. |
| | Previous remarks of the Evaluator | Firm has submitted its applied pharmacological group as Antipsychotic while it is Antiepileptic according to WHO ATC index (N03AX11). |
| | Previous decision | Deferred for correction of applied pharmacological group as the firm has submitted its pharmacological group as Antipsychotic while it is Antiepileptic according to WHO ATC index (N03AX11) |
| | Evaluation by PEC[XIII] | • Firm has submitted its correct pharmacological group as Anti- epileptic. |
| | **Decision:Approved** | |
| 634. | Name and address of manufacturer / Applicant | M/s Avant Pharmaceuticals, M- 028 H.I.T.E., Lasbela, Balochistan |
| | Brand Name +Dosage Form + Strength | Avemate 50mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Topiramate ……....50mg |
| | Diary No. Date of R& I & fee | Dy. No. 22918; 04-12-2017; Rs.20,000/- (04-12-2017) |
| | Pharmacological Group | Anti- psychotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | As per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Tritop 50mg tablet of M/s Semos Pharma (Reg. # 075818) |
| | GMP status | Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance. |
| | Previous remarks of the Evaluator | Firm has submitted its applied pharmacological group as Antipsychotic while it is Antiepileptic according to WHO ATC index (N03AX11). |
| | Previous decision | Deferred for correction of applied pharmacological group as the firm has submitted pharmacological group as Antipsychotic while it is Antiepileptic according to WHO ATC index (N03AX11). |
| | Evaluation by PEC[XIII] | • Firm has submitted its correct pharmacological group as Anti- epileptic. |
| | **Decision:Approved** | |

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| 635. | Name and address of manufacturer / Applicant | M/s Z- Jans Pharmaceuticals, 148-A, Industrial Estate, Hayatabad, Peshawar |
| | Brand Name +Dosage Form + Strength | Alpa- Z tablet 0.5mg |
| | Composition | Each tablet contains:<br>Alprazolam…0.5mg |
| | Diary No. Date of R& I & fee | Dy.No.4117;28-12-2016; Rs.20,000/- (28-12-2016) |
| | Pharmacological Group | Anxiolytic / Benzodiazepine derivative |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P |
| | Pack size & Demanded Price | as per SRO & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Australia (TGA Approved) |
| | Me-too status | Xanax tablet 0.5mg of M/s Pfizer Pharmaceuticals (Reg. # 012303) |
| | GMP status | Latest GMP inspection was conducted on 07-11-2017 and the submitted report does not mention any conclusion. |
| | Previous remarks of the Evaluator | • The applied dosage form i.e. tablet is not mentioned on fee- challan and strength is being overwritten as 0.5mg above 0.25mg under deposit slip # 0569580.<br>• Submitted GMP inspection report does not mention any conclusion.<br>• Firm has psychotropic section. |
| | Previous decision | Deferred in 281st DRB meeting for following reasons:<br>• Updated status of GMP of the firm from QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.<br>• Clarification of fees from Budgets and Accounts Division against the applied dosage form and strength. |
| | Evaluation by PEC | • The firm has submitted its latest inspection report conducted on 03-07-2018 and 02-08-2018 and the report concludes rectification of observations with grant of GMP certificate.<br>• Verification of fee- challan could not be confirmed by the firm. |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 636. | Name and address of manufacturer / Applicant | M/s Rock Pharmaceutical Laboratories (Pvt.) Limited, 134-B & 135-B, Noushehra Industrial Estate, Risalpur |
| | Brand Name +Dosage Form + Strength | Roxart tablet 80mg/ 480mg |
| | Composition | Each tablet contains:<br>Artemether……80mg<br>Lumefantrine ……...480mg |
| | Diary No. Date of R& I & fee | Dy.No.191; 24-04-2017; Rs.20,000/- (24-04-2017) |
| | Pharmacological Group | Antimalarial |
| | Type of Form | Form-5 |
| | Finished product Specification | International Pharmacopoeia |
| | Pack size & Demanded Price | 4's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | WHO Approved formulation |
| | Me-too status | Artheget tablet 80mg/ 480mg of M/s Getz Pharmaceuticals, Pak ( Reg. # 058405) |
| | GMP status | Last GMP inspection report dated 07-12-2017 with no conclusion. |
| | Previous remarks of the Evaluator | • The GMP report does not mention any conclusion. |
| | Previous decision | Deferred in 281st DRB meeting for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. |
| | Evaluation by PEC | • Firm has now submitted its latest inspection report |

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| | | conducted on 18-07-2018 and the report concludes grant of GMP certificate. |
| | **Decision:Approved** | |
| 637. | Name and address of manufacturer / Applicant | M/s Rock Pharmaceutical Laboratories (Pvt.) Limited, 134-B & 135-B, Noushehra Industrial Estate, Risalpur |
| | Brand Name +Dosage Form + Strength | Cafegot tablet 1mg/ 100mg |
| | Composition | Each tablet contains:<br>Ergotamine tartarate……...1mg<br>Caffeine ( anhydrous)……..…….....100mg |
| | Diary No. Date of R& I & fee | Dy.No.193; 24-04-2017; Rs.20,000/- (24-04-2017) |
| | Pharmacological Group | Ergot Alkaloid/ Xanthine |
| | Type of Form | Form-5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | 2x 10's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Cafergot of M/s Novartis Pharmaceuticals |
| | GMP status | Last GMP inspection report dated 07-12-2017 with no conclusion. |
| | Previous remarks of the Evaluator | • The GMP report does not mention any conclusion. |
| | Previous decision | Deferred in 281st DRB meeting for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status**.** |
| | Evaluation by PEC | Firm has now submitted its latest inspection report conducted on 18-7-2018 and report concludes grant of GMP certificate. |
| | **Decision:Approved** | |

**Evaluator PEC-XIV**

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| 638. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | AZOLOD Tablets 250mg |
| | Composition | Each film coated tablet contains:<br>Azithromycin as Dihydrate……..250mg |
| | Diary No. Date of R& I & fee | Dy.No. 8000/- dated 29-12-2010, 12000/- dated 28-10-13 |
| | Pharmacological Group | Macrolides |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO/ Pack of 20, 50,100, 250 and 500 tablets |
| | Approval status of product in Reference Regulatory Authorities. | Azithromycin 250 mg film-coated tablets by Milpharm Limited (MHRA Approved) |
| | Me-too status | Zetro 250mg Tablet by Getz Pharma (Reg# 066913) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification f following: **(M-250)**<br>a. Evidence of approval of section from Drug Licensing Division is not submitted.<br>b. Methylene chloride is used in film coating which is class II solvent and its use has been restricted because of its inherent toxicity.<br>c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary No. is not mentioned.<br>• The firm has submitted coating without methylene chloride. |
| | **Decision: Registration Board referred the case to QA & LT Division to update on GMP status of the firm.** | |

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| 639. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | AZOLOD Tablets 500mg |
| | Composition | Each film coated tablet contains:<br>Azithromycin as Dihydrate……..500mg |
| | Diary No. Date of R& I & fee | Dy.No. 738, 8000/- dated 29-12-2010, 12000/- 28-10-2013 |
| | Pharmacological Group | Macrolides |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO/ Pack of 20, 50,100, 250 and 500 tablets |
| | Approval status of product in Reference Regulatory Authorities. | Azithromycin 500 mg Film-Coated Tablets by TEVA UK Limited (MHRA Approved) |
| | Me-too status | Zetro 500mg Tablet by Getz Pharma (Reg # 053120) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification f following: **(M-250)**<br>a. Evidence of approval of section from Drug Licensing Division is not submitted.<br>b. Methylene chloride is used in film coating which is class II solvent and its use has been restricted because of its inherent toxicity.<br>c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • The firm has submitted coating without methylene chloride. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 640. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | IROP Syrup |
| | Composition | Each 15ml contains:<br>Iron protein succinylate 800mg equivalent to elemental Iron……..40mg |
| | Diary No. Date of R& I & fee | Dy.No. 738, 8000/- dated 29-12-2010, 12000/- 28-10-2013 |
| | Pharmacological Group | Hematinic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specs |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60,90, 120 and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Approved in Italy |
| | Me-too status | Wincuss Syrup 800mg/15 ml of Winthrox Karachi. |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>a. Evidence of approval of section from Drug Licensing Division is not submitted.<br>b. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |

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| 641. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | O-CIN Tablet 400mg |
| | Composition | Each film coated tablet contains:<br>Ofloxacin……400mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Tarivid 400 of MHRA approved |
| | Me-too status | Clamocid 400mg Tablets by M/s Rock Pharmaceuticals Laboratories |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification f following: **(M-250)**<br>a. Evidence of approval of section from Drug Licensing Division is not submitted.<br>b. Methylene chloride is used in film coating which is class II solvent and its use has been restricted because of its inherent toxicity.<br>c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary No. is not mentioned.<br>• The firm has submitted coating without methylene chloride. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 642. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | BISUB Tablet 265mg |
| | Composition | Each film coated tablet contains:<br>Bismuth Subsalicylate……...265mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Mucosal protective |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too status | Not confirmed |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification f following: **(M-250)**<br>a. Evidence of approval of section from Drug Licensing Division is not submitted.<br>b. Evidence of approval of same generic, dosage form in reference agencies is not submitted.<br>c. Applied drug is available locally as chewable tablet however firm has applied film coated.<br>d. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings |

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| | | pointed out during the inspection. |
| | Evaluation by PEC | • |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 643. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | BISUB Suspension |
| | Composition | Each 5ml contains:<br>Bismuth subsalicylate…….88mg |
| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Anti-diarrhoeal |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Pepti-Calm 525.6mg/30ml Oral Suspension of The Boots Company (MHRA approved) |
| | Me-too status | BISMOL Syrup of Macter International |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is required.<br>**b.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 644. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | K-ZIM Syrup 100mg/ 5ml |
| | Composition | Each 5ml contains:<br>Cefixime as Trihydrate……....100mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Cephalosporin antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specifications |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Cefixime 100 mg/5 ml Powder for Oral Suspension by M/s Generics Ltd (MHRA Approved) |
| | Me-too status | Cefim Suspension 100mg/5ml by M/s Hilton Pharma (Reg#022108) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Master formulation of liquid oral dosage form is submitted.<br>**c.** Precautions/controls submitted for liquid oral dosage form.<br>**d.** Finished product specifications are not submitted.<br>**e.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. Moreover, the status of the |

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| | | section for applied formulation is not clear from the report. |
| | Evaluation by PEC | • Reference formulation is Powder for oral suspension while applied formulation is syrup. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 645. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | CAYMOL Plus Tablet |
| | Composition | Each tablet contains:<br>Paracetamol……...200mg<br>Aspirin……..…300mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Liskoprin of Lisko Pvt Limited. |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not provided.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference drug agencies need to be submitted.<br>**c.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Approval status in reference agency is required to be submitted. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 646. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | CAYBION Capsules 50mg |
| | Composition | Each capsule contains:<br>Diclofenac sodium enteric coated pellets (32%)……50mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Approved in ANSM |
| | Me-too status | Amfac Capsules of Ambrosia Pharma (Reg#056576) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference agencies is not submitted. |

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| | | **c.** Source of Diclofenac sodium pellets, their composition, certificate of analysis, stability studies as per zone IV and in case of import of pellets, legalized GMP certificate of the source along with the requisite fee prescribed under the rules is not submitted.<br>**d.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary no. is missing<br>• Source of Pellets: M/s Vision Pharma (Diclofenac sodium Enteric coated pellets 32%) |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 647. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | CAYBION Capsules SR 100mg |
| | Composition | Each capsule contains:<br>Diclofenac sodium SR pellets (32%)……..100mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Diclomax Retard 100mg modified release capsules of Galen Ltd., UK (MHRA approved) |
| | Me-too status | Flamex SR capsules 100mg of M/s Werrick Pharma (Reg#020592) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference agencies is not submitted.<br>**c.** Source of Diclofenac sodium pellets, their composition, certificate of analysis, stability studies as per zone IV and in case of import of pellets, legalized GMP certificate of the source along with the requisite fee prescribed under the rules is not submitted.<br>**d.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection |
| | Evaluation by PEC | • Source of Pellets: M/s Vision Pharma (Diclofenac sodium SR pellets 32%)<br>• Diary no. is missing. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 648. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | C-PHOS Tablet 250mg |
| | Composition | Each film coated tablet contains:<br>Chloroquine Phosphate ……...250mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Antimalarial |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |

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| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | Cloroquin 250mg Tablet of klifton Pharma (Reg#058332) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Formulation is approved in reference drug agencies as uncoated tablet however applied formulation is film coated.<br>**b.** Reference of finished product spec need to be submitted as it is included in official pharmacopeia.<br>**c.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary no. is missing. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 649. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | DIMIN Tablet 50mg |
| | Composition | Each film coated tablet contains:<br>Diphenhydramine Hydrochloride…….50mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specs |
| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Not confirmed. |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following:<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference drug agencies is not submitted.<br>**c.** Me too status submitted is needs confirmation.<br>**d.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary no. is missing. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm** | |
| 650. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | GEMFLOX Tablet 320mg |
| | Composition | Each film coated tablet contains:<br>Gemifloxacin as mesylate……..…..320mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Fluoroquinolone |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specs |

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| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Factive Tablets of LG Life Sciences (USFDA approved) |
| | Me-too status | Gemixa Tablets of Bosch Pharma Karachi |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Methylene chloride is used as coating solvent which is class II as per ICH and its use has been restricted due to its inherent toxicity<br>**c.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary no. is missing.<br>• The firm has submitted coating without methylene chloride. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 651. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | MOXILEX Tablet 400mg |
| | Composition | Each film coated tablet contains:<br>Moxifloxacin as Hydrochloride……..400mg |
| | Diary No. Date of R& I & fee | Dy.No. , 8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Fluoroquinolone |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specs |
| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Avelox of Bayer UK (MHRA approved) |
| | Me-too status | Avelox of Bayer Health Care Karachi |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Methylene chloride is used as coating solvent which is class II as per ICH and its use has been restricted due to its inherent toxicity<br>**c.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary no. is missing.<br>• The firm has submitted coating without methylene chloride. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 652. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | DOXIN Tablet |
| | Composition | Each film coated tablet contains:<br>Doxylamine Succinate…….....10mg<br>Pyridoxine hydrochloride……..…..10mg |

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| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Anti-histamine + Vitamin B6 |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specs |
| | Pack size & Demanded Price | As per SRO/ Pack of 10, 20, 30, 50, 100, 250, and 500's |
| | Approval status of product in Reference Regulatory Authorities. | Doxylamine Succinate And Pyridoxine Hydrochloride (10/10) \| ANDA #205811 \| Tablet, Delayed Release;Oral \| Prescription \| Actavis Labs Fl Inc. Approved in USFDA |
| | Me-too status | Nausidox 10mg/10mg Tablet of OBS (Reg#076292) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following:<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference drug agencies is not submitted.<br>**c.** Methylene chloride issued in film coating which is class II solvent and its use has been restricted because of its inherent toxicity.<br>**d.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • The firm has submitted coating without methylene chloride.<br>• The formulation is not as per reference |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 653. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | FERRO-G Syrup |
| | Composition | Each 5ml contains:<br>Ferrous Gluconate 300mg equivalent to elemental Iron……...34mg |
| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Haematinic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Lawrgluconate of Lawrance Pharma (Reg#071165) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following:<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference drug agencies is not submitted.<br>**d.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • |
| | **Decision: Registration Board referred the case to QA & LT Division to update on GMP status of the firm.** | |

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| 654. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | FAPA SR Capsules 100mg |
| | Composition | Each capsule contains:<br>Diclofenac Potassium pellets 32% eq. to Diclofenac potassium…….100mg |
| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Difene 100mg SR Capsule of M/s Aries (Reg#060292) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and stength in FDA, TGA, EMA, Health Canada and in regultory body of Japan needs to be submitted.<br>**c.** Evidence of local availability submitted needs confirmation.<br>**d.** Source of Diclofenac sodium pellets, their composition, certificate of analysis, stability studies as per zone IV and in case of import of pellets, legalized GMP certificate of the source along with the requisite fee prescribed under the rules is not submitted.<br>**e.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 655. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | PROLOL Tablet 5mg |
| | Composition | Each film coated tablet contains:<br>Bisoprolol Fumarate……5mg |
| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Cardio selective Beta Blocker |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Bisprolol tablets of Accord health care UK (MHRA approved) |
| | Me-too status | Bison Tablets of M/s Siza Int (Reg#024042) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following:<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Methylene chloride issued in film coating which is class II |

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| | | solvent and its use has been restricted because of its inherent toxicity.<br>**c.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • The firm has submitted coating without methylene chloride. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 656. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | CALCILEX Chewable Tablet |
| | Composition | Each chewable tablet contains:<br>Calcium Gluconate……..500mg |
| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Calcium supplement |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Not confirmed. |
| | Me-too status | Not confirmed. |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference drug agencies is not provided<br>**c.** Evidence of local availability submitted needs confirmation.<br>**d.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 657. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | CAYMINATE Syrup |
| | Composition | Each 4ml contains:<br>Dimenhydrinate……..12.5mg |
| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Antiemetic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Dimenhydrinate oral Liquid of ALRA (Discontinued in USFDA) |
| | Me-too status | Hydrinate Liquid of M/s Lisko (Reg#025593) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing is not submitted. |

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| | | **b.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • Diary no. is missing. |
| | **Decision: Registration Board referred the case to to update on GMP status of the firm.** | |
| 658. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | CIGAR Syrup |
| | Composition | Each 10ml contains:<br>Pizotifen as hydrogen maleate……..….0.5mg |
| | Diary No. Date of R& I & fee | Dy.No. ,8000/- dated 29-12-2010, 12000/- dated 28-10-2013 |
| | Pharmacological Group | Antimigraine drug |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60, 90, 120, and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | Sanomigran Elixir 0.25mg /5ml by M/s phoenix, (MHRA approved) |
| | Me-too status | Aptigar Syrup (0.5mg/10ml) of Evergreen Pharma (Reg#054398) |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)**<br>**a.** Evidence of approval of section from Drug Licensing Division is not submitted.<br>**b.** Evidence of approval of same generic, dosage form and strength in reference drug agencies is not submitted.<br>**c.** Dosage of applied formulation is not submitted moreover the firm submitted that it is also used as appetite stimulant.<br>**d.** Quantity of API submitted in master formulation is not in conformance with the label claim.<br>**e.** Manufacturing method of cefixime syrup is submitted.<br>**f.** Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection |
| | Evaluation by PEC | The firm has provided Oral Liquid section (General). |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 659. | Name and address of manufacturer / Applicant | M/s Caylex Pharmaceuticals, (Pvt) Limited, 27-Km Raiwind road Lahore. |
| | Brand Name +Dosage Form + Strength | ZINPHATE Suspension |
| | Composition | Each 5ml contains:<br>Zinc Sulphate (monohydrate)……10mg |
| | Diary No. Date of R& I & fee | Dy.No. 8000/- dated 29-12-10, 12000/- dated 28-10-13 |
| | Pharmacological Group | Zinc Supplement |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per SRO/ Pack of 30, 60,90, 120 and 450ml |
| | Approval status of product in Reference Regulatory Authorities. | WHO recommended |
| | Me-too status | Zinxus Suspension of M/s Ferozsons |
| | GMP status | The firm has submitted copy of letter from QA division vide letter No.F. 4-17/98-QA dated 4th January, 2018 in which the Director QA & LT has allowed resuming the production of the firm M/s Caylex Pharma except in Cephalosporin section. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for rectification of following: **(M-250)** |

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| | | a. Evidence of approval of section from Drug Licensing Division is not submitted.<br>b. Quantity of API submitted in master formulation is not rational with the label claim.<br>c. Inspection of the firm was carried out on 13-05-14 by the panel of inspectors and number of observations/ shortcomings pointed out during the inspection. |
| | Evaluation by PEC | • The dosage form of Reference product is syrup while that of applied formulation is suspension.<br>• Diary No. is not mentioned. |
| | **Decision: Registration Board referred the case to QA & LT Division to to update on GMP status of the firm.** | |
| 660. | Name and address of manufacturer / Applicant | M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Axoff 40mg tablet |
| | Composition | Each film coated tablet contains:<br>Febuxostat……..40mg |
| | Diary No. Date of R& I & fee | Dy.2685; 15-06-2016; Rs.20,000/- (15-06-2016) |
| | Pharmacological Group | Anti-Gout |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Febuxin by M/s AGP, Karachi (Reg. No. 081104) |
| | GMP status | Last inspection conducted on 21-12-2016. |
| | Previous remarks of the Evaluator. | • No official monograph is available for applied formulation in USP or BP. |
| | Previous decision(s) | Deferred for updated status of GMP from QA&LT Division **(M-275)**. |
| | Evaluation by PEC | GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 661. | Name and address of manufacturer / Applicant | M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Axoff 80mg tablet |
| | Composition | Each film coated tablet contains:<br>Febuxostat……..80mg |
| | Diary No. Date of R& I & fee | Dy.2690; 15-06-2016; Rs.20,000/- (15-06-2016) |
| | Pharmacological Group | Anti-Gout |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Febuxin by M/s AGP, Karachi (Reg. No. 081105) |
| | GMP status | Last inspection conducted on 21-12-2016. |
| | Previous remarks of the Evaluator. | • No official monograph is available for applied formulation in USP or BP. |
| | Previous decision(s) | Deferred for updated status of GMP from QA&LT Division **(M-275)**. |
| | Evaluation by PEC | GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. |

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| | | The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 662. | Name and address of manufacturer / Applicant | M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Paradol tablets |
| | Composition | Each film coated tablet contains:<br>Paracetamol……..325mg<br>Tramadol hydrochloride……37.5mg |
| | Diary No. Date of R& I & fee | Dy. No 2691; 15-06-2016; Rs.20,000/- (15-06-2016) |
| | Pharmacological Group | Analgesic/ Opioid Analgesic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Ultracet by Janssen (USFDA) |
| | Me-too status | Distalgesic Tablets by Atco laboratories, Karachi (R. No. 073865) |
| | GMP status | Last inspection conducted on 21-12-2016. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for updated status of GMP from QA&LT Division **(M-275)**. |
| | Evaluation by PEC | GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 663. | Name and address of manufacturer / Applicant | M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Levictam 500mg tablet |
| | Composition | Each film coated tablets Contains:<br>Levetiracetam…….500mg |
| | Diary No. Date of R& I & fee | Dy. No 2687; 15-06-2016; Rs.20,000/- (15-06-2016) |
| | Pharmacological Group | Second generation antiepileptic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Keppra Tablets 500mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045685) |
| | GMP status | Last inspection conducted on 21-12-2016. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for updated status of GMP from QA&LT Division **(M-275)**. |
| | Evaluation by PEC | GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |

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| 664. | Name and address of manufacturer / Applicant | M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Levictam 250mg tablet |
| | Composition | Each film coated tablets Contains:<br>Levetiracetam…….250mg |
| | Diary No. Date of R& I & fee | Dy. No 2689; 15-06-2016; Rs.20,000/- (15-06-2016) |
| | Pharmacological Group | Second generation antiepileptic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Keppra Tablets 250mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045684) |
| | GMP status | Last inspection conducted on 21-12-2016. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for updated status of GMP from QA&LT Division **(M-275)**. |
| | Evaluation by PEC | GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 665. | Name and address of manufacturer / Applicant | M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Vamlodip-DS tablets |
| | Composition | Each film coated tablets Contains:<br>Amlodipine as besylate……10mg<br>Valsartan……..160mg |
| | Diary No. Date of R& I & fee | Dy. 2686; 15-06-2016; Rs.20,000/- (15-06-2016) |
| | Pharmacological Group | Anti-hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Valpine Tablets 10/160mg by M/s Fassgen Pharmaceuticals, (Reg. No. 073303) |
| | GMP status | Last inspection conducted on 21-12-2016. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for updated status of GMP from QA&LT Division **(M-275)**. |
| | Evaluation by PEC | GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 666. | Name and address of manufacturer / Applicant | M/s Swan Pharmaceuticals, 11-E, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Sertowan 50 mg tablet |
| | Composition | Each film coated tablets Contains:<br>Sertraline (as hydrochloride) …… 50mg |
| | Diary No. Date of R& I & fee | Dy. No 2688; 15-06-2016; Rs.20,000/- (15-06-2016) |

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| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Ertalin 50 mg Tablets of M/s Genome Pharma, (Reg.#076844) |
| | GMP status | Last inspection conducted on 21-12-2016. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for updated status of GMP from QA&LT Division **(M-275)**. |
| | Evaluation by PEC | GMP inspection dated 21-12-2016 concluded that the firm has to work very hard to improve and meet the GMP guidelines as per Drug Act, 1976 and rules framed thereunder. The company is advised to submit a comprehensive plan of rectification/improvements and then after rectifying the shortcomings submit compliance report. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** | |
| 667. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Phastive Capsule |
| | Composition | Each capsule contains:-<br>Omeprazole ……20mg<br>Sodium Bicarbonate ……1100mg |
| | Diary No. Date of R& I & fee | Dy No. 1167: 16-10-2015 PKR 20,000/-: 13-10-2015 |
| | Pharmacological Group | Anti-ulcer |
| | Type of Form | Form 5 |
| | Finished product Specification | Firm has claimed in house specification |
| | Pack size & Demanded Price | 7's, 14's, 28's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zegerid by Santarus Inc<br>(**USFDA** Approved) |
| | Me-too status | Faast plus by CCL |
| | GMP status | |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within the period of last one year) |
| | Previous decision(s) | Deferred for GMP inspection report conducted within a period of last 1 year **(M-273)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 668. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Phastive Capsule |
| | Composition | Each capsule contains:-<br>Omeprazole ……40mg<br>Sodium Bicarbonate ……1100mg |
| | Diary No. Date of R& I & fee | Dy No. 1168: 16-10-2015<br>PKR 20,000/-: 13-10-2015 |
| | Pharmacological Group | Antiulcer |
| | Type of Form | Form 5 |
| | Finished product Specification | Firm has claimed in house specification |
| | Pack size & Demanded Price | 7's, 14's, 28's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zegerid by Santarus Inc<br>(**USFDA** Approved) |
| | Me-too status | Faast plus by CCL |
| | GMP status | |

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| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within the period of last one year) |
| | Previous decision(s) | Deferred for GMP inspection report conducted within a period of last 1 year **(M-273)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 669. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Dight Tablet 5mg |
| | Composition | Each Film coated tablet contains:-<br>Rosuvastatin Calcium……..5mg |
| | Diary No. Date of R& I & fee | 209, 20-01-2016, 20,000/- |
| | Pharmacological Group | HMG Co-A reductase inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 5mg tablet of IPR (USFDA approved) |
| | Me-too status | Crestat Tablet of CCL |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within the period of last one year) |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 670. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Dight Tablet 10mg |
| | Composition | Each Film coated tablet contains:-<br>Rosuvastatin Calcium……..10mg |
| | Diary No. Date of R& I & fee | 219, 20-01-2016, 20,000/- |
| | Pharmacological Group | HMG Co-A reductase inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 10mg tablet of IPR (USFDA approved) |
| | Me-too status | Crestat Tablet of CCL |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 671. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Dight Tablet 20mg |

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| | Composition | Each Film coated tablet contains:-<br>Rosuvastatin Calcium……..20mg |
| | Diary No. Date of R& I & fee | 218, 20-01-2016, 20,000/- |
| | Pharmacological Group | HMG Co-A reductase inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Crestor 20mg tablet of IPR (USFDA approved) |
| | Me-too status | Crestat Tablet of CCL |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 672. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Riglip Tablets 50/500mg |
| | Composition | Each Tablets contains:-<br>Sitagliptin as phosphate monohydrate…..50mg<br>Metformin HCl …...……500mg |
| | Diary No. Date of R& I & fee | 216, 20-01-2016, 20,000/- |
| | Pharmacological Group | Anti-diabetic (Type II Diabetes Mellitus) |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 7's, 14's, 28's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Janumet film coated tablet 50/500mg of Merck Sharp & Dohme (USFDA) |
| | Me-too status | Treviamet film coated tablet 50/500mg of M/s Getz Pharmaceuticals |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 673. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Riglip Tablets 50/1000mg |
| | Composition | Each Tablets contains:-<br>Sitagliptin as phosphate monohydrate…..50mg<br>Metformin HCl (USP)……1000mg |
| | Diary No. Date of R& I & fee | 210, 20-01-2016, 20,000/- |
| | Pharmacological Group | Anti-diabetic (Type II Diabetes Mellitus) |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 7's, 14's, 28's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Janumet film coated tablet 50/1000mg of Merck Sharp & Dohme (USFDA) |

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| | Me-too status | Treviamet film coated tablet 50/1000mg of M/s Getz Pharmaceuticals |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 674. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Zyrian Capsule 50mg |
| | Composition | Each Capsule contains:-<br>Pregabalin……..…..50mg |
| | Diary No. Date of R& I & fee | 211, 20-01-2016, 20,000/- |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 7's, 14's, 28's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Lyrica capsule 50mg of Pfizer (USFDA approved) |
| | Me-too status | Dygab capsule 50mg of M/s Dyson Research Labs |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 675. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Zyrian Capsule 75mg |
| | Composition | Each Capsule contains:-<br>Pregabalin……..…..75mg |
| | Diary No. Date of R& I & fee | 212, 20-01-2016, 20,000/- |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 7's, 14's, 28's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Lyrica Capsule by PF Prism CV (USFDA Approved) |
| | Me-too status | Gabica by Getz |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed |

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| | | thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 676. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Zyrian Capsule 100mg |
| | Composition | Each Capsule contains:-<br>Pregabalin……..100mg |
| | Diary No. Date of R& I & fee | 213, 20-01-2016, 20,000/- |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 7's, 14's, 28's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Lyrica Capsule by PF Prism CV (USFDA Approved) |
| | Me-too status | Gabica by Getz |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 677. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Zyrian Capsule 150mg |
| | Composition | Each Capsule contains:-<br>Pregabalin……..150mg |
| | Diary No. Date of R& I & fee | 214, 20-01-2016, 20,000/- |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 7's, 14's, 28's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Lyrica 150mg Capsuleby M/s PF Prism CV, USFDA |
| | Me-too status | Gabica 150mg Capsule by M/s Getz Pharma (Reg#048724) |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-01-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 678. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Zyrian Capsule 300mg |
| | Composition | Each Capsule contains:-<br>Pregabalin……..300mg |
| | Diary No. Date of R& I & fee | 215, 20-01-2016, 20,000/- |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |

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| | Pack size & Demanded Price | 7's, 14's, 28's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Lyrica 300mg Capsule by M/s PF Prism CV, (USFDA) |
| | Me-too status | Gabica 300mg Capsule by M/s Getz Pharma (Reg#047368) |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 679. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Cygnet Tablet 500mg |
| | Composition | Each Film coated tablet Contains:-<br>Ciprofloxacin (as HCl)……500mg |
| | Diary No. Date of R& I & fee | 835, 13-02-2016, 20,000/- |
| | Pharmacological Group | Fluoroquinolone, antibacterial agent |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Ciproxin by Bayer<br>(MHRA Approved) |
| | Me-too status | Ciprox tablet by Amson |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved.** | |
| 680. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Cygnet Tablet 250mg |
| | Composition | Each Film coated tablet Contains:-<br>Ciprofloxacin (as HCl)……250mg |
| | Diary No. Date of R& I & fee | Nil (Duplicate), 20,000/-, 15-02-2016 |
| | Pharmacological Group | Fluoroquinolone, antibacterial agent |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Ciproxin by Bayer (MHRA Approved) |
| | Me-too status | Ciprox tablet by Amson |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |

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| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 681. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Cygnet Tablet 750mg |
| | Composition | Each Film coated tablet Contains:-<br>Ciprofloxacin (as HCl)……750mg |
| | Diary No. Date of R& I & fee | Nil (Duplicate), 20,000/-, 15-02-2016 |
| | Pharmacological Group | Fluoroquinolone, antibacterial agent |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Ciproxin by Bayer (MHRA Approved) |
| | Me-too status | Ciprox tablet by Amson |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 682. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Goulle 20mg Capsule |
| | Composition | Each capsule of enteric coated pellets (22.5%w/w) contains:-<br>Esomeprazole (as magnesium trihydrate)…….40mg |
| | Diary No. Date of R& I & fee | Dy. No.1310; 07-03-2016; Rs.100,000/- (03-03-2016) |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 7's,14's & 28's ; As per brand leader's price/PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | E-Z Capsule 20mg of M/s English Pharm (Reg.# 050151) |
| | GMP status | Last inspection conducted on 09-01-2015 and report recommends the resumption of production. |
| | Previous remarks of the Evaluator. | • Last inspection report conducted within last one year by DRAP shall be submitted.<br>Firm has submitted following:<br>• Legalized copy of GMP certificate for M/s Precise Chemipharma Pvt. Ltd, India (source of Esomeprazole enteric coated 8.5% w/w pellets) issued by FDA Maharashtra.<br>• COA of Esomeprazole enteric coated 8.5% w/w pellets.<br>• Stability study data for Esomeprazole enteric coated 8.5% w/w pellets. |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was |

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|---|---|---|
| | | considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 683. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Goulle 40mg Capsule |
| | Composition | Each capsule of enteric coated pellets (22.5%w/w) contains:-<br>Esomeprazole (as magnesium trihydrate)…….40mg |
| | Diary No. Date of R& I & fee | Dy. No.1131; 07-03-2016; Rs.100,000/- (25-02-2016) |
| | Pharmacological Group | Proton pump inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 7's,14's & 28's ; As per brand leader's price/PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | E-Z Capsule 40mg of M/s M/s English Pharm (Reg.# 050150) |
| | GMP status | Last inspection conducted on 09-01-2015 and report recommends the resumption of production. |
| | Previous remarks of the Evaluator. | • Last inspection report conducted within last one year by DRAP shall be submitted.<br>Firm has submitted following:<br>• Legalized copy of GMP certificate for M/s Precise Chemipharma Pvt. Ltd, India (source of Esomeprazole enteric coated 8.5% w/w pellets) issued by FDA Maharashtra.<br>• COA of Esomeprazole enteric coated 8.5% w/w pellets.<br>• Stability study data for Esomeprazole enteric coated 8.5% w/w pellets. |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved** | |
| 684. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Troisa Cream |
| | Composition | Each Gram Contains:-<br>Eflornithine hydrochloride (as monohydrate)……139mg |
| | Diary No. Date of R& I & fee | Dy No. 2287: 26-5-2016PKR 20,000/-: 25-5-2016 |
| | Pharmacological Group | Ornithine decarboxylase inhibitor |
| | Type of Form | Form 5 |
| | Finished product Specification | Firm has claimed in house specification |
| | Pack size & Demanded Price | 10g, 15g, 30g: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Vaniqa cream by Skinmedica<br>(USFDA Approved) |
| | Me-too status | Depilus cream by Atco |
| | GMP status | |
| | Previous remarks of the Evaluator. | Latest GMP inspection report is not provided |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |

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| 685. | Name and address of manufacturer / Applicant | M/s Seatle (Pvt) Ltd., 45-KM, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Leadmox Tablet |
| | Composition | Each Tablet contains:-<br>Moxifloxacin hydrochloride eq to Moxifloxacin….400mg |
| | Diary No. Date of R& I & fee | 217, 20-01-2016, 20,000/- |
| | Pharmacological Group | Fluoroquinolone, antibacterial agent |
| | Type of Form | Form-5 |
| | Finished product Specification | As per innovator's specifications |
| | Pack size & Demanded Price | 5's, 10's, 20's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Swismox 400mg Tablet of M/s Swiss, Karachi |
| | GMP status | The panel inspection conducted on 11-12-14 & 09-1-2015 recommended the resumption of production. |
| | Previous remarks of the Evaluator. | • Latest GMP inspection report (which should have been conducted within period of one year). |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report which should have been conducted within period of one year **(M-274)**. |
| | Evaluation by PEC | GMP inspection dated 25-10-2018 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder. |
| | **Decision: Approved with innovator's specification.** | |
| 686. | Name and address of manufacturer / Applicant | M/s. Abbott Laboratories (Pakistan) Ltd, Karachi. |
| | Brand Name +Dosage Form + Strength | Moksi IV Infusion 400mg. |
| | Composition | 250ml infusion contains:<br>Moxifloxacin hydrochloride……400mg |
| | Diary No. Date of R& I & fee | Dy No. 304, 16/12/2014, Rs.20,000/- |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Firm claimed that the Finished product specification are neither available in any pharmacopoeia nor Innovator specifications are present in any reference authority. Therefore we request the DRAP to provide us finished product specifications of innovator product since the innovator product is registered with DRAP. |
| | Pack size & Demanded Price | 250mL, As per brand leader (Avelox). |
| | Approval status of product in Reference Regulatory Authorities. | Avelox 400mg/250ml solution for infusion by Bayer,<br>MHRA approved. |
| | Me-too status | Avelox 400mg Infusion by Bayer Healthcare. |
| | GMP status | Last GMP Inspection of M/s Abbott Laboratories conducted on 15-02-2016 with conclusive remarks of recommendation for the grant of additional section of manufacturing of aseptically filled lyophilized products. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for submission of latest GMP inspection report conducted within 1 year **(M-269)**. |
| | Evaluation by PEC | Routine GMP inspection dated 24-10-2018 & 06-11-2018 concluded that the building, facilities & procedures demonstrated at the time of inspection found at acceptable level of GMP compliance. The management is also committed for continual improvement & has assured further cGMP compliance. |
| | **Decision: Approved with innovator's specification.** | |
| 687. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma, Plot # 25, St# S6 RCCI Rawat Rawalpindi. |
| | Brand Name +Dosage Form + Strength | Judol Table |

| | | |
|---|---|---|
| | Composition | Each tablet contains:<br>Alfacalcidol……..…0.5mcg |
| | Diary No. Date of R& I & fee | Dy. No 2650, (13-06-2016), Rs. 20,000/- |
| | Pharmacological Group | Vitamin –D Analogue |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | Pack of 1 x 10's; As per DPC |
| | Approval status of product in Reference Regulatory Authorities. | PMDA approved |
| | Me-too status | Alfamak Tablets 0.5mcg of Makson (Reg#070017) |
| | GMP status | GMP inspection conducted on 31-01-2018 concluded that M/s Jupiter Pharma is operating at a fair level of cGMP compliance as of today. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred as 10 molecules per section has already been approved **(M-260).** |
| | Evaluation by PEC | The firm has provided Tablet section (General). |
| | **Decision: Approved with innovator's specification.** | |
| 688. | Name and address of manufacturer / Applicant | M/s Jupiter Pharma,<br>Plot # 25, St# S6 RCCI Rawat Rawalpindi. |
| | Brand Name +Dosage Form + Strength | Mides Tablet |
| | Composition | Each film coated tablet contains:<br>Desloratadine ……..5mg |
| | Diary No. Date of R& I & fee | Dy. No 2655, (13-06-2016), Rs. 20,000/- |
| | Pharmacological Group | Anti-histamine |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | Pack of 1 x 10's; As per DPC |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | Alenor – Macter |
| | GMP status | GMP inspection conducted on 31-01-2018 concluded that M/s Jupiter Pharma is operating at a fair level of cGMP compliance as of today. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred as 10 molecules per section has already been approved **(M-260).** |
| | Evaluation by PEC | The firm has provided Tablet section (General). |
| | **Decision: Approved with innovator's specification.** | |
| 689. | Name and address of manufacturer / Applicant | M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Referox tablet 250mg |
| | Composition | Each dispersible tablet contains:<br>Deferasirox……. 250mg |
| | Diary No. Date of R& I & fee | Dy No. 29491: 03.09.2018 PKR 20,000/-: 03.09.2018 |
| | Pharmacological Group | Iron chelating agents |
| | Type of Form | Form 5 |
| | Finished product Specification | The firm has claimed manufacturer specs. |
| | Pack size & Demanded Price | 10's, 30's |
| | Approval status of product in Reference Regulatory Authorities. | EXJADE 250 mg Tablets for oral suspension by Novartis Pharma. Approved by US-FDA |
| | Me-too status | Arefed 250 mg dispersible tablets, by Genome Pharmaceuticals, Hattar, Reg. No. 85092 |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |

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| | Evaluation by PEC | • |
| | **Decision: The Board was apprised that the application was considered out of queue as per decision of 257th meeting of Registration Board. The Board approved the application with innovator's specification.** | |
| 690. | Name and address of manufacturer / Applicant | M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Referox tablet 500mg |
| | Composition | Each dispersible tablet contains:<br>Deferasirox……. 500mg |
| | Diary No. Date of R& I & fee | Dy No. 29491: 03.09.2018 PKR 20,000/-: 03.09.2018 |
| | Pharmacological Group | Iron chelating agents |
| | Type of Form | Form 5 |
| | Finished product Specification | The firm has claimed manufacturer specs. |
| | Pack size & Demanded Price | As per SRO; 10's, 30's |
| | Approval status of product in Reference Regulatory Authorities. | EXJADE 500 mg Tablets for oral suspension by Novartis Pharma. Approved by US-FDA |
| | Me-too status | Arefed 500 mg dispersible tablets, by Genome Pharmaceuticals, Hattar, Reg. No. 85093 |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | • |
| | **Decision: The Board was apprised that the application was considered out of queue as per decision of 257th meeting of Registration Board. The Board approved the application with innovator's specification.** | |
| 691. | Name and address of manufacturer / Applicant | M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Voricon Tablet 200mg |
| | Composition | Each film coated tablet contains:-<br>Voriconazole……200mg |
| | Diary No. Date of R& I & fee | Dairy No. 5614 dated 4.06.2013, Rs:20,000/- |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | As Per SRO; 10's |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | Vozo 200mg Tablet of Hilton Pharma |
| | GMP status | Panel inspection dated 30-08-2017 recommended for renewal of DML. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for following: **(M-258)**<br>• Commitment as per 251st meeting of RB is required.<br>Availability in SRA is not provided by the firm.<br>Reference literature for detailed specification and analytical method is required.<br>Latest Inspection Report is required.<br>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | The firm has submitted following:<br>Commitments as per 251st meeting of RB are required.<br>The formulation is approved in MHRA.<br>• The firm has submitted in-house specs and detail of analytical method. |
| | **Decision: Approved with innovator's specification.** | |
| 692. | Name and address of manufacturer / Applicant | M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |

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|---|---|---|
| | Brand Name +Dosage Form + Strength | Fuzo SR Tablet 10mg |
| | Composition | Each tablet contains:-<br>Alfuzosin HCl…….10mg |
| | Diary No. Date of R& I & fee | Dairy No. 5564 dated 5.06.2013, Rs:20,000/- |
| | Pharmacological Group | Selective alpha 1- adrenergic blocker |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | Rs. 980/ 30's |
| | Approval status of product in Reference Regulatory Authorities. | Uroxatral extended release tablets, **USFDA** |
| | Me-too status | Luzio SR Tablet 10mg by Wilshire Laboratories, |
| | GMP status | Panel inspection dated 30-08-2017 recommended for renewal of DML. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for following: **(M-258)**<br>• Commitment as per 251st meeting of RB is required.<br>• Availability in SRA is not provided by the firm.<br>• Reference literature for detailed specification and analytical method is required.<br>• Latest Inspection Report is required.<br>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | The firm has submitted following:<br>Commitments as per 251st meeting of RB are required.<br>The formulation is approved in MHRA.<br>The firm has submitted in-house specs and detail of analytical method. |
| | **Decision: Deferred for revision of formulation and label claim as per the reference regulatory authorty approved reference product.** | |
| 693. | Name and address of manufacturer / Applicant | M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Bami Tablet 600mg |
| | Composition | Each film coated tablet contains:-<br>Bamifylline Hydrochloride……...600mg |
| | Diary No. Date of R& I & fee | Dairy No. 5613 dated 4.06.2013, Rs:20,000/- |
| | Pharmacological Group | (Bronchodilators & antiasthma) |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | Rs. 361/-, 30's |
| | Approval status of product in Reference Regulatory Authorities. | AIFA, **Italy** |
| | Me-too status | Bamifix Tablet 600mg by Chiesi Pharma |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for following: **(M-258)**<br>• Commitment as per 251st meeting of RB is required.<br>• Availability in SRA is not provided by the firm.<br>• Reference literature for detailed specification and analytical method is required.<br>• Latest Inspection Report is required.<br>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | The firm has submitted following:<br>Commitments as per 251st meeting of RB are required.<br>The formulation is approved in MHRA.<br>The firm has submitted in-house specs and detail of analytical method. |
| | **Decision: Approved with innovator's specification.** | |

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| 694. | Name and address of manufacturer / Applicant | M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Feriwin-F Tablet |
| | Composition | Each film coated tablet contains:-<br>Iron Protein Succinylate……..20mg<br>Folic acid……2.5mg |
| | Diary No. Date of R& I & fee | Dairy No. 5567 dated 5.06.2013, Rs:20,000/- |
| | Pharmacological Group | Heamatinic Drug |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 10's, 20's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Sucrofer-F Tablets of CCL pharma (Reg#052640) |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Deferred for following: **(M-258)**<br>• Commitment as per 251st meeting of RB is required.<br>• Availability in SRA is not provided by the firm.<br>• Reference literature for detailed specification and analytical method is required.<br>• Latest Inspection Report is required.<br>Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | The firm has submitted following:<br>Commitments as per 251st meeting of RB are required.<br>The firm has submitted revised Form-5 stating label claim as below:<br>Each film coated tablet contains:-<br>Iron Protein Succinylate eq. to elemental Iron…..20mg<br>Folic acid……2.5mg<br>The firm has submitted in-house specs and detail of analytical method. |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| 695. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Termi 250mg Tablet |
| | Composition | "Each Tablet Contains:<br>Terbinafine as HCL…250mg" |
| | Diary No. Date of R& I & fee | Dy.No 14606 dated 19-04-2018 Rs.20,000/- (19-04-2018) |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1 x 10's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Neoterbin Tablets 250mg by M/s Neomedix Pharmaceuticals, Islamabad. (Reg.# 081411) |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | • |
| | **Decision:Approved** | |
| 696. | Name and address of manufacturer / Applicant | Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Hirso 13.9% Cream |

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|---|---|---|
| | Composition | "Each 100g Contains:<br>Eflornithine as Hydrochloride Monohydrate…..13.9g" |
| | Diary No. Date of R& I & fee | Dy.No 14605 (19-04-2018) Rs.20,000/- Dated 19-04-2018 |
| | Pharmacological Group | Antiprotozoals |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Depilus Cream of M/s Atco Lab. Karachi (Reg.# 073868) |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | • |
| | **Decision:Approved** | |
| 697. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Micin Gel 1% |
| | Composition | Each g of gel contains:<br>Clindamycin as phosphate……1% |
| | Diary No. Date of R& I & fee | Duplicate, 22-12-2010, 8,000/-, (Photocopy attached), 22-12-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Anti-infectives for treatment of acne<br>ATC Code; D10AF01 |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 15g, 20g |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Uniclin Gel by M/s Kaizen Pharma, Karachi (Reg. No. 076304) |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | • Duplicate dossier |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | • |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 698. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Isonon Plus Gel |
| | Composition | Each g contains:<br>Erythromycin…20mg<br>Isotretinoin…..0.5mg |
| | Diary No. Date of R& I & fee | Duplicate, 23-09-2010, 8,000/-, (Photocopy attached), 23-09-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Anti-acne preparations<br>ATC Code: D10AD54 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. |
| | Pack size & Demanded Price | 10g |
| | Approval status of product in Reference Regulatory Authorities. | Isotrexin® Gel (MHRA Approved) |
| | Me-too status | Tretocin by Derma tecno Pakistan |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |

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| | Previous remarks of the Evaluator. | • Duplicate Dossier. |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | • |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 699. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Tacrus Ointment 0.03% |
| | Composition | Each gram contains:<br>Tacrolimus (as monohydrate)…0.3mg (0.03%w/w) |
| | Diary No. Date of R& I & fee | Duplicate, 22-12-2010, 8,000/-, (Photocopy attached), 22-12-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Agents for dermatitis, excluding corticosteroid<br>ATC Code: D11AH01 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. Specs. |
| | Pack size & Demanded Price | 10g |
| | Approval status of product in Reference Regulatory Authorities. | PROTOPIC (tacrolimus) Ointment 0.03%w/w by M/s LEO PHARMA AS (USFDA Approved) |
| | Me-too status | Tacroderm Ointment 0.03% by M/s Caraway Pharmaceuticals (Reg#069932) |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | Duplicate dossier |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | • |
| | **Decision: Approved with innovator's specification.**<br>**Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.**<br>**Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| 700. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Myfate DS Tablet |
| | Composition | Each uncoated tablet contains:<br>Sucralfate…1g |
| | Diary No. Date of R& I & fee | Duplicate, 23-09-2010, 8,000/-, (Photocopy attached), 23-09-2010, 12,000/- (Photocopy attached), 31-03-2015 |
| | Pharmacological Group | Anti-ulcer ATC Code: A02BX02 |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's, 8's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved (Uncoated) |
| | Me-too status | Registration Number:011748<br>Brand Name: SUCFATE 1GM TAB Each tablet contains:-SUCRALFATE 1000mg<br>Manufacturer Name:SIZA |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | Firm has revised their formulation from film coated to uncoated tablet without submission of fee. |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | • |
| | **Decision: Deferred for submission of requisite fee for change of formulation.** | |

| | | |
|---|---|---|
| 701. | Name and address of manufacturer / Applicant | M/s Shrooq Pharmaceuticals (Pvt.) Ltd., 21-Km, Feroz Pur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Tenovir Tablet 300mg |
| | Composition | Each film coated tablet contains:<br>Tenofovir Disoproxil fumarate……300mg |
| | Diary No. Date of R& I & fee | Duplicate, 14-12-2009, 8,000/-, (Photocopy attached), 14-12-2009, |
| | Pharmacological Group | Nucleoside reverse transcriptase inhibitors<br>ATC Code: J05AF07 |
| | Type of Form | Form 5 |
| | Finished product Specification | Mfg. Specs |
| | Pack size & Demanded Price | 30's in PVC jar |
| | Approval status of product in Reference Regulatory Authorities. | Tenofovir by Teva Pharma<br>(USFDA Approved) |
| | Me-too status | Tenofo-B by Getz |
| | GMP status | The firm was last inspected on 07.06.2017 & 30.08.2017, wherein the panel recommended the renewal of DML |
| | Previous remarks of the Evaluator. | • Approved with box warning in USFDA. |
| | Previous decision(s) | Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** |
| | Evaluation by PEC | |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |

## Case No. 03: Registration applications of newly granted DML or New section (Human)

### a. New DML

**M/s Norwich Pharmaceuticals, Islamabad**

CLB in its 267th meeting has granted New license with following 3 sections. The details of products applied for each section is provided below:

| Section | No. of molecules applied | No. of products applied |
|---|---|---|
| Capsule section (Cephalosporin) | | |
| Dry powder injection (Cephalosporin) | 6 | 18 |
| Dry powder suspension (Cephalosporin) | | |

The letter was issued on 8th January 2019.

| **Dry Powder injection (Cephalosporin) section: Molecules-6/ Products-18** | | |
|---|---|---|
| 702. | **Name and address of manufacturer / Applicant** | **M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad** |
| | Brand Name +Dosage Form + Strength | Cefron 250mg Injection |
| | Composition | Each Vial Contains:<br>Ceftazidime pentahydrate eq. to Ceftazidime…250mg |
| | Diary No. Date of R& I & fee | Dy. No. 3407 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Fortum powder for solution for injection by M/s GlaxoSmithKline UK (**MHRA** Approved) |
| | Me-too status | Panacef Injection by CCL |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 703. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Cefron 500mg Injection |
| | Composition | Each Vial Contains:<br>Ceftazidime pentahydrate eq. to Ceftazidime…500mg |

| | | |
|---|---|---|
| | Diary No. Date of R& I & fee | Dy. No. 3408 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Fortum powder for solution for injection by M/s GlaxoSmithKline UK (**MHRA** Approved) |
| | Me-too status | Panacef Injection by CCL |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 704. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Cefron 1gm Injection |
| | Composition | Each Vial Contains:<br>Ceftazidime pentahydrate Eq. to Ceftazidime…1000mg |
| | Diary No. Date of R& I & fee | Dy. No. 3409 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Fortum powder for solution for injection by M/s GlaxoSmithKline UK (**MHRA** Approved) |
| | Me-too status | Panacef Injection by CCL |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 705. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Furox 750mg Injection |
| | Composition | Each Vial Contains:<br>Cefuroxime sodium eq. to Cefuroxime…750mg |
| | Diary No. Date of R& I & fee | Dy. No. 3394 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cefuroxime powder for solution for injection (**MHRA** Approved) |
| | Me-too status | ZINACEF 750MG INJ by M/s GSK Pakistan |
| | GMP status | |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 706. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Furox 1.5gm Injection |
| | Composition | Each Vial Contains:<br>Cefuroxime sodium eq. to Cefuroxime…1.5gm |
| | Diary No. Date of R& I & fee | Dy. No. 3395 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cefuroxime powder for solution for injection (**MHRA** Approved) |
| | Me-too status | Zecef Injection 1.5gm by Bosch Pharmaceuticals |
| | GMP status | New license |

| | | |
|---|---|---|
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved.** | |
| 707. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | L-Pime 500mg Injection |
| | Composition | Each Vial Contains:<br>Cefepime hydrochloride eq. to Cefepime…500mg<br>(with L-Arginine) |
| | Diary No. Date of R& I & fee | Dy. No. 3392 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cefipime hydrochloride Injection by Hospira, Inc. (**USFDA** approved) |
| | Me-too status | Uspime Injection by Usawa Pharmaceuticals |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 708. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | L-Pime 1gm Injection |
| | Composition | Each Vial Contains:<br>Cefepime hydrochloride eq. to Cefepime…1gm<br>(with L-Arginine) |
| | Diary No. Date of R& I & fee | Dy. No. 3392 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cefipime hydrochloride Injection by Hospira, Inc. (**USFDA** approved) |
| | Me-too status | Uspime Injection by Usawa Pharmaceuticals |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 709. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norbac 1gm Injection |
| | Composition | Each Vial Contains:<br>Cefoperazone sodium Eq. to Cefoperazone…500mg<br>Sulbactam Sodium Eq. to Sulbactam…500mg |
| | Diary No. Date of R& I & fee | Dy. No. 3396 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP Specs |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PMDA Japan Approved |
| | Me-too status | Cebac Injection by Bosch Pharma |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 710. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norbac 2gm Injection |

| | | |
|---|---|---|
| | Composition | Each Vial Contains:<br>Cefoperazone sodium Eq. to Cefoperazone…1000mg<br>Sulbactam Sodium Eq. to Sulbactam…1000mg |
| | Diary No. Date of R& I & fee | Dy. No. 3403 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP Specs |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by 3 European countries:<br>**Czech:**<br>http://www.sukl.eu/modules/medication/detail.php?code=0015273&tab=info<br>**Slovakia:**<br>https://www.sukl.sk/hlavna-stranka/english-version/special-pages/medical-product-detail?page_id=842&lie_id=6343A<br>**Poland:**<br>http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results<br>Links are assessed on 1st Oct 2018 |
| | Me-too status | Bezone Injection by Medisave |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 711. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norcef 250mg IM Injection |
| | Composition | Each Vial Contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…250mg |
| | Diary No. Date of R& I & fee | Dy. No. 3390 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference R egulatory Authorities. | Rocephin Injection by Roche<br>(**MHRA** Approved) |
| | Me-too status | Rocephin Injection by Roche |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 712. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norcef 250mg IV Injection |
| | Composition | Each Vial Contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…250mg |
| | Diary No. Date of R& I & fee | Dy. No. 3398 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Rocephin Injection by Roche<br>(**MHRA** Approved) |
| | Me-too status | Rocephin Injection by Roche |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 713. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norcef 500mg IM Injection |

| | | |
|---|---|---|
| | Composition | Each Vial Contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…500mg |
| | Diary No. Date of R& I & fee | Dy. No. 3401 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Rocephin Injection by Roche<br>(**MHRA** Approved) |
| | Me-too status | Rocephin Injection by Roche |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 714. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norcef 500mg IV Injection |
| | Composition | Each Vial Contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…500mg |
| | Diary No. Date of R& I & fee | Dy. No. 3400 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Rocephin Injection by Roche<br>(**MHRA** Approved) |
| | Me-too status | Rocephin Injection by Roche |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 715. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norcef 1gm IV Injection |
| | Composition | Each Vial Contains:<br>Ceftriaxone sodium eq. to ceftriaxone…1000mg |
| | Diary No. Date of R& I & fee | Dy. No. 3402 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Rocephin Injection by Roche<br>(**MHRA** Approved) |
| | Me-too status | Rocephin Injection by Roche |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 716. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Norcef 2gm IV Injection |
| | Composition | Each Vial Contains:<br>Ceftriaxone sodium eq. to ceftriaxone…2gm |
| | Diary No. Date of R& I & fee | Dy. No. 3397 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Rocephin Injection by Roche<br>(**MHRA** Approved) |
| | Me-too status | Rocephin Injection by Roche |

| | | |
|---|---|---|
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 717. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Taxim 250mg Injection |
| | Composition | Each Vial Contains:<br>Cefotaxime Sodium Eq. to Cefotaxime…250mg |
| | Diary No. Date of R& I & fee | Dy. No. 3404 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Claforan 250mg Injection by Sanofi Aventis<br>(**Netherland** Approved) |
| | Me-too status | Baxim Injection by Nabiqasim |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 718. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Taxim 500mg Injection |
| | Composition | Each Vial Contains:<br>Cefotaxime sodium eq. to Cefotaxime…500mg |
| | Diary No. Date of R& I & fee | Dy. No. 3405 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cefotaxime Injection<br>(**MHRA** Approved) |
| | Me-too status | Baxim Injection by Nabiqasim |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 719. | Name and address of manufacturer / Applicant | M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Taxim 1gm Injection |
| | Composition | Each Vial Contains:<br>Cefotaxime sodium eq. to Cefotaxime…1000mg |
| | Diary No. Date of R& I & fee | Dy. No. 3406 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cefotaxime Injection<br>(**MHRA** Approved) |
| | Me-too status | Baxim Injection by Nabiqasim |
| | GMP status | New license |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |

| TABLET (GENERAL)<br>22 Products/ 10 Molecules | | |
|---|---|---|
| 720. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Linzovic 400mg Tablet |
| | Composition | Each Tablet Contains:<br>Linezolid……..…400mg |
| | Diary No. Date of R& I & fee | Dy.No 1711 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturers specification |
| | Pack size & Demanded Price | 10's, 12's, & 14's ;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Zyvox 400 mg tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Barizold 400mg Tablet by M/s Barrett Hodgson (Reg#076342) |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |
| 721. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Linzovic 600mg Tablet |
| | Composition | Each Tablet Contains:<br>Linezolid…600mg |
| | Diary No. Date of R& I & fee | Dy.No 1712 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturers specification |
| | Pack size & Demanded Price | 10's, 12's, & 14's ;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Zyvox 400 mg tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Ecasil 600mg tablet by M/s Sami (Reg#066904) |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |
| 722. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Itopic 50mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Itopride as HCL…50mg |
| | Diary No. Date of R& I & fee | Dy.No 1719 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Prokinetics |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1 x 10's , 1 x 20's, 1 x 30's & 1 x 50's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved |
| | Me-too status (with strength and dosage form) | Itop 50mg Tablet by M/s Nexus. |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |

| | | |
|---|---|---|
| 723. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Itopic 150mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Itopride as HCL…150mg |
| | Diary No. Date of R& I & fee | Dy.No 1720 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Prokinetics |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1 x 10's , 1 x 20's, 1 x 30's & 1 x 50's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved |
| | Me-too status (with strength and dosage form) | Dysrid-150mg Tablets by M/s Onyx Pharmaceuticals |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |
| 724. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Creva 10mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Rosuvastatin…10mg |
| | Diary No. Date of R& I & fee | Dy.No 1701 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Statin or HMG CoA Reductase Inhibitor |
| | Type of Form | Form -5 |
| | Finished product Specifications | Manufacturers specification Specifications |
| | Pack size & Demanded Price | 1 x 10's , 1 x 20's, 1 x 30's:as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Crestor 10mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Easetec 10mg tablet by M/s Pharmatec (Reg#067564) |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | Correction of Salt form Rosuvastatin as calcium without submission of fee |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| 725. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Creva 20mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Rosuvastatin…20mg |
| | Diary No. Date of R& I & fee | Dy.No 1702 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Statin or HMG CoA Reductase Inhibitor |
| | Type of Form | Form -5 |
| | Finished product Specifications | Manufacturers specification Specifications |
| | Pack size & Demanded Price | 1 x 10's , 1 x 20's, 1 x 30's:as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Crestor 20mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Easetec 20mg tablet by M/s Pharmatec (Reg#067565) |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | Correction of Salt form Rosuvastatin as calcium without submission of fee |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| 726. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |

| | | |
|---|---|---|
| | Brand Name +Dosage Form + Strength | Creva 40mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Rosuvastatin…40mg |
| | Diary No. Date of R& I & fee | Dy.No 1703 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Statin or HMG CoA Reductase Inhibitor |
| | Type of Form | Form -5 |
| | Finished product Specifications | Manufacturers specification Specifications |
| | Pack size & Demanded Price | 1 x 10's , 1 x 20's, 1 x 30's:as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Crestor 40mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Rosocard Tablets of M/s Himont Pharma |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | Correction of Salt form Rosuvastatin as calcium without submission of fee |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| 727. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Lorvic 4mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Lornoxicam…4mg |
| | Diary No. Date of R& I & fee | Dy.No 1725 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1 x 10's , 1 x 20's, 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Xefo 4 mg tablet (EMA approved) |
| | Me-too status (with strength and dosage form) | LoxiBar 4mg Tablet Of M/S Barret Hodgson |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 728. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Lorvic 8mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Lornoxicam…8mg |
| | Diary No. Date of R& I & fee | Dy.No 1695 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 1 x 10's , 1 x 20's, 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Xefo 8 mg tablet (EMA approved) |
| | Me-too status (with strength and dosage form) | LoxiBar 8mg Tablet Of M/S Barret Hodgson |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 729. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Rison 1mg Tablets |
| | Composition | Each Tablet Contains:<br>Risperidone……1mg |
| | Diary No. Date of R& I & fee | Dy.No 2917 dated 22-01-2019 Rs.20,000/- 22-01-2019 |

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|---|---|---|
| | Pharmacological Group | Sedative |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 10's ,20's, 30's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | RISPERDAL 1MG of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Rislet 1mg Tablet M/s. High-Q Pharmaceuticals |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 730. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Rison 2mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Risperidone……..…2mg |
| | Diary No. Date of R& I & fee | Dy.No 2918 dated 22-01-2019 Rs.20,000/- 22-01-2019 |
| | Pharmacological Group | Sedative |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 10's ,20's, 30's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | RISPERDAL 2MG of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Rislet 2mg Tablet M/s. High-Q Pharmaceuticals |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 731. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Rison 3mg Tablets |
| | Composition | Each Tablet Contains:<br>Risperidone……..…3mg |
| | Diary No. Date of R& I & fee | Dy.No 2919 dated 22-01-2019 Rs.20,000/- 22-01-2019 |
| | Pharmacological Group | Sedative |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 10's ,20's, 30's As per SRO |
| | Approval status of product in Reference Regulatory Authorities | RISPERDAL 3MG of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Rislet 3mg Tablet M/s. High-Q Pharmaceuticals |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 732. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Rison 4mg Tablets |
| | Composition | Each Tablet Contains:<br>Risperidone……..…4mg |
| | Diary No. Date of R& I & fee | Dy.No 2920 dated 22-01-2019 Rs.20,000/- 22-01-2019 |
| | Pharmacological Group | Sedative |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 10's ,20's, 30's As per SRO |

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| | Approval status of product in Reference Regulatory Authorities | RISPERDAL 4MG of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Rislet 4mg Tablet M/s. High-Q Pharmaceuticals |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 733. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Arovent 10mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Montelukast as Sodium…10mg |
| | Diary No. Date of R& I & fee | Dy.No 1700 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Anti-asthmatic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1 x 14's , 1 x 28's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ga Singulair Of (USFDA Approved) |
| | Me-too status (with strength and dosage form) | Mecost 10mg Tablet M/s Sigma |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 734. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Lomide 50mg Tablets |
| | Composition | Each Tablet Contains:<br>Lacosamide……50mg |
| | Diary No. Date of R& I & fee | Dy.No 1707 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Antiepileptic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vimpat tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Nurosa 50mg Table M/s Helix Pharma |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 735. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Lomide 100mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Lacosamide……100mg |
| | Diary No. Date of R& I & fee | Dy.No 1708 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Antiepileptic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vimpat tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Nurosa 100mg Table M/s Helix Pharma |

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| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 736. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Lomide 200mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Lacosamide……200mg |
| | Diary No. Date of R& I & fee | Dy.No 1709 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Antiepileptic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vimpat tablet of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Atcomid 200mg Tablet M/s Atco Lab |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 737. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Cox-E 30mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Etoricoxib…….30mg |
| | Diary No. Date of R& I & fee | Dy.No 1696 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Anti-inflammatory and anti-rheumatic drugs |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer,s specification |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Arcoxia 30mg tablet Of ( (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 738. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Cox-E 60mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Etoricoxib…….60mg |
| | Diary No. Date of R& I & fee | Dy.No 1697 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Anti-inflammatory and anti-rheumatic drugs |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer,s specification |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Arcoxia 60mg tablet Of ( (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Etroxin tablet 60mg Of M/S Akson Pharmaceuticals |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved with innovator's specification** | |

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| 739. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Epiral 50mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Eperisone……50mg |
| | Diary No. Date of R& I & fee | Dy.No 1717 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Muscle relaxant, Centrally acting agent |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer,s specification |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Expose 50mg film coated tablets by ALFASIGMA S.P.A.(AIFA Italy Approved) |
| | Me-too status (with strength and dosage form) | Perispa 50 Mg Tablets by Platinum Pharma (Reg# 039302) |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | Correction of Salt form Eperisone as HCl without submission of fee . |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| 740. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Dep CR 12.5mg Tablet |
| | Composition | Each enteric film coated Tablet Contains:<br>Paroxetine……12.5mg |
| | Diary No. Date of R& I & fee | Dy.No 1698 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Selective serotonin-reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | PAXIL CR of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 741. | Name and address of manufacturer / Applicant | M/s Invictus Pharmaceuticals, Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi |
| | Brand Name +Dosage Form + Strength | Dep CR 25mg Tablet |
| | Composition | Each enteric film coated Tablet Contains:<br>Paroxetine……25mg |
| | Diary No. Date of R& I & fee | Dy.No 1699 dated 14-01-2019 Rs.20,000/- 14-01-2019 |
| | Pharmacological Group | Selective serotonin-reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1 x 10's, 1 x 20's & 1 x 30's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | PAXIL CR of (USFDA approved) |
| | Me-too status (with strength and dosage form) | Panox CR Tablet 25 mg M/s Regal Pharmaceuticals, |
| | GMP status | Last inspection conducted on 13-11-2018 and panel recommend grant of DML |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |

**Case. No. M/s Zamko Pharmaceuticals (Pvt) Ltd. Lahore. (New Licence)**

The Central Licensing Board in its 267th meeting held on 31st December, 2018 has considered and approved the grant of DML by the way of formulation of firm M/s **Zamko Pharmaceuticals (Pvt) Ltd**. 641-A Sundar Industrial Estate, Lahore (DML:00890) as under:-

| Sr. No | Section | No. of products | No. of molecules |
|---|---|---|---|
| 1 | Tablet (General) Section | 15 | 09 |
| 2 | Capsule (General) Section | - | - |
| 3 | Oral powder suspension (General) Section | 10 | 07 |

**Tablet (General) Section**
**15 Products/ 09 Molecules**

| | | |
|---|---|---|
| 742. | Name and Address of Manufacturer / Applicant | **M/s Zamko Pharmaceuticals (Pvt) Ltd.** 641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | **Zamlide 600mg Tablet** |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3546 dated 24-01-2019 Rs.20,000/- 25-1-2019 |
| | Composition | Each film coated Tablet Contains:<br>Linezolid…600mg |
| | Pharmacological Group | Other antibacterials |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Zyvox film coated tablet 600mg. By Pharmacia and Up-john. (USFDA Approved). |
| | Me-too Status | Nezolid Tablet of M/s Searl I.V. Lhr. (Reg. # 050325) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 743. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zoxacin 250mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3509 dated 24-01-2019 Rs.20,000/-<br>Dated 25-01-2019 |
| | Composition | Each film coated Tablet Contains:<br>Ciprofloxacin (as hydrochloride) …250mg |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cipro 250mg Tablet by M/s Bayer Health Care Pharmaceuticals Inc.USA & Germany (USFDA Approved) |
| | Me-too Status | Mercip 250mg tablet by M/s Merck (Reg#024601) |
| | GMP Status | 13-04-2018<br>Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 744. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Clicin 500mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3545 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film coated Tablet Contains:<br>Clarithromycin…500mg |
| | Pharmacological Group | Macrolides |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's /As per SRO |

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| | Approval Status of Product in Reference Regulatory Authorities. | Clarithromycin 500mg Film-coated Tablets by M/s Ranbaxy (UK) Limited, (MHRA approved) |
| | Me-too Status | CLARION 500MG TABLET by M/s. 'Ferozsons Labs (Reg#0002873) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 745. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Moxacin 400mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3541 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film-coated tablet contains:<br>Moxifloxacin(as hydrochloride)…....400mg |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Avelox 400 mg film-coated tablets by Bayer plc (MHRA Approved) |
| | Me-too Status | Metoxim 400mg Tablet by M/s Foray Pharmaceutical<br>(Reg No:056083) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 746. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zonac 50mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3539 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each enteric coated Tablet Contains:<br>Diclofenac Sodium…50mg |
| | Pharmacological Group | Acetic acid derivatives and related substances |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 100's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Diclofenac Sodium 50mg Gastro-Resistant Tablets by M/s Dexcel®-Pharma Ltd (MHRA Approved) |
| | Me-too Status | Camotaren SR 50mg tablet by M/s MENDOZA (Reg#012260) |
| | GMP Status | 13-04-2018<br>Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 747. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zamkast 10mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3534 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film-coated tablet contains:<br>Montelukast (as sodium) …10mg |
| | Pharmacological Group | Leukotriene receptor antagonists |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Singulair tablets 10mg of M/s Merck Sharp & Dohme, Australia (TGA Approved) |

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| | Me-too Status | Montiget 10mg tablets of M/s Getz Pharma<br>(Reg. # 034838) |
| | GMP Status | 13-04-2018<br>Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 748. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Clicin 250mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3544 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film coated tablet contains: -<br>Clarithromycin …250mg |
| | Pharmacological Group | Macrolide antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Clarithromycin 250mg Film-coated Tablets by M/s Ranbaxy (UK) Limited, (MHRA approved) |
| | Me-too Status | Pathocin Tablet 250mg by M/s Wilson Pharmaceuticals (Reg#016724) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | . |
| | **Decision: Approved** | |
| 749. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zonac SR 100mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3538 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each sustained release Tablet Contains:<br>Diclofenac Sodium…100mg |
| | Pharmacological Group | Acetic acid derivatives and related substances |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 20's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Dicloflex Retard 100 mg by M/s Dexcel®-Pharma Ltd (MHRA Approved) |
| | Me-too Status | Konac SR Tablets 100mg by M/s Remington Pharmaceutical (Reg#020535) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| 750. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zolor 10mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3543 (24-01-2019) Rs.20,000/- 25-01-2019 |
| | Composition | Each film-coated Tablet Contains:<br>Loratadine…10mg |
| | Pharmacological Group | Other antihistamines for systemic use |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Clarityn Allergy 10mg Tablets by M/s Bayer plc (MHRA Approved) |
| | Me-too Status | Senergy OD10mg tablet of M/s Highnoon (Reg.#017672) |

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| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Approved in MHRA and Netherland as uncoated while is applied as film-coated. |
| | **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** | |
| 751. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zolocin 500mg Tablets |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3537 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film-coated Tablet Contains:<br>Levofloxacin (as hemihydrate) …500mg |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | EVOXIL 500 MG FILM-COATED TABLETS by Beacon Pharmaceutical (MHRA Approved) |
| | Me-too Status | Lefloxid tablet 500mg by M/s Wnsfield Pharma (Reg#046819) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| 752. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zamkast 4mg Chewable Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3540 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each chewable tablet contains;<br>Montelukast (as sodium).....4mg |
| | Pharmacological Group | Leukotriene receptor antagonists |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Singulair 4mg chewable tablet by M/s Merck Sharp & Dohme Corp, USFDA approved |
| | Me-too Status | Exma 4mg chewable tablet by M/s Asian Continental (Reg#081007) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 753. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zambin 500mcg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3528 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film Coated Tablet Contains:<br>Mecobalamin…500mcg |
| | Pharmacological Group | Vitamin B12 (cyanocobalamin and analogues) |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack Size & Demanded Price | 10x10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Methicobide tablet 500 mcg sugar-coated, by Daito Corporation. Approved by PMDA Japan |

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| | Me-too Status | Elgin 500 mcg tablet of M/s Novartis Pharma (Pvt) Limited (Reg. # 032638) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Firm has applied as film coated tablet whereas formulation approved in PMDA is sugar coated. |
| | **Decision: Deferred for submission of evidence of approval of applied formulation as "film coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.** | |
| 754. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zoxacin 500mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3508 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film coated Tablet Contains:<br>Ciprofloxacin (as hydrochloride) …250mg |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cipro 500mg Tablet by M/s Bayer Health Care Pharmaceuticals Inc.USA & Germany (USFDA Approved) |
| | Me-too Status | Mercip 500mg Tablet by M/s Merck (Reg#024602) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 755. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zolocin 250mg Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3536 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each film-coated Tablet Contains:<br>Levofloxacin (as hemihydrate) …250mg |
| | Pharmacological Group | Fluoroquinolones |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | EVOXIL 250 MG FILM-COATED TABLETS by Beacon Pharmaceutical (MHRA Approved) |
| | Me-too Status | Cravit Tablets 250mg by M/s Hilton (Reg#022245) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 756. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zamkast 5mg Chewable Tablet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3542 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each chewable tablet contains:<br>Montelukast (as sodium)…5mg |
| | Pharmacological Group | Leukotriene receptor antagonists |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Singulair 5mg chewable tablet by M/s Merck Sharp & Dohme Corp, USFDA approved |

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| | Me-too Status | NenKast 5mg chewable tablet by M/s Nenza Pharmaceuticals (Reg#079342) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **Oral powder suspension (General) Section<br>10 Products/ 07 Molecules** | | |
| 757. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zoxacin 250mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3533 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Ciprofloxacin (TM micro pellets 35%) …250mg |
| | Pharmacological Group | Fluoroquinolone antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Ciproxin 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved. |
| | Me-too Status | Hiflox Dry suspension 250mg/5ml by M/s Hilton (Reg#067499) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Source of pellets: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Deferred for further deliberation upon the salt form of API, in view of reference product.** | |
| 758. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zoxacin 125mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3512 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Ciprofloxacin (TM micro pellets 35%) …125mg |
| | Pharmacological Group | Fluoroquinolone antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too Status | Hiflox Dry suspension 125mg/5ml by M/s Hilton (Reg#067498) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Registration Board in its 269th meeting decided as follows:<br>Keeping in view the following statement written in Qualitative and quantitative composition "2.5 mL suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age, Registration Board decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA<br>• Source of pellets: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Deferred for further deliberation upon the salt form of API, in view of reference product.** | |

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| 759. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zamlide 100mg/5ml Dry Powder Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3522 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Linezolid…100mg |
| | Pharmacological Group | Other antibacterials |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 60ml /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Linezolid 100 mg/5 ml granules for oral suspension by Pfizer. (MHRA Approved) |
| | Me-too Status | Nezolid 100mg Suspension of Searle Pak, Karachi<br>(Reg. # 050326) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 760. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Mycin 250mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3535 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Fosfomycin Calcium…250mg |
| | Pharmacological Group | Other antibacterials |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack Size & Demanded Price | 60ml /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | FOSFOCINA Suspension 250mg/5ml by M/s LABORATORIOS ERN, S.A. Barcelona, España (Spain Approved) |
| | Me-too Status | Fosfonex 250mg/5ml Suspension of M/s Nexus Pharma (Reg#075836) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Firm has applied as Fosfomycin Calcium…250mg, whereas, formulation approved in Spain is Fosfomycin (as Calcium)…250mg |
| | **Decision: Deferred for revision of salt forms of the API in the formulation as per the reference product along with submission of fee for revision of formulation.** | |
| 761. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zolocin 125mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3515 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Levofloxacin (as hemihydrate) …125mg |
| | Pharmacological Group | Quinolone antibacterials |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 60ml /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too Status | Could not be confirmed |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |

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| | Remarks of the Evaluator. | • Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting is required.<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required. |
| | **Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data** | |
| 762. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zithro 200mg/5ml Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3531 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Azithromycin (as dihydrate) …200mg |
| | Pharmacological Group | Macrolide |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Zithromax 200mg/ 5ml powder for oral suspension of M/s Pfizer Limited (MHRA Approved) |
| | Me-too Status | Azomax 200mg oral suspension of M/s Novartis Pharma, Pakistan (Reg. # 022201) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 763. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zamadin 40mg/5ml Dry Powder Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3519 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Famotidine…40mg |
| | Pharmacological Group | Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) (H2-receptor antagonists) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Pepcid 40mg/5ml for oral suspension 40mg/5ml by M/s Salix Pharma, (USFDA Approved) |
| | Me-too Status | Zepcin Dry Suspension 40mg/5ml by M/s Cirin Pharmaceuticals (Reg#064330) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 764. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Clicin 125mg/5ml Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3525 dated 24-01-2019 Rs.20,000/- 25-1-2019 |
| | Composition | Each 5ml Contains:<br>Clarithromycin (as EC taste masked granules)…125mg |
| | Pharmacological Group | Macrolide Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml, 60ml/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Biaxin granules for oral suspension 125mg/5ml by M/s Abbvie, USFDA approved. |

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| | Me-too Status | Claritek Dry Suspension 125mg/5ml by M/s Getz Pharma (Reg#009846) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Source of pellets: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Approved** | |
| 765. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Clicin 250mg/5ml Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3532 dated 24-01-2019 Rs.20,000/- 25-1-2019 |
| | Composition | Each 5ml Contains:<br>Clarithromycin (as EC taste masked granules)…250mg |
| | Pharmacological Group | Macrolide Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml, 60ml/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Biaxin granules for oral suspension 250mg/5ml by M/s Abbvie,(USFDA approved.) |
| | Me-too Status | Claritek Dry Suspension 250mg/5ml by M/s Getz Pharma (Reg#061347) |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Source of pellets: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Approved** | |
| 766. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt) Ltd.<br>641-A Sundar Industrial Estate, Lahore |
| | Brand Name + Dosage Form + Strength | Zolocin 250mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 3533 dated 24-01-2019 Rs.20,000/- Dated 25-01-2019 |
| | Composition | Each 5ml Contains:<br>Levofloxacin (as hemihydrate) …250mg |
| | Pharmacological Group | Quinolone antibacterials |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 60ml /As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too Status | Could not be confirmed |
| | GMP Status | 13-04-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting is required.<br>• Evidence of applied formulation/ drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm is required. |
| | **Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data** | |

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| 767. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAMZOLE 20mg capsules |
| | Diary No. Date of R & I & fee | Dy No. 3518; 25-01-2019; Rs.20,000/- |
| | Composition | Each capsule contains:<br>Esomeprazole (as magnesium trihydrate)… 20mg<br>(As enteric coated pellets)<br>Source of pellets: M/s Vision Pharma Islamabad. |
| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 14's;As fixed by government |
| | Approval Status of Product in Reference Regulatory Authorities. | Approved by MHRA |
| | Me-too Status | BS-Zole Capsule 20mg of M/s. Berlex Lab International |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 768. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAMZOLE 40mg capsules |
| | Diary No. Date of R & I & fee | Dy No. 3514;25-01-2019; Rs.20,000/- |
| | Composition | Each capsule contains:<br>Esomeprazole (as magnesium trihydrate)… 40mg<br>(As enteric coated pellets)<br>Source of pellets: M/s Vision Pharma Islamabad. |
| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 14's; As fixed by government |
| | Approval Status of Product in Reference Regulatory Authorities. | Approved by MHRA |
| | Me-too Status | BS-Zole Capsule 40mg of M/s. Berlex Lab International |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 769. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAMPROLE 20mg capsules |
| | Diary No. Date of R & I & fee | Dy No. 3529;25-01-2019; Rs.20,000/- |
| | Composition | Each capsule contains:<br>Omeprazole….20mg<br>(enteric coated pellets)<br>Source of pellets: M/s Vision Pharma Islamabad. |
| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | As fixed by government |
| | Approval Status of Product in Reference Regulatory Authorities. | Approved by MHRA |
| | Me-too Status | Jumep -20 Capsule of M/s Jupiter Pharma |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 770. | Name and address of manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | ZAMPROLE 40mg capsules |

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| | Diary No. Date of R& I & fee | Dy No. 3548;25-01-2019; Rs.20,000/- |
| | Composition | Each capsule contains:<br>Omeprazole….40mg<br>(enteric coated pellets)<br>Source of pellets: M/s Vision Pharma Islamabad. |
| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | As fixed by government |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA |
| | Me-too status | Jumep -40 Capsule of M/s Jupiter Pharma |
| | GMP status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 771. | Name and address of manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | ZAMPHENE Capsule 50mg |
| | Diary No. Date of R& I & fee | Dy No. 3526;25-01-2019; Rs.20,000/- |
| | Composition | Each capsule contains:<br>Clomiphene citrate……..50mg |
| | Pharmacological Group | Ovulation stimulants, synthetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | 10's, 30's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA(as provided by the firm)<br>Clomid 50mg Tablets by M/s Sanofi |
| | Me-too status | Prolifin Capsule 50mg (Reg#010250)Of Chiesi Pharmaceuticals (as provided by the firm) |
| | GMP status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in 275th meeting.<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 772. | Name and address of manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | ZAMBLIN 300mg Capsule |
| | Diary No. Date of R& I & fee | Dy No. 3524;25-01-2019; Rs.20,000/- |
| | Composition | Each Capsule Contains:<br>Pregabalin……300mg |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Gabica 300mg Capsule of Getz Pharma |
| | GMP status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Monograph for test/analysis of Applied formulation is not present in USP. |
| | **Decision: Approved with innovator's specification.** | |

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| 773. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name+ Dosage Form + Strength | ZAMBLIN 150mg Capsule |
| | Diary No. Date of R & I & fee | Dy No. 3510;25-01-2019; Rs.20,000/- |
| | Composition | Each Capsule Contains:<br>Pregabalin……150mg |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 14's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Pregabalin 150mg Hard capsules Accord Healthcare Limited United Kingdom, Hungary. |
| | Me-too Status | Gabica150mg Capsule of Getz Pharma |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Monograph for test/analysis of Applied formulation is not present in USP. |
| | **Decision: Approved with innovator's specification.** | |
| 774. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAMBLIN 100mg Capsule |
| | Diary No. Date of R & I & fee | Dy No. 3521;25-01-2019; Rs.20,000/- |
| | Composition | Each Capsule Contains:<br>Pregabalin…….100mg |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 14's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Pregabalin 100mg Hard capsules Accord Healthcare Limited United Kingdom, Hungary. |
| | Me-too Status | Gabica100mg Capsule of Getz Pharma |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Monograph for test/analysis of Applied formulation is not present in USP. |
| | **Decision: Approved with innovator's specification.** | |
| 775. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd, 641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAMBLIN 75mg Capsule |
| | Diary No. Date of R & I & fee | Dy No. 3513;25-01-2019; Rs.20,000/- |
| | Composition | Each Capsule Contains:<br>Pregabalin…….75mg |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 14's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Pregabalin 75mg Hard capsules Accord Healthcare Limited United Kingdom, Hungary. |
| | Me-too Status | Gabica 75mg Capsule of Getz Pharma |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Monograph for test/analysis of Applied formulation is not present in USP. |
| | **Decision: Approved with innovator's specification.** | |
| 776. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAMBLIN 50mg Capsule |
| | Diary No. Date of R & I & fee | Dy No. 3520;25-01-2019; Rs.20,000/- |
| | Composition | Each Capsule Contains:<br>Pregabalin…….50mg |
| | Pharmacological Group | Anti-epileptic |
| | Type of Form | Form-5 |

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|---|---|---|
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 14's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Pregabalin 50mg Hard capsules Accord Healthcare Limited United Kingdom, Hungary. |
| | Me-too Status | Gabica 50mg Capsule of Getz Pharma |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Monograph for test/analysis of Applied formulation is not present in USP. |
| | **Decision: Approved with innovator's specification.** | |
| 777. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAFLAM 75mg SR Capsule |
| | Diary No. Date of R & I & fee | Dy No. 3517;25-01-2019; Rs.20,000/- |
| | Composition | Each Capsule Contains:<br>Diclofenac sodium…….75mg<br>(as sustained release pellets)<br>Source of pellets: M/s Vision Phrma Islamabad. |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 20's: As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Diclomax SR Capsules 75mg;United Kingdom, Itlay (as provided by the firm) |
| | Me-too Status | Dicloyan-S Roryan Pharmaceutical Industries (Pvt) Ltd Pakistan. |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting** | |
| 778. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name + Dosage Form + Strength | ZAFLAM RETARD 100mg Capsule |
| | Diary No. Date of R & I & fee | Dy No. 3511;25-01-2019; Rs.20,000/- |
| | Composition | Each Capsule Contains:<br>Diclofenac sodium …….100mg<br>(as sustained release pellets)<br>Source of pellets: M/s Vision Phrma Islamabad. |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 20's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Diclomax Retard Capsules 100mg;United Kingdom, Itlay (as provided by the firm) |
| | Me-too Status | Dicloyan-S Roryan Pharmaceutical Industries (Pvt) Ltd Pakistan. |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting** | |
| 779. | Name and address of manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | MYCIN Capsule 500mg |
| | Diary No. Date of R& I & fee | Dy No. 3549;25-01-2019; Rs.20,000/- |

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|---|---|---|
| | Composition | Each Hard Capsule contains:<br>Fosfomycin calcium.....500mg |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Ph,Eur |
| | Pack size & Demanded Price | 10's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in Spain<br>FOSFOSINA 500mg Hard capsules; SPAIN |
| | Me-too status | Osfocin Capsule 500mg of Krka Pak, Karachi |
| | GMP status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable. |
| | **Decision: Deferred for evidence of approval of applied formulation i.e. Fosfomycin calcium 500mg capsule in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.** | |
| 780. | Name and address of manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | ZAMITRA Capsule 100mg |
| | Diary No. Date of R& I & fee | Dy No. 3516;25-01-2019; Rs.20,000/- |
| | Composition | Each capsule contains:<br>Itraconazole.....100mg<br>(Immediate ReleasePellets)<br>Source of pellets: M/s Vision Pharma Islamabad. |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 4's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Traconol Capsule 100mg of Fozan Pharmaceuticals |
| | GMP status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 781. | Name and address of manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | ZITHRO Capsule 250mg |
| | Composition | Each Hard Capsule contains:<br>Azithromycin (as dihydrate).....250mg |
| | Diary No. Date of R& I & fee | Dy No. 3527;25-01-2019; Rs.20,000/- |
| | Pharmacological Group | Antibiotic(Macrolide) |
| | Type of Form | Farm 5 |
| | Finished product Specification | USP Specifications |
| | Pack size & Demanded Price | 10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Azomaxof Novartis Pharma |
| | GMP status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |
| 782. | Name and address of manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name +Dosage Form + Strength | ZAMCON Capsule 150mg |
| | Composition | Each Hard Capsule contains:<br>Fluconazole.....150mg |
| | Diary No. Date of R& I & fee | Dy No. 3530;25-01-2019; Rs.20,000/- |
| | Pharmacological Group | Antifungal |

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|---|---|---|
| | Type of Form | Farm 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1's : as per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Trac Capsules 150mg of Fozan Pharmaceuticals |
| | GMP status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator | |
| | **Decision: Approved with BP specifications.** | |
| 783. | Name and Address of Manufacturer / Applicant | M/s Zamko Pharmaceuticals (Pvt.) Ltd.,<br>641-A Sundar Industrial Estate, Lahore. |
| | Brand Name+ Dosage Form + Strength | ZAMPRID OD Capsule 150 mg |
| | Diary No. Date of R & I & fee | Each Hard Capsule Contains:<br>Itopride Hydrochloride …150mg<br>(sustained release pellets)<br>Source of pellets: M/s Vision Pharma Islamabad. |
| | Composition | Dy. No. 3547;25-01-2019; Rs.20,000/- |
| | Pharmacological Group | Prokinetic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's specifications |
| | Pack Size & Demanded Price | 14's, 30's; as per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Ganaton OD of M/s Abbott Laboratories (PMDA) India Approved |
| | Me-too Status | NOGERD by Helix Pharma(Reg#067043) |
| | GMP Status | Letter Issuance Date : 8th January, 2019 |
| | Remarks of the Evaluator. | Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting as provided evidence is of India which is not one among the reference agencies. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |

## b. New/Additional section(s)

**Evaluator PEC-III**

**Case no. 01 M/s Caliph Pharma, Risalpur**

Firm was granted 2 new / additional sections vide letter by secretary Licensing Board through letter No. F.3-6/2005-Lic (Vol-I) dated 17-01-2019. According to the letter CLB in its 267th meeting has approved following sections, for which the firm has applied for products as under:

| Section | No. of molecules applied | No. of products applied |
|---|---|---|
| Cream/ointment/Lotion section (General) | 10 | 18 |
| Sachet Section (General) | 10 | 11 |

| | | |
|---|---|---|
| **Cream/ointment/Lotion section (General): Molecules-10/ Products-18** | | |
| 784. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Ketocal 2% w/w Lotion |
| | Composition | Each Gram of Lotion Contains:<br>Ketoconazole…20mg (2% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4374 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Antifungals for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Dandrazol 2% w/w topical solution by Transdermal (**MHRA** Approved) |
| | Me-too status | Ketonaz lotion by Sante (Reg#073453) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |

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| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 785. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Ketocal 2% w/w Cream |
| | Composition | Each Gram Contains:<br>Ketoconazole…20mg (2% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 5093 dated 06-02-2019 Rs.20,000/- 04-02-2019 |
| | Pharmacological Group | Antifungals for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Nizoral 2% w/w cream by Janssen<br>(**MHRA** Approved) |
| | Me-too status | Ketoval cream by Valor Pharma (Reg#027868) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 786. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Tacrocal 0.1% w/w Ointment |
| | Composition | Each Gram Contains:<br>Tacrolimus as Monohydrate…….....1mg (0.1% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4376 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Agents for dermatitis, excluding corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Protopic 0.1% w/w ointment by LEO Pharma<br>(**MHRA** Approved) |
| | Me-too status | Eczemus 0.1% ointment by Brookes (Reg#045493) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 787. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Tacrocal 0.03% w/w Ointment |
| | Composition | Each Gram Contains:<br>Tacrolimus as Monohydrate…0.3mg (0.03% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4377 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Agents for dermatitis, excluding corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Protopic 0.03% w/w ointment by LEO Pharma<br>(**MHRA** Approved) |
| | Me-too status | Eczemus 0.03% ointment by Brookes (Reg#045494) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.**<br>**Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.** | |

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| 788. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Minoxical 5% w/v Lotion |
| | Composition | Each ml of lotion Contains:<br>Minoxidil…50mg (5% w/v) |
| | Diary No. Date of R& I & fee | Dy.No 4373 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Other dermatologicals |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Regaine for men extra strength 5% w/v topical solution by McNeil (**MHRA** Approved) |
| | Me-too status | Minoxin Plus lotion by Brookes Pharma (Reg#034492) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 789. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Clobetacal Ointment 0.05% w/w |
| | Composition | Each Gram Contains:<br>Clobetasol Propionate…0.5mg (0.05% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4366 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ClobaDerm 500mcg/g ointment by Auden (**MHRA** Approved) |
| | Me-too status | Cobi-scot ointment by Scotmann (Reg#037761) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved** | |
| 790. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Clobetacal 0.05% w/w Cream |
| | Composition | Each Gram Contains:<br>Clobetasol Propionate…0.5mg (0.05% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4367 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ClobaDerm 500mcg/g cream by Auden (**MHRA** Approved) |
| | Me-too status | Dermit Cream 0.05% w/w by Fynk Pharma (Reg#080078) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 791. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Mometacal 0.1% w/w Ointment |
| | Composition | Each Gram Contains:<br>Mometasone Furoate…1mg (0.1% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4371 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Corticosteroids |

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| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Elocon 0.1% w/w ointment by Merck (**MHRA** Approved) |
| | Me-too status | Momate 0.1% ointment by Maxitech (Reg#083745) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved.** | |
| 792. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Mometacal 0.1% w/w Lotion |
| | Composition | Each Gram of lotion Contains:<br>Mometasone Furoate…1mg (0.1% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4370 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Elocon 0.1% w/w scalp lotion by Merck (**MHRA** Approved) |
| | Me-too status | Momate 0.1% lotion by Maxitech (Reg# 083744) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 793. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Nixcal 5% w/w Lotion |
| | Composition | Each Gram of lotion Contains:<br>Permethrin…50mg (5% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 4372 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Scabicides |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Permethrin lotion 5% w/w by GSK (**MHRA** Approved) |
| | Me-too status | Nedax plus lotion by Stiefel (Reg#037852) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 794. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Nixcal 5% w/w Cream |
| | Composition | Each Gram Contains:<br>Permethrin…50mg (5% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 5092 dated 06-02-2019 Rs.20,000/- 04-02-2019 |
| | Pharmacological Group | Scabicides |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Permethrin 5% w/w cream by Sandoz (**MHRA** Approved) |
| | Me-too status | Lotrix cream by GSK (Reg#010516) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended |

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| | | renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 795. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Clindacal 1% w/v Lotion |
| | Composition | Each ml Contains:<br>Clindamycin as Phosphate…10mg (1% w/v) |
| | Diary No. Date of R& I & fee | Dy.No 4375 dated 31-01-2019<br>Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Anti-infectives for treatment of acne |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Dalacin T 1%w/v Topical solution by Pfizer<br>(**MHRA** Approved) |
| | Me-too status | Dalacin T lotion by Pfizer (Reg#013582) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 796. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Clindacal 2% w/w Vaginal Cream |
| | Composition | Each Gram Contains:<br>Clindamycin as Phosphate…20mg (2% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 5091 dated 06-02-2019 Rs.20,000/- 04-02-2019 |
| | Pharmacological Group | Gynaecological anti-infectives and antiseptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Dalacin Cream 2% w/w by Pfizer<br>(**MHRA** Approved) |
| | Me-too status | Dalacin V cream by Pfizer (Reg#018574) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 797. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Diprocal-G Cream |
| | Composition | Each Gram Contains:<br>Betamethasone as Dipropionate…0.5mg (0.05%w/w)<br>Gentamicin as sulphate…1mg (0.1%w/w) |
| | Diary No. Date of R& I & fee | Dy.No 5094 dated 06-02-2019<br>Rs.20,000/- Dated 04-02-2019 |
| | Pharmacological Group | Topical glucocorticoid along with aminoglycoside antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Diprogenta cream by MSD<br>(**Germany** Approved) |
| | Me-too status | Effigenta Cream by Mass Pharma (Reg#024375) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |

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|---|---|---|
| 798. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Diprocal-G Ointment |
| | Composition | Each Gram Contains:<br>Betamethasone as Dipropionate…0.5mg (0.05% w/w)<br>Gentamicin as sulphate…1mg (0.1% w/w) |
| | Diary No. Date of R& I & fee | Dy.No 5097 dated 06-02-2019 Rs.20,000/- 04-02-2019 |
| | Pharmacological Group | Topical glucocorticoid along with aminoglycoside antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Diprogenta Ointment by MSD<br>(**Germany** Approved) |
| | Me-too status | Effigenta ointment by Mass Pharma (Reg# 024376) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 799. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Diprocal-S Ointment |
| | Composition | Each Gram Cont ains:<br>Betamethasone as Dipropionate…0.5mg<br>Salicyclic Acid…30mg |
| | Diary No. Date of R& I & fee | Dy.No 5095 dated 06-02-2019 Rs.20,000/- 04-02-2019 |
| | Pharmacological Group | Corticosteroids combination with analgesic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Diprosalic 0.05% w/w / 3%w/w ointment by Merck<br>(**MHRA** Approved) |
| | Me-too status | Provate-S ointment by Reko Pharma (Reg#027190) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 800. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Diprocal-S Lotion 0.05% w/w / 2%w/w |
| | Composition | Each Gram of lotion Contains:<br>Betamethasone as Dipropionate…0.5mg<br>Salicyclic Acid…20mg |
| | Diary No. Date of R& I & fee | Dy.No 5096 dated 06-02-2019 Rs.20,000/- 04-02-2019 |
| | Pharmacological Group | Corticosteroids combination with analgesic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Diprosalic Scalp application 0.05%w/w / 2%w/w cutaneous solution by Merck UK (**MHRA** Approved) |
| | Me-too status | Provate-S Lotion by Saffron (Reg# 060354) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 801. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Daktacal Cream 2% w/w / 1% w/w |

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|---|---|---|
| | Composition | Each Gram Contains:<br>Miconazole Nitrate…20mg<br>Hydrocortisone (as Acetate)…10mg |
| | Diary No. Date of R& I & fee | Dy.No 5098 dated 06-02-2019 Rs.20,000/- 04-02-201 |
| | Pharmacological Group | Antifungals for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Daktacort hydrocortisone cream (2%w/w / 1%w/w) by McNeil Products (**MHRA** Approved) |
| | Me-too status | Albicost cream by Shrooq Pharma (Reg# 040842) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| **Sachet Section (General):<br>Molecules-10/ Products-11** | | |
| 802. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Zegecal 20/1680 mg Sachet |
| | Composition | Each Sachet Contains:<br>Omeprazole…20mg<br>Sodium Bicarbonate…1680mg |
| | Diary No. Date of R& I & fee | Dy.No 4379 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Proton Pump Inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zegerid Powder for oral suspension by Santaurus (**USFDA** Approved) |
| | Me-too status | Risek Insta Sachet by Getz |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 803. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Zegecal 40/1680 mg Sachet |
| | Composition | Each Sachet Contains:<br>Omeprazole…40mg<br>Sodium Bicarbonate…1680mg |
| | Diary No. Date of R& I & fee | Dy.No 4380 (31-01-2019) Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Proton Pump Inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zegerid Powder for oral suspension by Santaurus (**USFDA** Approved) |
| | Me-too status | Risek Insta Sachet by Getz |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 804. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Mucocal 200mg Sachet |
| | Composition | Each Sachet Contains:<br>Acetylcysteine…200mg |

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| | Diary No. Date of R& I & fee | Dy.No 4381 (31-01-2019) Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Mucolytics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Acetylcysteine 200mg powder for oral solution by Colonis (**MHRA** Approved) |
| | Me-too status | Mucolator 200mg Sachet by Abbott (Reg#017693) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 805. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Electrocal Sachet |
| | Composition | Each Sachet Contains:<br>Pre-Cooked Rice Powder…6gm<br>Sodium Citrate…0.580gm<br>Sodium Chloride…0.350gm<br>Potassium Chloride…0.300gm |
| | Diary No. Date of R& I & fee | Dy.No 4378 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Electrolytes with carbohydrates |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Dioralyte Relief Blackcurrant Sachets by Sanofi Aventis (**MHRA** Approved) |
| | Me-too status | Peditral-R Sachet by Searle (Reg#076282) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 806. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Hepa-Cal 3gm Sachet |
| | Composition | Each Sachet Contains:<br>L-Ornithine L-Aspartate…3gm |
| | Diary No. Date of R& I & fee | Dy.No 4386 dated 31-01-2019<br>Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Hepato-protective |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Hepa-Merz 3g granules by Merz Pharma<br>(**AGES Austria** Approved) |
| | Me-too status | Couthy 3gm sachet by Martin Dow (Reg#070474) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 807. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Stroncal 2g Sachet |
| | Composition | Each Sachet Contains:<br>Strontium Ranelate…2g |
| | Diary No. Date of R& I & fee | Dy.No 4383 dated 31-01-2019<br>Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Other drugs affecting bone structure and mineralization |

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| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Strontium ranelate Aristo 2g granules for oral suspension by Aristo (**MHRA** Approved) |
| | Me-too status | Onita Sachet 2g by PharmEvo (Reg#057746) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 808. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Ibucal 600mg Sachet |
| | Composition | Each Sachet Contains:<br>Ibuprofen…600mg |
| | Diary No. Date of R& I & fee | Dy.No 4388 dated 31-01-2019<br>Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Brufen granules by Mylan<br>(**MHRA** Approved) |
| | Me-too status | Hibufen 600mg Sachet by Hiranis (Reg#081554) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 809. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Montecal 4mg Sachet |
| | Composition | Each Sachet Contains:<br>Montelukast as Sodium…4mg |
| | Diary No. Date of R& I & fee | Dy.No 4384 dated 31-01-2019<br>Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Leukotriene receptor antagonists |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Singulair pediatric 4mg granules by Merck<br>(**MHRA** Approved) |
| | Me-too status | Singulair 4mg oral granules by Merck (Reg#031377) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision:Approved** | |
| 810. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Mebecal 135mg/3.5g Sachet |
| | Composition | Each Sachet Contains:<br>Mebeverine hydrochloride…135mg<br>Ispaghula Husk…3.5g |
| | Diary No. Date of R& I & fee | Dy.No 4382 dated 31-01-2019 Rs.20,000/- 30-01-2019 |
| | Pharmacological Group | Antispasmodic / laxative |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference | Fybogel Mebeverine granules for oral suspension in unit |

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| | Regulatory Authorities. | sachet by Reckitt Benckiser (**MHRA** Approved) |
| | Me-too status | Mebipas sachet by Hilton Pharma (Reg#066844) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 811. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Macrocal Sachet |
| | Composition | Each Sachet Contains:<br>Macrogol 3350…13.125g<br>Sodium Chloride…0.3507<br>Potassium Chloride…0.0466g<br>Sodium Bicarbonate…0.1785g |
| | Diary No. Date of R& I & fee | Dy.No 4387 dated 31-01-2019<br>Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Osmotically active laxative |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MOVICOL 13.8g sachet, powder for oral solution by Norgine Ltd. (**MHRA** Approved) |
| | Me-too status | Marfinal Sachet 13.8gm by Martin Dow (Reg#080647) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |
| 812. | Name and address of manufacturer / Applicant | M/s Caliph Pharmaceuticals Pvt Ltd. Plot # 17, Special Industrial Zone, Risalpur, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Fosfocal 3g Sachet |
| | Composition | Each Sachet Contains:<br>Fosfomycin as Trometamol…3g |
| | Diary No. Date of R& I & fee | Dy.No 4385 dated 31-01-2019<br>Rs.20,000/- Dated 30-01-2019 |
| | Pharmacological Group | Other antibacterials |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator's specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Monuril 3g granules for oral solution by Zambon (**MHRA** Approved) |
| | Me-too status | Uronol sachet 3g by Faas Pharma (Reg#083971) |
| | GMP status | Panel inspection report dated 6-11-2018 recommended renewal of DML and grant of 2 additional sections. |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-IV**

**Case no. 02 M/s Berlex Lab International 10-Km Nagshah chowk, Karachi road Multan**

Central Licensing Board in its 265th meeting held on 09th & 10th august, 2018 has considered and approved the various sections including "**Injectable (General) section (SVP)"** and accordingly secretary CLB has issued letter for "Grant of Additional Section" dated 04-09-2018.

| **Injectable (General) section (SVP)<br>16 Products/ 10 Molecules** | | |
|---|---|---|
| 813. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Amkan 100mg/2ml Injection |
| | Composition | Each Ampoule Contains:<br>Amikacin as Sulphate……100mg/2ml |

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|---|---|---|
| | Diary No. Date of R& I & fee | Dy.No;37855 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's x 2ml;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Amikin Injection Of MHRA Approved |
| | Me-too status (with strength and dosage form) | Nekrocin 100 Injection of M/s Safe Pharmaceuticals, |
| | GMP status | GMP & grant license inspection report conducted on 05-7-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 814. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Amkan 250mg/2ml Injection |
| | Composition | Each Ampoule Contains:<br>Amikacin as Sulphate…….…250mg/2ml |
| | Diary No. Date of R& I & fee | Dy.No;37856 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's x 2ml;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Briklin 250mg/2ml by EMA |
| | Me-too status (with strength and dosage form) | Aminocin 250mg Injection of M/s Macquins International, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 815. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Amkan 500mg/2ml Injection |
| | Composition | Each Ampoule Contains:<br>Amikacin as Sulphate…….…500mg/2ml |
| | Diary No. Date of R& I & fee | Dy.No;37857 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's x 2ml;As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Amikacin Injection Of USFDA Approved |
| | Me-too status (with strength and dosage form) | Dunkin 500mg Injection of M/s Amros Karachi . |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 816. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Cobalim 500mcg/ml Injection |
| | Composition | Each Ampoule Contains:<br>Mecobalamin…….…500mcg |
| | Diary No. Date of R& I & fee | Dy.No;42689 13-12-2018 Rs. 20,000-(13-12-2018) |
| | Pharmacological Group | Co-enzyme-type vitamin B12 |
| | Type of Form | Form 5 |

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| | Finished product Specifications | Manufacture's specification |
| | Pack size & Demanded Price | 1ml x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | PMDA approved |
| | Me-too status (with strength and dosage form) | Wycomin 500 mcg Injection by Wnsfeild Pharmaceutical, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |
| 817. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Xofer 100mg/5ml Injection |
| | Composition | Each 5ml Ampoule Contains:<br>Iron sucrose compex eq to elemental Iron……..…100mg |
| | Diary No. Date of R& I & fee | Dy.No;42690 13-12-2018 Rs. 20,000-(13-12-2018) |
| | Pharmacological Group | Iron replacement product |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 5ml x 5's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Venofer 100mg/5ml Injection of MHRA approved |
| | Me-too status (with strength and dosage form) | Bisleri 100mg/5ml Injection of M/S Sami Pharma |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 818. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Xocol 500mg/4ml Injection |
| | Composition | Each 4ml Ampoule Contains:<br>Citicoline (as sodium)……..…500mg |
| | Diary No. Date of R& I & fee | Dy.No;37854 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Psychostimulants, Agents Used For ADHD And Nootropics (Other psychostimulants and nootropics) |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturers specification |
| | Pack size & Demanded Price | 4ml x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | ITICOLINE PANPHARMA 500 mg/ 4ml, solution injectable (IM,IV) ampoule by M/s PANPHARMA (ANSM, France Approved) |
| | Me-too status (with strength and dosage form) | SOMAZINA INJECTION 500mg/4ml by Alina pharma (Reg.No. 016975) |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |
| 819. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Xocol 250mg/2ml Injection |
| | Composition | Each 2ml Ampoule Contains:<br>Citicoline (as sodium)……..…250mg |
| | Diary No. Date of R& I & fee | Dy.No;37853 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Psychostimulants, Agents Used For ADHD And Nootropics (Other psychostimulants and nootropics) |
| | Type of Form | Form 5 |

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| | Finished product Specifications | Manufacturers specification |
| | Pack size & Demanded Price | 2ml x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | ITICOLINE PANPHARMA 500 mg/ 4ml, solution injectable (IM,IV) ampoule by M/s PANPHARMA (ANSM, France Approved) |
| | Me-too status (with strength and dosage form) | Neurotec Injection. 250mg/2ml by M/s Schazoo Laboratories, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |
| 820. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Tritamol 100mg/2ml Injection |
| | Composition | Each 2ml Ampoule Contains:<br>Tramadol HCl……250mg |
| | Diary No. Date of R& I & fee | Dy.No;37846 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2ml x 5's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Zydol Injection of MHRA approved |
| | Me-too status (with strength and dosage form) | Tramed 100mg Injection by M/s Cirin Pharmaceuticals,, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| 821. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Ketarax 10mg/ml Injection |
| | Composition | Each Ampoule Contains:<br>Ketorolac Tromethamine……10mg |
| | Diary No. Date of R& I & fee | Dy.No;42691 13-12-2018 Rs. 20,000-(13-12-2018) |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1ml x 5's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Toradol 10mg/ml of TGA approved |
| | Me-too status (with strength and dosage form) | Ketopan Injection 30mg by M/s Welwrd Pharmaceuticals, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 822. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Ketarax 30mg/ml Injection |
| | Composition | Each Ampoule Contains:<br>Ketorolac Tromethamine……30mg |
| | Diary No. Date of R& I & fee | Dy.No;42692 13-12-2018 Rs. 20,000-(13-12-2018) |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1ml x 5's ; As per SRO |

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|---|---|---|
| | Approval status of product in Reference Regulatory Authorities | Toradol 30mg/ml of TGA approved |
| | Me-too status (with strength and dosage form) | Ketopan Injection 30mg by M/s Welwrd Pharmaceuticals, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 823. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Ketam 500mg/10ml Injection |
| | Composition | Each Ampoule Contains:<br>Ketamine (as HCl)……..…500mg/10ml |
| | Diary No. Date of R& I & fee | Dy.No;37852 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | General Anesthesia |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 10ml x 1's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ketalar 50 Mg/Ml Injection, of MHRA approved |
| | Me-too status (with strength and dosage form) | Misket 50mg/ml Injection by M/s Mission |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 824. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Ketam 100mg/2ml Injection |
| | Composition | Each Ampoule Contains:<br>Ketamine (as HCl)……..…100mg/2ml |
| | Diary No. Date of R& I & fee | Dy.No;37851 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | General Anesthesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 2ml x 5's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Ketalar 50 Mg/Ml Injection, of MHRA approved |
| | Me-too status (with strength and dosage form) | Misket 50mg/ml Injection by M/s Mission |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision: Deferred for evidence of approval of applied fill volume i.e Ketamine (as hydrochloride) 100mg/2ml in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 825. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Diclotal 2ml Injection |
| | Composition | Each Ampoule Contains:<br>Diclofenac sodium……..…75mg<br>Lidocaine HCl…….20mg |
| | Diary No. Date of R& I & fee | Dy.No;42693 13-12-2018 Rs. 20,000-(13-12-2018) |
| | Pharmacological Group | NSAID & Local Anesthesia |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturers specification |
| | Pack size & Demanded Price | 2ml x 10's ; As per SRO |
| | Approval status of product in | Diclofenac-Mepha 75 ampoules, of Mepha pharma AG |

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|---|---|---|
| | Reference Regulatory Authorities | approved by switerzerland |
| | Me-too status (with strength and dosage form) | Difam Plus Injection by M/s Bosch |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification for IM route only.** | |
| 826. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Xovit 5mg/ml Injection |
| | Composition | Each ml Contains: Cholecalciferol……..…5mg |
| | Diary No. Date of R& I & fee | Dy.No;37834 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Vitamin D analogue |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1ml x 1's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Vitamin D3 Good 5mg/ 1 ml IM solution for injection of ( ANSM France approved) |
| | Me-too status (with strength and dosage form) | Calciferol Injection M/s Global Pharmaceuticals, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision:Approved** | |
| 827. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Xalbuphine 10mg/ml Injection |
| | Composition | Each ml Ampoule Contains: Nalbuphine hydrochloride…….10mg |
| | Diary No. Date of R& I & fee | Dy.No;37847 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Opioid Analgesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 1ml x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Nubain Injection 10mg/ml of Health Canada approved |
| | Me-too status (with strength and dosage form) | Nalfy Injection 10mg by M/s. Vision Pharmaceuticals, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |
| 828. | Name and address of manufacturer / Applicant | M/s Berlex Lab International 10-Km Nagshah chowk Karachi road Multan |
| | Brand Name +Dosage Form + Strength | Xalbuphine 20mg/ml Injection |
| | Composition | Each ml Ampoule Contains: Nalbuphine hydrochloride…….20mg |
| | Diary No. Date of R& I & fee | Dy.No;37848 15-11-2018 Rs. 20,000-(15-11-2018) |
| | Pharmacological Group | Opioid Analgesic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 1ml x 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Nubain Injection 20mg/ml of Health Canada approved |
| | Me-too status (with strength and dosage form) | Nalfy Injection 20mg by M/s. Vision Pharmaceuticals, |
| | GMP status | GMP & grant license inspection report conducted on 05-07-2018 |

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| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification** | |

**Evaluator PEC-XII**

**Case no. 03 M/s Rotex Pharma (Pvt) Ltd, Islamabad. (New Section)**

The Central Licensing Board in its 266th meeting held on 24th Oct, 2018 has considered and approved the grant of 15 additional section of firm M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad (DML:000651) as under:-

| Sr. No | Section | No. of molecules | No. of products |
|---|---|---|---|
| 1 | Cream/ ointment (General) | 10 | 11 |
| 2 | Topical (Steroid section) | 09 | 10 |
| 3 | Oral Dry Suspension (General) | 10 | 12 |

| | | |
|---|---|---|
| | **Cream/ ointment (General)<br>11 Products/ 10 Molecule** | |
| 829. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Racto 0.03%w/w Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41127 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each Gram Contains:<br>Tacrolimus (as monohydrate)…0.3mg (0.03%w/w) |
| | Pharmacological Group | Agent for dermatitis excluding corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 10g , 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | PROTOPIC (tacrolimus) Ointment 0.03%w/w by M/s LEO PHARMA AS (USFDA Approved) |
| | Me-too Status | Prolimus ointment 0.03% of M/s Kaizen Pharma (Reg.#073752) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.<br>Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.** | |
| 830. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Racto 0.1%w/w Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41129 (06-12-2018) Rs.20,000/- 06-12-2018 |
| | Composition | Each Gram Contains:<br>Tacrolimus (as monohydrate)…1mg (0.1%w/w) |
| | Pharmacological Group | Agent for dermatitis excluding corticosteroids |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 10g , 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | PROTOPIC (tacrolimus) Ointment 0.1%w/w by M/s LEO PHARMA AS (USFDA Approved) |
| | Me-too Status | Aimus ointment of M/s Aims Pharmaceuticals (Reg.#069939) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.<br>Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.** | |

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| 831. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Rocim 2%w/w Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41133 (06-12-2018) Rs.20,000/- (06-12-2018) |
| | Composition | Each gram contains:<br>Mupirocin …20mg (2%w/w) |
| | Pharmacological Group | Other antibiotics for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 5g, 10g,15g, 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Bactroban 2% Ointment by M/s GlaxoSmithKline (MHRA Approved) |
| | Me-too Status | Bactroban 2% Ointment by M/s GlaxoSmithKline (Reg#010399) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 832. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Reson 0.05% Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41544 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each Gram Contains:<br>Isotretinoin…0.5mg (0.05%w/w) |
| | Pharmacological Group | Retinoids for treatment of acne |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 10g / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Isotrex 0.05% Cream by GSK<br>(MHRA Approved) |
| | Me-too Status | Acnecid Cream by M/s Reko Pharmacal (Reg.#024688) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 833. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Citex 0.005% Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41549 (07-12-2018) Rs.20,000/- (07-12-2018) |
| | Composition | Each Gram Contains:<br>Calcipotriol (as monohydrate) …0.05mg (0.005%w/w) |
| | Pharmacological Group | Other antipsoriatics for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Calcipotriol Cream 50 micrograms/g by M/s Sandoz Limited (MHRA Approved) |
| | Me-too Status | Calcipot Cream 0.005% by M/s Valor Pharmaceuticals (Reg#069823) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 834. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | C-Zole-V 1%w/w Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41534 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |

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|---|---|---|
| | Composition | Each gm of cream contains:<br>Clotrimazole ……..10mg (1% w/w) |
| | Pharmacological Group | Azole Antifungal |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10g,15g, 20g, 35g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Clotrimazole 1% w/w Cream by M/s Teva UK Limited (MHRA approved) |
| | Me-too Status | Dermofit 1% Cream by M/s Baxter (Reg#073438) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 835. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Flor-H 13.9%w/w Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41539 (07-12-2018) Rs.20,000/- (07-12-2018) |
| | Composition | Each Gram Contains:<br>Eflornithine hydrochloride (as monohydrate)…139mg (13.9%w/w) |
| | Pharmacological Group | Other agents against leishmaniasis and trypanosomiasis |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 15g, 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | VANIQA (eflornithine hydrochloride) Cream, 13.9% by M/s Bristol-Myers Squibb Company (USFDA Approved) |
| | Me-too Status | Vaniflor Cream 13.9% by M/s Highnoon (Reg.#071575) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 836. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Plane 0.1%w/w Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41542 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each Gram Contains:<br>Adapalene…1mg (0.1%w/w) |
| | Pharmacological Group | Retinoids for topical use in acne |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 15g, 45g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Differin 0.1% w/w Cream by M/s Galderma (UK) Limited (MHRA Approved) |
| | Me-too Status | Elucider Cream 0.1% by M/s Hoover Pharmaceuticals (Reg.#062458) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 837. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Terfugal 1%w/w Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41545 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each Gram Contains:<br>Terbinafine hydrochloride…10mg (1%w/w) |
| | Pharmacological Group | Other antifungals for topical use |

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|---|---|---|
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack Size & Demanded Price | 10g,15g, 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | LAMISIL 1% w/w Cream by M/s GlaxoSmithKline Consumer Healthcare (UK) Trading Limited (MHRA Approved) |
| | Me-too Status | Lamisil Cream 1% by M/s Sandoz (Reg.#) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 838. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Fast 2% Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41110 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each Gram Contains:<br>Fusidic Acid…20mg (2%w/w) |
| | Pharmacological Group | Other antibiotics for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 5g,15g / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fucidin 20 mg/g Cream by M/s LEO Laboratories Limited (MHRA Approved) |
| | Me-too Status | FUCIDIN CREAM by M/s Leo (Reg.#015539) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 839. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Citop 0.005% Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41111 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each Gram Contains:<br>Calcipotriol …0.05mg (0.005%w/w) |
| | Pharmacological Group | Other antipsoriatics for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Dovonex Ointment by M/s LEO Laboratories Ltd (MHRA Approved) |
| | Me-too Status | DAIVONEX OINTMENT 0.005% by M/s ZAM ZAM CORP (Reg#015726) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **Topical (Steroid section)<br>10 Products/ 9 Molecules** | | |
| 840. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Flunone Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41067 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each gram contains:<br>Fluocinolone acetonide…0.1mg (0.01%w/w)<br>Hydroquinone…40mg (4%w/w) |

| | | |
|---|---|---|
| | | Tretinoin…0.5mg (0.05%w/w) |
| | Pharmacological Group | Corticosteroid+ melanin synthesis inhibitor+retinoid |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 10g,15g, 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | TRI-LUMA Cream 0.01%/4%/0.05% by M/s GALDERMA laboratories, L.P (USFDA Approved) |
| | Me-too Status | Trimelasin Cream by M/s Valor Pharmaceuticals (Reg#031104) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 841. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Betacal Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41130 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each gram contains:<br>Calcipotriol (as monohydrate) …0.05mg (0.005%w/w)<br>Betamethasone (as dipropionate)…0.5mg (0.05%w/w) |
| | Pharmacological Group | Anti-psoriatic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 15g, 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Dalbecal 50 microgram/ g + 0.5 mg/ g Ointment by M/s Teva UK Limited (MHRA Approved) |
| | Me-too Status | Daivobet Ointment by M/s Zam Zam corporation (Reg # 031379) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 842. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Fubasome Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41116 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each Gram Contains:<br>Fusidic Acid…20mg (2%w/w)<br>Betamethasone (as valerate) …1mg (0.1%w/w) |
| | Pharmacological Group | Corticosteroids, potent, combinations with antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 5g, 10g,15g,/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream by M/s Goapharma (MHRA Approved) |
| | Me-too Status | Fucicort Leo Cream by M/s Leo Pharma (Reg.#012803) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 843. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Presol 0.1%w/w Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41551 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each Gram Contains:<br>Methylprednisolone aceponate…1mg |

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|---|---|---|
| | Pharmacological Group | Corticosteroids, potent (group III) |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 5g, 10g / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | ADVANTAN methylprednisolone aceponate 1mg/g cream by M/s Bayer Australia Ltd (TGA Approved) |
| | Me-too Status | Advantan 0.1% w/w cream by M/s Bayer Health Care (Reg#018644) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 844. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Beta-One Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41543 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each Gram Contains:<br>Betamethasone (as dipropionate) …0.5mg (0.05%w/w)<br>Clotrimazole…10mg (1%w/w) |
| | Pharmacological Group | Corticosteroids and antiinfectives in combination |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10g, 15g, 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Lotriderm Cream by M/s Expono Ltd (MHRA Approved) |
| | Me-too Status | Lotriderm -B Cream by M/s Hoover Pharmaceuticals (Reg.#064534) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 845. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Beta-Gen Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41535 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each Gram Contains:<br>Betamethasone (as dipropionate)…0.5mg (0.05%w/w)<br>Gentamicin (as sulphate) …1mg (0.1%w/w) |
| | Pharmacological Group | Corticosteroids and antiinfectives in combination |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 5g, 10g,15g,/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Diprogenta Cream by Beragena Arzneimittel GmbH (Germany Approved) |
| | Me-too Status | Effigenta Cream by Mass Pharma (Reg.#024375) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 846. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Hydrozole 1% Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41536 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |

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|---|---|---|
| | Composition | Each gram contains:<br>Clotrimazole…10mg (1% w/w)<br>Hydrocortisone (as acetate)… 10mg (1% w/w) |
| | Pharmacological Group | Corticosteroids and antiinfectives in combination |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 10g, 20g / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Canesten HC Cream by M/s Bayer plc (MHRA Approved) |
| | Me-too Status | Hydrozole Cream by M/s Stiefel Laboratories Pakistan (Pvt) Ltd (Reg#029329) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with change of brand name** | |
| 847. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Beta-Gen Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41540 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each gram contains:<br>Betamethasone (as dipropionate)…..0.5mg (0.05% w/w)<br>Gentamicin (as sulphate)……..1mg (0.1% w/w) |
| | Pharmacological Group | Corticosteroids, potent, combinations with antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 5g, 10g,15g, 30g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Diprogenta Ointment by M/s MSD (Germany Approved) |
| | Me-too Status | Effigenta Ointment by M/s Mass Pharma (Reg.#024376) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 848. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Tesol 0.05%w/w Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41518 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 |
| | Composition | Each Gram Contains:<br>Clobetasol (as propionate) …0.5mg (0.05%w/w) |
| | Pharmacological Group | Corticosteroids, very potent (group IV) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 5g, 10g,15g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Clobetasol Propionate 0.05% w/w Ointment by M/s Accord Healthcare Limited (MHRA Approved) |
| | Me-too Status | Clobevate Ointment 0.05% by M/s Stiefel Laboratories (Re#029330) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 849. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Fudrosone Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41113 (06-12-2018) Rs.20,000/- 06-12-2018 |

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|---|---|---|
| | Composition | Each Gram Contains:<br>Fusidic Acid…20mg (2%w/w)<br>Hydrocortisone Acetate…10mg (1%w/w) |
| | Pharmacological Group | Corticosteroids, weak, combinations with antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 5g, 10g,15g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fucidin H Cream by M/s LEO Laboratories Limited (MHRA Approved) |
| | Me-too Status | Fucidin H Cream by M/s Leo Pharmaceutical Products (Reg.#023123) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| **Oral Dry Suspension (General)<br>12 Products/ 10 Molecules** | | |
| 850. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Texklar 125mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40133 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5 ml after reconstitution contains:<br>Clarithromycin (as EC taste masked granules 27.5%) ……125mg |
| | Pharmacological Group | Macrolide Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Biaxin granules for oral suspension 125mg/5ml by M/s Abbvie, (USFDA approved.) |
| | Me-too Status | Claritek Dry Suspension 125mg/5ml by M/s Getz Pharma (Reg#009846) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | • Source of pellets: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Approved** | |
| 851. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Fortycin 250mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40147 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5 ml after reconstitution contains:<br>Fosfomycin Calcium Eq. to Fosfomycin…250mg |
| | Pharmacological Group | Other antibacterials |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack Size & Demanded Price | 60ml/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | FOSFOCINA SUSPENSIÓN 250mg/ml by M/s Laboratorios ERN, S.A. (Approved by Spanish Agency of Medicines and Health Products) |
| | Me-too Status | Focin Suspension 250mg/5ml by M/s Tabros Pharma (Reg.#015946) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 852. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |

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| | Brand Name + Dosage Form + Strength | Volvic 40mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40130 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5 ml after reconstitution contains:-<br>Famotidine …40mg |
| | Pharmacological Group | Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) (H2-receptor antagonists) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Pepcid 40mg/5ml for oral suspension 40mg/5ml by M/s Salix Pharma, (USFDA Approved) |
| | Me-too Status | Zepcin Dry Suspension 40mg/5ml by M/s Cirin Pharmaceuticals (Reg#064330) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 853. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Fluzol 50mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40148 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5ml of reconstituted suspension contains:<br>Fluconazole…50mg |
| | Pharmacological Group | Anti-Fungal |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 35ml/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Diflucan 10 mg/ml powder for oral suspension by Pfizer Limited, (MHRA approved) |
| | Me-too Status | Zefung oral suspension, 50mg/5ml by M/s Nexus Pharma Karachi. (Reg# 081593) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 854. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Lemoxol 15/90 mg Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40217 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5ml of reconstituted suspension contains:<br>Artemether…15 mg<br>Lumefantrine…90 mg |
| | Pharmacological Group | Anti-Malarial |
| | Type of Form | Form 5 |
| | Finished Product Specification | International Pharmacopoeia specifications |
| | Pack Size & Demanded Price | 30ml, 60ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | WHO approved formulation |
| | Me-too Status | Artem plus dry suspension15mg+90mg/5ml by M/s Hilton Pharmaceuticals (Reg#055015) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

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| 855. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Scanlux 250mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40219 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5 ml after reconstitution contains:<br>Ciprofloxacin (taste Mask micro pellets 35%)…250mg |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml,60ml,100ml/ / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Ciproxin 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved. |
| | Me-too Status | Hiflox Dry suspension 250mg/5ml by M/s Hilton (Reg#067499 |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | • Source of granules: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Deferred for further deliberation upon the salt form of API, in view of reference product.** | |
| 856. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Oxazolid 100mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40139 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5ml of reconstituted suspension contains:<br>Linezolid…100mg |
| | Pharmacological Group | Anibacterial agent of Oxazolidinone class |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 60ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Linezolid 100 mg/5 ml granules for oral suspension by M/s Pfizer Limited, MHRA approved. |
| | Me-too Status | Barizold Dry Suspension100 mg/5 ml by M/s Barret Hodgson(Reg#076343) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 857. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Scanlux 125mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40137 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5 ml after reconstitution contains:<br>Ciprofloxacin (taste Mask micro pellets 35%)…125mg |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too Status | Hiflox Dry suspension 125mg/5ml by M/s Hilton (Reg#067498) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | • Source of granules: Vision Pharmaceuticals, Islamabad.<br>• Registration Board in its 269th meeting decided as follows: |

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| | | Keeping in view the following statement written in Qualitative and quantitative composition "2.5 mL suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age, Registration Board decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA. |
| | **Decision: Deferred for further deliberation upon the salt form of API, in view of reference product.** | |
| 858. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Vorit 200mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40165 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5ml reconstituted suspension contains:<br>Voriconazole…200mg |
| | Pharmacological Group | Triazole antifungal |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 60ml, 70ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | VFEND powder for suspension 200mg/5ml by M/s PF PRISM CV (USFDA Approved) |
| | Me-too Status | VORIF 200mg/5ml suspension by M/s Ferozsons Pharmaceuticals (Reg#073330) |
| | GMP Status | 19-09-2018; Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 859. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Texklar 250mg/5ml DS Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40143 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Composition | Each 5ml reconstituted suspension contains<br>Clarithromycin (as EC taste masked granules 27.5%)…125mg |
| | Pharmacological Group | Macrolide Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Biaxin granules for oral suspension 250mg/5ml by M/s Abbvie, (USFDA approved.) |
| | Me-too Status | Claritek Dry Suspension 250mg/5ml by M/s Getz Pharma (Reg#061347) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | • Source of pellets: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Approved** | |
| 860. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | ARY 200mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41063 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each 5ml reconstituted suspension contains:<br>Acyclovir…200mg |
| | Pharmacological Group | Antiviral |

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|---|---|---|
| | Type of Form | Form 5 |
| | Finished Product Specification | USP (oral suspension) |
| | Pack Size & Demanded Price | 60ml/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Zovirax Suspension 200mg/5ml by M/s Mylan Pharma Inc.(USFDA Approved) |
| | Me-too Status | Acylex Suspension 200mg/5ml by M/s Ferozsons Labs (Reg#012684) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | • Availability of applied formulation as Powder for suspension could not be confirmed from Reference Regulatory Authorities and available me too database |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 861. | Name and Address of Manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd., Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name + Dosage Form + Strength | Azi 200mg/5ml Dry Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 41055 dated 06-12-2018 Rs.20,000/- Dated 06-12-2018 |
| | Composition | Each 5ml reconstituted suspension contains<br>Azithromycin (as dihydrate) as taste masked pellets (35%)…200mg |
| | Pharmacological Group | Macrolide |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 15ml / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Zithromax Powder for Oral Suspension 200mg/5ml by M/s Pfizer Limited, (MHRA approved.) |
| | Me-too Status | Azoreg 200mg/5ml, by M/s Regal Pharmaceuticals Rawat (Reg.# 081982) |
| | GMP Status | 19-09-2018<br>Grant of Additional sections<br>Panel Recommended grant of additional sections |
| | Remarks of the Evaluator. | • Source of pellets: Vision Pharmaceuticals, Islamabad. |
| | **Decision: Deferred for confirmation from Licensing Division whether M/s Vision Pharmaceuticals, Islamabad is permitted to manufacture Azithromycin as taste masked pellets/granules.** | |

**Evaluator PEC-VI**

| **Liquid Ampoule SVP (General)<br>20 products/ 10 molecules** | | |
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| 862. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | AQUATEX Injection 5ml |
| | Diary No. Date of R& I & fee | DY No. 14224, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 5ml ampoule contains:<br>Water for injection….5ml |
| | Pharmacological Group | Diluent |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 5ml x 100Amp / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Sterile water for injection by M/s Pfizer Ltd (MHRA Approved) |
| | Me-too status | Aqua r ampoule by M/s Regal Pharmaceuticals (Reg.#082010) |

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| | GMP status | New Sections (Inspection Date: 19th Sep. 2018) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 863. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | AQUATEX Injection 10ml |
| | Diary No. Date of R& I & fee | DY No. 13892, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 10ml ampoule contains:<br>Water for injection ……10ml |
| | Pharmacological Group | Diluent/solvent |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10ml / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Sterile water for injection by M/s Pfizer Ltd (MHRA Approved) |
| | Me-too status | Water for Injection of M/s Visison Pharma (Reg.# 032340) |
| | GMP status | New Sections (Inspection Date: 19th Sep. 2018) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 864. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | ROTACAINE 1% w/v Injection |
| | Diary No. Date of R& I & fee | DY No. 14208, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each ml ampoule contains:<br>Lidocaine HCl ……. 10mg |
| | Pharmacological Group | Local anaesthetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 2ml x 50's & 2ml x 100's/ MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lidocaine injection 1% w/v (MHRA Approved) |
| | Me-too status | Lidocaine 1% Injection of M/s Zafa Pharmaceuticals.<br>(Reg. # 030216) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 865. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | ROTACAINE 2% w/v Injection |
| | Diary No. Date of R& I & fee | DY No. 14117, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each ml ampoule contains:<br>Lignocaine HCl ……. 20mg |
| | Pharmacological Group | Local anaesthetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 2ml x 50's & 2ml x 100's/ MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lidocaine injection 2% w/v (MHRA Approved) |
| | Me-too status | Lignox 2% injection (2ml) of M/s Novamed (Reg.#076968) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 866. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | NALPAIN Injection 10mg/ml |

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|---|---|---|
| | Diary No. Date of R& I & fee | DY No. 14223, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each ampoule contains:<br>Nalbuphine hydrochloride ……. 10mg |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-House |
| | Pack size & Demanded Price | 10amp x 1ml: pack of 5's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by Health Canada |
| | Me-too status | Kinz 10mg/ml Injection by M/s Sami |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 867. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | NALPAIN Injection 20mg/ml |
| | Diary No. Date of R& I & fee | DY No. 14222, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 1ml ampoule contains:<br>Nalbuphine hydrochloride ……. 20mg |
| | Pharmacological Group | Analgesic |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-House |
| | Pack size & Demanded Price | 5amp x 1ml: pack of 5's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Nubain Injection 20mg/ml by M/s Sandoz Canada Incorporated, Health Canada approved |
| | Me-too status | Kinz 20mg/ml injection by M/s Sami (Reg. No. 018687) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 868. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | VOLPAN injection 100mg/2ml |
| | Diary No. Date of R& I & fee | DY No. 14194, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 2ml ampoule contains:<br>Tramadol hydrochloride ……. 100mg |
| | Pharmacological Group | Opioid |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer specs. |
| | Pack size & Demanded Price | 5amp x 2ml: / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Tramal 50ml/ml Injection by M/s Searle (Reg. No. 010072) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 869. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | ROTA-D Injection |
| | Diary No. Date of R& I & fee | DY No. 14180, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 1ml ampoule contains:<br>Cholecalciferol ……. 200,000IU (5mg) |
| | Pharmacological Group | Vitamin D analogue |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer specs. |

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|---|---|---|
| | Pack size & Demanded Price | 1's x 1ml / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Vitamin D3 BON of Bouchara, France Approved |
| | Me-too status | D-Tres 5mg/ml Injection by M/s Sami (Reg#076115) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 870. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | AMICIN Injection 100mg/2ml |
| | Diary No. Date of R& I & fee | DY No. 14216, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 2ml ampoule contains:<br>Amikacin as sulphate ……. 100mg |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2ml: pack of 1's, 5's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved |
| | Me-too status | Amikin of M/s Bristol Myers (Reg. No. 010666) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 871. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | AMICIN Injection 250mg/1ml |
| | Diary No. Date of R& I & fee | DY No. 14166, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 1ml ampoule contains:<br>Amikacin as sulphate ……. 250mg |
| | Pharmacological Group | Antibiotic for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1ml: pack of 1's, 5's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Health Canada Approved |
| | Me-too status | Amikacil I.M / I.V INJECTION 250MG / 1MLReg. No. 023105 |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for clarification of submitted pharmacological group for applied formulation.** | |
| 872. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | AMICIN Injection 500mg/2ml |
| | Diary No. Date of R& I & fee | DY No. 14163, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 2ml ampoule contains:<br>Amikacin as sulphate ……. 500mg |
| | Pharmacological Group | Antibiotic for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2ml: pack of 1's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by Health Canada |
| | Me-too status | Kimdon Injection 500mg reg # 036915 |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for clarification of submitted pharmacological group for applied formulation.** | |

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| 873. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | TRANSMIC Injection 1g /10ml |
| | Diary No. Date of R& I & fee | DY No. 14122, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 10ml ampoule contains:<br>Tranexamic acid ……. 1gm |
| | Pharmacological Group | Fibrinolytic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 10ml: pack of 1's, 5's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cyklokapron 500mg solution for injection by M/s Pfizer (Could not be confirmed) |
| | Me-too status | Traxacid Injection by M/s Asian Continental (Could not be confirmed) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | International availability and me-too status could not be confirmed. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 874. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | TRANSMIC Injection 250mg /5ml |
| | Diary No. Date of R& I & fee | DY No. 14118, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 5ml ampoule contains:<br>Tranexamic acid ……. 250mg |
| | Pharmacological Group | Fibrinolytic / Haemostatic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 5ml: pack of 1's & 5's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PMDA Approved |
| | Me-too status | Tremic-250 Injection by M/s Fynk Pharma. (Reg.# 062677) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 875. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | TRANSMIC Injection 500 mg /5ml |
| | Diary No. Date of R& I & fee | DY No. 13876, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 5ml ampoule contains:<br>Tranexamic acid ……. 500mg |
| | Pharmacological Group | Fibrinolytic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 5ml: pack of 5's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Cyklokapron 500mg solution for injection by M/s Pfizer (MHRA Approved) |
| | Me-too status | Tremic-500 Injection by M/s Fynk Pharma. (Reg.# 062678) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |

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| 876. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | C-LINE Injection 1g/4ml |
| | Diary No. Date of R& I & fee | DY No. 14224, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 4ml ampoule contains:<br>Citicoline (as sodium) ……. 1g |
| | Pharmacological Group | Psychostimulant Nootropics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer Specs. |
| | Pack size & Demanded Price | 4ml: pack of 1's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by Spanish regulatory authority |
| | Me-too status | Citolin by Global Pharma |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 877. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | C-LINE Injection 250mg/2ml |
| | Diary No. Date of R& I & fee | DY No. 14191, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 2ml ampoule contains:<br>Citicoline (as sodium) ……. 250mg |
| | Pharmacological Group | Psychostimulant Nootropics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer Specs. |
| | Pack size & Demanded Price | 2ml: pack of 1's, 5's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by ANSM France |
| | Me-too status | Cerebolin Injection 250mg/2ml by M/s Zam Zam (Reg#021969) |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 878. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | C-LINE Injection 500mg/4ml |
| | Diary No. Date of R& I & fee | DY No. 13843, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 4ml ampoule contains:<br>Citicoline (as sodium) ……. 500mg |
| | Pharmacological Group | Psychostimulant Nootropics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer Specs. |
| | Pack size & Demanded Price | 4ml: pack of 1's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Citicolin Panpharma 500mg/4ml solution injectable by M/s PANPHARMA; Approved by ANSM France |
| | Me-too status | SOMAZINA Injection500 by Alina pharma Reg. No. 016975 |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 879. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | ATRACUR Injection 25mg/2.5ml |
| | Diary No. Date of R& I & fee | DY No. 14195, 14-12-2018, Rs. 20,000, 5-12-2018 |

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|---|---|---|
| | Composition | Each 2.5ml ampoule contains:<br>Atracurium besylate……. 25mg |
| | Pharmacological Group | Non depolarizing muscle relaxant |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2.5ml: pack of 5's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Atracurium Besilate 10mg/ml Solution for injection 2.5ml (MHRA Approved) |
| | Me-too status | Atrum-3H 25mg/2.5ml Injection Reg # 039339 |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 880. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | ATRACUR Injection 50mg/5ml |
| | Diary No. Date of R& I & fee | DY No. 14228, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 5ml ampoule contains:<br>Atracurium besylate……. 50mg |
| | Pharmacological Group | Non depolarizing muscle relaxant |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 5ml: pack of 5's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Atracurium Besilate 10mg/ml Solution for injection 5ml by M/s Hikma Farmaceutica (Portugal) S.A., (MHRA Approved) |
| | Me-too status | Atrum-3H 50mg/5ml Injection Reg # 039340 |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 881. | Name and address of manufacturer / Applicant | M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad |
| | Brand Name +Dosage Form + Strength | MECONEURO Injection 500mcg/ml |
| | Diary No. Date of R& I & fee | DY No. 14214, 14-12-2018, Rs. 20,000, 5-12-2018 |
| | Composition | Each 1ml ampoule contains:<br>Mecobalamin……. 500mcg |
| | Pharmacological Group | Vitamin B12 analogue |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer specs. |
| | Pack size & Demanded Price | 1ml: pack of 5's & 10's / MRP. Rs. As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PMDA Approved |
| | Me-too status | Wycomin 500 mcg Injection of Wnsfeild Pharmaceutical |
| | GMP status | New Sections (Inspection Date: **19th Sep. 2018**) |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-XIV**

| **Sachet Section (10 molecules/ 11products)** | | |
|---|---|---|
| 882. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | V-COL Oral Sachet |
| | Composition | Each sachet contains:<br>Macrogol……..13.125 g<br>Sodium Chloride……0.3507 g<br>Sodium Bicarbonate……..0.1785 g<br>Potassium chloride……0.0466 g |

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|---|---|---|
| | Diary No. Date of R& I & fee | 40245, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Osmotically acting laxative |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Movicol 13.8g Sachet, powder for oral solution by M/s Norgine limited (MHRA approved) |
| | Me-too status | Marfinal Sachet 13.8g by M/s Martin Dow (Reg#080647) |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 883. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | PEDICURE –R Oral Sachet |
| | Composition | Each sachet contains:<br>Pre-cooked Rice powder…….6gm<br>Sodium chloride……350mg<br>Sodium Citrate……580mg<br>Potassium chloride……..300mg |
| | Diary No. Date of R& I & fee | 40246, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Electrolyte |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 10's, 50's, 100's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Dioralyte Relief Blackcurrant sachet of Aventis Pharma Ltd., UK **(MHRA approved)** |
| | Me-too status | Hilyte-R Sachet of M/s Hilton Pharma (Reg#073733) |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 884. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | BRUTEX Oral Sachet |
| | Composition | Each sachet contains:<br>Ibuprofen (effervescent granules)…….600mg |
| | Diary No. Date of R& I & fee | 40236, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Anti-inflammatory and anti-rheumatic |
| | Type of Form | Form 5 |
| | Finished product Specification | BP specifications |
| | Pack size & Demanded Price | 14's, 10's, 50's, 100's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Brufen Granules 600mg by M/s BGP Products Ltd. (MHRA Approved) |
| | Me-too status | Brufen 600mg Sachet by Abbott Laboratories (Pakistan) Limited (Reg. # 044414) |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 885. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | CITROMED oral Sachet |
| | Composition | Each 5gm sachet contains:<br>Sodium Bicarbonate……1.76g<br>Sodium citrate……...0.63g<br>Citric acid……0.72g<br>Tartaric acid……0.89g |
| | Diary No. Date of R& I & fee | 40241, 05-12-2018, 20,000/-, 04-12-2018 |

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| | Pharmacological Group | Urinary Alkaliniser |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 20's, 100's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Citro soda Sachet of Abbott Labs<br>Sodium Bicarbonate……1.76g<br>Sodium citrate……...0.63g<br>Citric acid……0.72g<br>Tartaric acid…….0.98g<br>Me-too is different. |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 886. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | MEBETEX PLUS Oral Sachet |
| | Composition | Each Sachet contains:<br>Mebeverine HCl…….135mg<br>Ispaghula Husk……3.5gm |
| | Diary No. Date of R& I & fee | 40238, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Antispasmodic/laxative |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 10's & 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Fybogel Mebeverine effervescent granules by M/s Reckitt Benckiser Healthcare (UK) Ltd. (MHRA approved) |
| | Me-too status | MEVULAK Sachet of M/s Sami (Reg.#076311) |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 887. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | BIOFOS Oral Sachet |
| | Composition | Each Sachet contains:<br>Fosfomycin as trometamol…….3gm |
| | Diary No. Date of R& I & fee | 40185, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 1's, 2's, 5's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | Fosib 3gm Sachet by M/s Ciba Pharmaceuticals (Reg.# 081515) |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 888. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | RONITA Oral Sachet |

| | | |
|---|---|---|
| | Composition | Each Sachet Contains:<br>Strontium Ranelate……..2g |
| | Diary No. Date of R& I & fee | 40234, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Anti-osteoporotic |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 7's, 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PROTOS strontium ranelate 2g granules for oral suspension sachet by Servier Laboratories (TGA Australia Approved) |
| | Me-too status | Onita Sachet by PharmEvo( (Reg# 057746) |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 889. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | MONTERO Oral Sachet |
| | Composition | Each sachet contains:<br>Montelukast as sodium…….4mg |
| | Diary No. Date of R& I & fee | 40213, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | USP |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Singulair Sachet 4mg Granules of Merck, USFDA |
| | Me-too status | Montiget Sachet of M/s GETZ Pharma |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 890. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | TIME ORAL Sachet |
| | Composition | Each Sachet contains:<br>Omeprazole…….20mg<br>Sodium Bicarbonate……..1680mg |
| | Diary No. Date of R& I & fee | 40237, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Proton pump inhibitor / antacid |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 10's, 14's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA |
| | Me-too status | Bold Insta Sachet of M/s Scotmann Pharma |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 891. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | TIME ORAL Sachet |
| | Composition | Each Sachet contains:<br>Omeprazole……40mg<br>Sodium Bicarbonate……..1680mg |
| | Diary No. Date of R& I & fee | 40247, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Proton pump inhibitor / antacid |
| | Type of Form | Form 5 |

| | | |
|---|---|---|
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 10's, 14's, 28's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in USFDA |
| | Me-too status | Bold Insta Sachet of M/s Scotmann Pharma |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 892. | Name and address of manufacturer / Applicant | M/s Rotex (Pvt) Ltd. Plot No. 206 & 207, Industrial triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | OSMOLET O.R.S SACHET |
| | Composition | Each Sachet contains:<br>Anhydrous Glucose……..13.5g<br>Tri sodium citrate dihydrate……..2.9g<br>Sodium chloride…….2.6g<br>Potassium chloride…….1.5g |
| | Diary No. Date of R& I & fee | 40246, 05-12-2018, 20,000/-, 04-12-2018 |
| | Pharmacological Group | Electrolyte |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house specifications |
| | Pack size & Demanded Price | 20's, 25's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Reduced Osmolarity Oral Rehydration Slat (WHO Approved) |
| | Me-too status | Orsol Sachet by M/s Kaizan (Reg#073897) |
| | GMP status | Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General). |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with IP specifications.** | |

**Evaluator PEC-XIV**

| **Liquid Injectable Ampoule Vial General Section:10 Molecules/11 Products** | | |
|---|---|---|
| 893. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novibion Injection |
| | Composition | Each 3ml Contains:<br>Pyridoxine Hydrochloride……100mg<br>Thiamine Hydrochloride ……..…100mg<br>Cyanocobalamin……..…1000mcg |
| | Diary No. Date of R& I & fee | Dy.No 2069, 17-01-2019 Rs.20,000/-, 16-01-2019 |
| | Pharmacological Group | Vitamin B compounds |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | Rs. 666.00/ 25 ampoules |
| | Approval status of product in Reference Regulatory Authorities. | Neurobion solution for Injection 3ml by M/s Merck Selbstmedikation GmbH (Germany Approved) |
| | Me-too status | Neurolina Injection 3ml by M/s Alina Combine (Reg#076143) |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section:<br>Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | Master formulation shows fill volume 1ml while the reference formulation is 3ml. |
| | **Decision: Deferred for the clarification of filled volume as in reference regulatory authorities the approved drug is in 3 ml volume while in applied product master formulation shows fill volume 1ml** | |
| 894. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd.<br>Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Aquanov 5ml Injection |
| | Composition | Each Ampoule Contains:<br>Water for Injection……5ml |

| | | |
|---|---|---|
| | Diary No. Date of R& I & fee | Dy.No 2070, 17-01-2019 Rs.20,000/-,16-01-2019 |
| | Pharmacological Group | Diluent/Solvent |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | Rs. 575.00/100's |
| | Approval status of product in Reference Regulatory Authorities. | Sterile water for injection by M/s Pfizer Limited, **MHRA** approved. |
| | Me-too status | Aqua R ampoule by M/s Regal Pharmaceuticals (Reg#082010) |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 895. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Diclonov 75mg/3ml Injection |
| | Composition | Each ampoule Contains: Diclofenac Sodium……75mg |
| | Diary No. Date of R& I & fee | Dy. No. 2068, 17-01-2019, Rs.20,000/-,16-01-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | 3264/100's |
| | Approval status of product in Reference Regulatory Authorities. | Voltarol ampoules 75mg/3ml UK, (MHRA approved) |
| | Me-too status | Artecid Injection of M/s.Biolabs (Reg#075186) |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 896. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novalox 400mg/250ml Vial For Infusion |
| | Composition | Each 250ml Vial for Infusion Contains: Moxifloxacin Hydrochloride eq. to Moxifloxacin……..400mg |
| | Diary No. Date of R& I & fee | Dy.No 2081, 17-01-2019 , Rs.20,000/-,16-01-2019 |
| | Pharmacological Group | Quinolones |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | 250ml; Rs. 1200.00 per pack |
| | Approval status of product in Reference Regulatory Authorities. | Avelox 400mg/250ml solution for infusion by Bayer, **MHRA approved.** |
| | Me-too status | Avelox 400mg Infusion by Bayer Healthcare. |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product** | |
| 897. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novafin 10mg/ml Ampoule |
| | Composition | Each 1ml ampoule Contains: Nalbuphine Hydrochloride.……10mg |
| | Diary No. Date of R& I & fee | Dy.No 2082, 17-01-2019 , Rs.20,000/- Dated 16-01-2019 |
| | Pharmacological Group | Opioid analgesic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |

| | | |
|---|---|---|
| | Pack size & Demanded Price | 1ml ×5's; Rs. 594.14 per pack |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Sonotic Injection by Brookes Pharma (Reg. # 057729) |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 898. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd.<br>Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novafin 20mg/ml Ampoule |
| | Composition | Each 1ml Ampoule Contains:<br>Nalbuphine Hydrochloride……..…20mg |
| | Diary No. Date of R& I & fee | Dy.No 2083, 17-01-2019, Rs.20,000/-, 16-01-2019 |
| | Pharmacological Group | Opioid analgesic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | 1ml × 5's; 945.60 per pack |
| | Approval status of product in Reference Regulatory Authorities. | Nubain Injection 20mg/ml by M/s Sandoz Canada Incorporated,**Health Canada** approved |
| | Me-too status | Kinz 20mg/ml Injection by M/s Sami (Reg#018687) |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 899. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd.<br>Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novamin 500mcg/ml Ampoule |
| | Composition | Each 1ml Ampoule Contains:<br>Mecobalamin……..500mcg |
| | Diary No. Date of R& I & fee | Dy.No 2076, 17-01-2019, Rs.20,000/-, 16-01-2019 |
| | Pharmacological Group | Coenzyme type-vitamin B12 |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | 1ml × 10's; Rs. 552.00 per pack |
| | Approval status of product in Reference Regulatory Authorities. | Approved in PMDA |
| | Me-too status | Wycomin 500 mcg Injection of Wnsfeild Pharmaceutical |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 900. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd.<br>Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novamol 1gm/100ml Infusion |
| | Composition | Each 100ml IV Infusion Contains:<br>Paracetamol……..…1gm |
| | Diary No. Date of R& I & fee | Dy.No 2078, 17-01-2019, Rs.20,000/-, 16-01-2019 |
| | Pharmacological Group | Analesic & Antipyretic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 100ml; Rs. 103.68 per pack |
| | Approval status of product in Reference Regulatory Authorities. | Perfalgan 10mg/ml, solution for infusion (MHRA approved) |
| | Me-too status | Provas Infusion 10mg/ml of M/s Sami |
| | GMP status | The central licensing Board in its 267th meeting has considered |

| | | |
|---|---|---|
| | | and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product** | |
| 901. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novacip 200mg/100ml Vial for Infusion |
| | Composition | Each 1ml Vial for Infusion Contains: Ciprofloxacin as Lactate…….2mg |
| | Diary No. Date of R& I & fee | Dy.No 2079, 17-01-2019, Rs.20,000/-,16-01-2019 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 100ml; Rs. 202.80 per pack |
| | Approval status of product in Reference Regulatory Authorities. | Ciprofloxacin 2 mg/ml Solution for Infusion by M/s Hospira UK Ltd (MHRA) |
| | Me-too status | Reflox Infusion of M/s Regal Pharmaceutical |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product** | |
| 902. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Avanic 500mg/100ml vial for Infusion |
| | Composition | Each 100ml vial of Solution for Infusion contains: Levofloxacin Hemihydrate eq. to Levofloxacin….500mg |
| | Diary No. Date of R& I & fee | Dy.No 2073, 17-01-2019, Rs.20,000/-,16-01-2019 |
| | Pharmacological Group | Fluoroquinolone Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | Rs. 750.00 per Pack 100ml |
| | Approval status of product in Reference Regulatory Authorities. | Levofloxacin infusion by Teva UK (MHRA Approved) |
| | Me-too status | Levaquin infusion by Barret Hodgson |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product** | |
| 903. | Name and address of manufacturer / Applicant | M/s Novartana Pharmaceuticals Pvt Ltd. Plot No. 87-B, Sundar Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Novotop 500mg/100ml Vial for Infusion |
| | Composition | Each 100ml vial for Infusion Contains: Metronidazole……..…500mg |
| | Diary No. Date of R& I & fee | Dy.No. 2084,17-01-2019, Rs.20,000/-, 16-01-2019 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer |
| | Pack size & Demanded Price | 100ml; 111.60 per pack |
| | Approval status of product in Reference Regulatory Authorities. | Metronidazole 5mg/ml Solution for Infusion by Teva UK (MHRA Approved) |
| | Me-too status | Metrodex infusion by Caraway Pharma |
| | GMP status | The central licensing Board in its 267th meeting has considered and approved the grant following one additional section: Liquid Injectable ampoule/vial (General) section. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product** | |

## c. Remaining Products of New Section/New License

**Evaluator PEC-III**

**M/s Moringa Pharmaceuticals, Lahore**

The following files were received from section R-V vide letter No. F.8-6/2013-Reg-V stating that the firm was granted two new sections against which the firm has claimed molecules / products as described in the table below:

| Section | No. of molecules already registered | No. of new molecules applied by the firm |
|---|---|---|
| Tablet (General) | 7 | 2 |
| Capsule (General) | 6 | 4 |

| | | |
|---|---|---|
| **Tablet (General) section: Molecules-2 / Products-5** | | |
| 904. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Alomor-M 12.5/500 mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Alogliptin (as benzoate)…12.5mg<br>Metformin hydrochloride…500mg |
| | Diary No. Date of R& I & fee | Dy. No 35448: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Antidiabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 1x10's: Rs. 1000/- |
| | Approval status of product in Reference Regulatory Authorities. | Kazano Tablets by Takeda Pharms<br>(**USFDA** Approved) |
| | Me-too status | Could not be confirmed |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | |
| | **Decision: Deferred for submission of application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.** | |
| 905. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Alomor-M 12.5/1000 mg Tablets |
| | Composition | Each film coated Tablet Contains:<br>Alogliptin (as benzoate)…12.5mg<br>Metformin hydrochloride…1000mg |
| | Diary No. Date of R& I & fee | Dy. No 35449: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Antidiabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 1x10's: Rs. 1000/- |
| | Approval status of product in Reference Regulatory Authorities. | Kazano Tablets by Takeda Pharms<br>(**USFDA** Approved) |
| | Me-too status | Could not be confirmed |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision: Deferred for submission of application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.** | |
| 906. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Levlo 1mg Tablet |
| | Composition | Each film coated tablet contains:<br>Pitavastatin (as calcium)…..1mg |
| | Diary No. Date of R& I & fee | Dy. No 35452: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP Specs |

| | | |
|---|---|---|
| | Pack size | 10's: Rs. 150/- |
| | Approval status of product in Reference Regulatory Authorities. | Alipza film-coated tablets by Kowa Pharmaceutical (**MHRA** Approved) |
| | Me-too status | Pitastin Tablet by Atco |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision:Approved** | |
| 907. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Levlo 2mg Tablet |
| | Composition | Each film coated tablet contains:<br>Pitavastatin (as calcium)…..2mg |
| | Diary No. Date of R& I & fee | Dy. No 35453: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP Specs |
| | Pack size | 10's: Rs. 150/- |
| | Approval status of product in Reference Regulatory Authorities. | Alipza film-coated tablets by Kowa Pharmaceutical (**MHRA** Approved) |
| | Me-too status | Pitastin Tablet by Atco |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision:Approved** | |
| 908. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Levlo 4mg Tablet |
| | Composition | Each film coated tablet contains:<br>Pitavastatin (as calcium)…..4mg |
| | Diary No. Date of R& I & fee | Dy. No 35454: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | HMG CoA reductase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP Specs |
| | Pack size | 10's: Rs. 150/- |
| | Approval status of product in Reference Regulatory Authorities. | Alipza film-coated tablets by Kowa Pharmaceutical (**MHRA** Approved) |
| | Me-too status | Pitastin Tablet by Atco |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision:Approved** | |
| **Capsule (General) Section: Molecules-4 / Products-6** | | |
| 909. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Traxid 250mg Capsule |
| | Composition | Each Capsule Contains:<br>Tranexamic Acid…250mg |
| | Diary No. Date of R& I & fee | Dy. No 35450: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Anti-fibrinolytics |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP Specs |
| | Pack size | 20's: Rs. 166/- |
| | Approval status of product in Reference Regulatory Authorities. | PMDA Japan Approved |
| | Me-too status | Tranex 250mg Capsule of Mission Karachi. |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |

| | | |
|---|---|---|
| | Remarks of the Evaluator[3]. | • |
| | **Decision:Approved** | |
| 910. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Traxid 500mg Capsule |
| | Composition | Each Capsule Contains:<br>Tranexamic Acid…500mg |
| | Diary No. Date of R& I & fee | Dy. No 35451: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Anti-fibrinolytics |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP Specs |
| | Pack size | 20's: Rs. 334.72/- |
| | Approval status of product in Reference Regulatory Authorities. | Tranex Capsule by Malesci Institute Pharmacobiological SPA (**AIFA Italy Approved)** |
| | Me-too status | Statin Capsule by Wilson |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision:Approved** | |
| 911. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Ribamor 200mg Capsule |
| | Composition | Each Capsule Contains:<br>Ribavirin…200mg |
| | Diary No. Date of R& I & fee | Dy. No 35446: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Antiviral |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP Specs |
| | Pack size | 4x7's: Rs. 295/- |
| | Approval status of product in Reference Regulatory Authorities. | (**USFDA** Approved) |
| | Me-too status | Zinger Capsule by Tabros Pharma |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision:Approved** | |
| 912. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Ribamor 400mg Capsule |
| | Composition | Each Capsule Contains:<br>Ribavirin…400mg |
| | Diary No. Date of R& I & fee | Dy. No 35447: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Antiviral |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP Specs |
| | Pack size | 4x7's: Rs. 340/- |
| | Approval status of product in Reference Regulatory Authorities. | (**USFDA** Approved) |
| | Me-too status | Zinger Capsule by Tabros Pharma |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision:Approved** | |
| 913. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Rid-XR 150mg Capsule |
| | Composition | Each Capsule Contains:<br>Itopride SR…150mg |

| | | |
|---|---|---|
| | Diary No. Date of R& I & fee | Dy. No 35440: 25-10-2018 Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Propulsive |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 10's: Rs. 336/- |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Itotab-OD Capsule by Opal Laboratories |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • Evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which as adopted by Registration Board in its 275th meeting.** | |
| 914. | Name and address of manufacturer / Applicant | M/s Moringa Pharmaceuticals. 35-A, Sunder Industrial Estate, Lahore |
| | Brand Name +Dosage Form + Strength | Azydec 500mg Capsule |
| | Composition | Each Capsule Contains:<br>Azithromycin…500mg |
| | Diary No. Date of R& I & fee | Dy. No 35438: 25-10-2018<br>Rs. 20,000/-: 25-10-2018 |
| | Pharmacological Group | Macrolide antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size | 3's: Rs. 125/- |
| | Approval status of product in Reference Regulatory Authorities. | Available in WHO Model List of Essential Medicines 20th List published in March 2017 (accessed from: https://www.who.int/medicines/publications/essentialmedicines/20th_EML2017.pdf?ua=1) on 4th February 2019. |
| | Me-too status | Zithrosan 500mg Capsules by Elko |
| | GMP status | Last inspection dated 06-06-2018 Panel recommended renewal of DML |
| | Remarks of the Evaluator[3]. | • |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which as adopted by the Registration Board in its 275th meeting.** | |

**Evaluator PEC-V**

| **Capsule General Section: Applied 10 Molecules/15 Products** | | |
|---|---|---|
| **Capsule Section<br>Remaining 5 Molecules** | | |
| 915. | Name and address of Manufacturer / Applicant | M/s Dew-Max Pharmaceuticals Pvt Limited Plot No.6, Street#SS-4, National Industrial Zone Rawat, Islamabad |
| | Diary No. Date of R&I & fee | Dy.No 40580 dated 06-12-2018 Rs.20,000/- Dated 05-12-2018 |
| | Brand Name+DosageForm+Strength | Linco 500mg Capsule, L-Mycin, Lycin, Lencocin |
| | Composition | "Each Hard Gelatin Capsule Contains:<br>Lincomycin HCl eq. to Lincomycin…500mg" |
| | Pharmacological Group | Macrolide |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 3x4's, 10's,12's 20's,100's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities | LINCOCINE 500 mg capsule<br>ANSM approved |
| | Me-too status | 080450; F-Linco Capsule 500mg<br>M/s Fresh Pharmaceuticals, Islamabad |
| | GMP status | Grant of DML. |
| | Remarks of Evaluator | |
| | **Decision:Approved.** | |

| | | |
|---|---|---|
| 916. | Name and address of Manufacturer / Applicant | M/s Dew-Max Pharmaceuticals Pvt Limited Plot No.6, Street#SS-4, National Industrial Zone Rawat, Islamabad |
| | Diary No. Date of R&I & fee | Dy.No 40578 dated 06-12-2018 Rs.20,000/- 05-12-2018 |
| | Brand Name+DosageForm+Strength | Pirodex 20mg Capsule, Piro-Cam, Piro-Cap, Felcam |
| | Composition | "Each Hard Gelatin Capsule Contains:<br>Piroxicam…20mg" |
| | Pharmacological Group | Antiinflammatory and antirheumatic products, non-steroid, Oxicams |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1x10's, 20's, 100's. As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved. |
| | Me-too status | 079975; Camcard 20mg Capsule<br>M/s Ardin Karachi . . |
| | GMP status | Grant of DML. |
| | Remarks of Evaluator | |
| | **Decision:Approved** | |
| 917. | Name and address of Manufacturer / Applicant | M/s Dew-Max Pharmaceuticals Pvt Limited Plot No.6, Street#SS-4, National Industrial Zone Rawat, Islamabad |
| | Diary No. Date of R&I & fee | Dy.No 40566 dated 06-12-2018 Rs.20,000/- 05-12-2018 |
| | Brand Name+DosageForm+Strength | Fungi-EZ 150mg Capsule, Flucon, Flumax, Fungi-Nil |
| | Composition | "Each Hard Gelatin Capsule Contains:<br>Fluconazole…150mg" |
| | Pharmacological Group | Antimycotics For Systemic Use |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1x1's, 1x4's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved. |
| | Me-too status | 078578 "Feflozim Capsules<br>M/s Wisdom Pharmaceuticals Industry, 78-A Industrial Estate, Hayatabad Peshawar |
| | GMP status | Grant of DML. |
| | Remarks of Evaluator | Present in BP, JP, IP not in USP |
| | **Decision:Approved with BP specifications with change of brand name.** | |
| 918. | Name and address of Manufacturer / Applicant | M/s Dew-Max Pharmaceuticals Pvt Limited Plot No.6, Street#SS-4, National Industrial Zone Rawat, Islamabad |
| | Diary No. Date of R&I & fee | Dy.No 40579 dated 06-12-2018 Rs.20,000/- 05-12-2018 |
| | Brand Name+DosageForm+Strength | Aziro 250mg Capsule, Azi-Dew, Azid, Azorax |
| | Composition | "Each Hard Gelatin Capsule Contains:<br>Azithromycin Dihydrate Eq. to Azithromycin…250mg" |
| | Pharmacological Group | Macrolide |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1x10's, 1 x6's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | 078577 "Hosrin Capsules<br>By M/s Wisdom Pharmaceuticals Industry, 78-A Industrial Estate, Hayatabad Peshawar |
| | GMP status | Grant of DML. |
| | Remarks of Evaluator | 3 % overage has been added. On query Firm provided the formulation without overage |
| | **Decision:Approved.** | |
| 919. | Name and address of Manufacturer / Applicant | M/s Dew-Max Pharmaceuticals Pvt Limited Plot No.6, Street#SS-4, National Industrial Zone Rawat, Islamabad |
| | Diary No. Date of R&I & fee | Dy.No 40571 dated 06-12-2018 Rs.20,000/- 05-12-2018 |
| | Brand Name+DosageForm+Strength | R-zole 10mg Capsule, Hi-Cid, Hi-Dex, Rapra, Rabra |

| | | |
|---|---|---|
| | Composition | "Each Capsule Contains:<br>Rabeprazole Sodium Eq. to Rabeorazole as Enteric Coated Pellets…10mg" |
| | Pharmacological Group | Proton pump inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator |
| | Pack Size & Demanded Price | 14's, 10's, 20's,30's, 50's,100's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities | USFDA<br>(rabeprazole sodium) |
| | Me-too status | Me too in this strength could not be firmed. |
| | GMP status | Grant of DML. |
| | Remarks of Evaluator | • Source of pellets.<br>• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 920. | Name and address of Manufacturer / Applicant | M/s Dew-Max Pharmaceuticals Pvt Limited Plot No.6, Street#SS-4, National Industrial Zone Rawat, Islamabad |
| | Diary No. Date of R&I & fee | Dy.No 40572 dated 06-12-2018 Rs.20,000/- 05-12-2018 |
| | Brand Name+ Dosage Form+ Strength | R-zole 20mg Capsule, Hi-Cid, Hi-Dex, Rapra, Rabra |
| | Composition | "Each Capsule Contains:<br>Rabeprazole Sodium Eq. to Rabeorazole as Enteric Coated Pellets…20mg" |
| | Pharmacological Group | Proton pump inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator |
| | Pack Size & Demanded Price | 14's, 10's, 20's,30's, 50's,100's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Not confirmed in this strength. |
| | Me-too status | 065410 Rebeadvan capsule 20mg<br>M/s Advanced Pharmaceuticals, RCCI, Rawat |
| | GMP status | Grant of DML. |
| | Remarks of Evaluator | • Source of pellets.<br>• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |

**Evaluator PEC-VIII**

CLB in its 238th Meeting held on **19th November, 2014** has considered & approved the grant of Capsule Section (general) & **Renewal of Injectable Ampoule (Psychotropic) Section** of M/s. Venus Pharma, 23 km Multan road, Lahore. R-V vides its letter No. F.8-6/2013-Reg-V dated 14th of November, 2018 informed about three molecules & products registered in the Psychotropic Injection section:

| Sr.# | Section | Name of drug |
|---|---|---|
| 1. | Renewal of Injectable Ampoule (Psychotropic) Section | Nalbuphine hydrochloride 20mg/ml Injection. |
| | | Tramadol hydrochloride 50mg/ml Injection. |
| | | Ephedrine (as sulphate) 50mg/ml Injection |

Now the applicant has applied for the following:

| **Injectable Ampoule (Psychotropic) Section; Molecule:07, Products; 07** | | |
|---|---|---|
| 921. | Name and address of manufacturer / Applicant | M/s Venus Pharma 23 km Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Predol Injection 5mg |
| | Diary No. Date of R& I & fee | Dy No.17645, 11-05-2018, Rs.20,000/- |
| | Composition | Each ml contains:-<br>Haloperidol….....5mg |
| | Pharmacological Group | Antipsychotics |

| | | |
|---|---|---|
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specification |
| | Pack size & Demanded Price | 25's (1ml); Rs.250/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Halotec Plain Injection of Pharmatec Karachi |
| | GMP status | GMP Certificate issued on 27-08-2018 |
| | Remarks of the Evaluator. | |
| | Previous Decision | Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. |
| | Evaluation by PEC | Applied formulation does not fall in the category of controlled drugs. |
| | **Decision: Registration Board decided to defer the case for the following reasons:<br>For confirmation of required manufacturing facility as the applied formulation does not fall in the category of controlled (Psychotropic) drugs.<br>For consideration of case on its turn.** | |
| 922. | Name and address of manufacturer / Applicant | M/s Venus Pharma 23 km Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Fluzine Injection 25mg IM |
| | Diary No. Date of R& I & fee | Dy No.17647, 11-05-2018, Rs.20,000/- |
| | Composition | Each ml contains:-<br>Fluphenazine decanoate….25mg |
| | Pharmacological Group | Antipsychotics |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specification |
| | Pack size & Demanded Price | 1's (1ml); Rs.95/-,10's (1ml); Rs.650/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Halotec Plain Injection of Pharmatec Karachi |
| | GMP status | GMP Certificate issued on 27-08-2018 |
| | Remarks of the Evaluator. | |
| | Previous Decision | Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. |
| | Evaluation by PEC | Applied formulation does not fall in the category of controlled drugs. |
| | **Decision: Registration Board decided to defer the case for the following reasons:<br>For confirmation of required manufacturing facility as the applied formulation does not fall in the category of controlled (Psychotropic) drugs.<br>For consideration of case on its turn.** | |
| 923. | Name and address of manufacturer / Applicant | M/s Venus Pharma 23 km Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Viogesic Injection 0.3mg |
| | Diary No. Date of R& I & fee | Dy No.17640, 11-05-2018, Rs.20,000/- |
| | Composition | Each ml contains:-<br>Buprenorphine(as hydrochloride) ….0.3mg |
| | Pharmacological Group | Antipsychotics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 5's (1ml); Rs.95/-,10's (1ml); Rs.650/- |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Segesic Injection 0.3mg/ml of Saydon Pharmaceuticals Industries |
| | GMP status | GMP Certificate issued on 27-08-2018 |

| | | |
|---|---|---|
| | Remarks of the Evaluator. | Applied formulation is not present in Available BP & USP. |
| | Previous Decision | Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. |
| | Evaluation by PEC | |
| | **Decision: Approved with innovator's specification.** | |
| 924. | Name and address of manufacturer / Applicant | M/s Venus Pharma 23 km Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Diazocin Injection |
| | Diary No. Date of R& I & fee | Dy No.17640, 11-05-2018, Rs.20,000/- |
| | Composition | Each ml contains:-<br>Diazepam….5mg |
| | Pharmacological Group | Anxiolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | 5's (2ml); As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Dipam 5mg Injection of Medicraft Pharmaceuticals (Pvt) Ltd |
| | GMP status | GMP Certificate issued on 27-08-2018 |
| | Remarks of the Evaluator. | |
| | Previous Decision | Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. |
| | Evaluation by PEC | |
| | **Decision: Approved with innovator's specification.** | |
| 925. | Name and address of manufacturer / Applicant | M/s Venus Pharma 23 km Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Midazocin Injection |
| | Diary No. Date of R& I & fee | Dy No.17641, 11-05-2018, Rs.20,000/- |
| | Composition | Each ml contains:-<br>Midazolam (as hydrochloride)….1mg/ml |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | 5's & 10's (5ml); As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA but discontinued however it is mentioned **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** |
| | Me-too status | Midaz 5mg/5ml Injection of Sami |
| | GMP status | GMP Certificate issued on 27-08-2018 |
| | Remarks of the Evaluator. | |
| | Previous Decision | Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. |
| | Evaluation by PEC | |
| | **Decision: Approved with innovator's specification.** | |
| 926. | Name and address of manufacturer / Applicant | M/s Venus Pharma 23 km Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Chlorozine Injection |
| | Diary No. Date of R& I & fee | Dy No.17643, 11-05-2018, Rs.20,000/- |
| | Composition | Each ml contains:-<br>Chlorpromazine hydrochloride….25mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | 10's (2ml); Rs.250/- |

| | | |
|---|---|---|
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA (Emc) |
| | Me-too status | Chlorpromazine 2ml Injection Of Indus Pharma |
| | GMP status | GMP Certificate issued on 27-08-2018 |
| | Remarks of the Evaluator. | |
| | Previous Decision | Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. |
| | Evaluation by PEC | Applied formulation does not fall in the category of controlled drugs. |
| | **Decision: Registration Board decided to defer the case for the following reasons:**<br>**For confirmation of required manufacturing facility as the applied formulation does not fall in the category of controlled (Psychotropic) drugs.**<br>**For consideration of case on its turn.** | |
| 927. | Name and address of manufacturer / Applicant | M/s Venus Pharma 23 km Multan Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Morfin Injection |
| | Diary No. Date of R& I & fee | Dy No.17642, 11-05-2018, Rs.20,000/- |
| | Composition | Each ml contains:-<br>Morphine sulphate….10mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | 100's (1ml); As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in MHRA |
| | Me-too status | Morfscot Injections 10mg of Scotsmann Pharmaceuticals, |
| | GMP status | GMP Certificate issued on 27-08-2018 |
| | Remarks of the Evaluator. | Reference product is approved as morphine sulphate pentahydrate 10mg/ml Injection which is different from applied formulation i.e. morphine sulphate 10mg/ml injection. Submit Form 5, master formulation & manufacturing method in accordance with label claim. |
| | Previous Decision | Registration Board in its 286th meeting deferred the case for detailed deliberation in next meeting. |
| | Evaluation by PEC | |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-XII**

**Case. No. M/s Roryan Pharmaceuticals, Peshawar. (New Section)**

The Central Licensing Board in its 266th meeting held on 24th Oct, 2018 has considered and approved the grant of 15 additional section of firm M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, KPK, Pakistan (DML:000566) as under:-

| Sr. No | Section | No. of products | No. of molecules |
|---|---|---|---|
| 1 | Cream/ ointment (General) | 11 | 10 |

**Cream/ ointment (General)**
**11 Products/ 10 Molecule**

| | | |
|---|---|---|
| 928. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Scabicef 5% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39875 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Cream Contains:<br>Permethrin…50mg (5%w/) |
| | Pharmacological Group | Ectoparasiticides, incl. scabicides (Pyrethrines, incl. synthetic compounds) |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |

| | | |
|---|---|---|
| | Pack Size & Demanded Price | 30g/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Permethrin 5% w/w Cream by M/s Sandoz Limited (MHRA Approved) |
| | Me-too Status | Lotrix cream 5% by M/s WELLCOME (Reg#010516) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 929. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Burnomit 1% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39879 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Cream Contains:<br>Silver Sulfadiazine…10mg (1%w/w) |
| | Pharmacological Group | Chemotherapeutics for topical use (Sulfonamides) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 15g/As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Flamazine 1%w/w Cream by M/s B&S Healthcare (MHRA Approved) |
| | Me-too Status | SILZIN cream 1% by M/s COMBAT EURASIAN PHARMA (Reg#007484) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 930. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Robizol 1% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39876 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Cream Contains:<br>Bifonazole…10mg (1%w/w) |
| | Pharmacological Group | Antifungals for topical use (Imidazole and triazole derivatives) |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 15g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Canesten Bifonazole Once Daily Athlete's Foot 1% w/w Cream |
| | Me-too Status | MYCOSPOR cream 1% by M/s BAYER (Reg#007484) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 931. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Fungicef 1% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39880 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Cream Contains:<br>Econazole nitrate…10mg (1%w/w) |
| | Pharmacological Group | Antifungals for topical use (Imidazole and triazole derivatives) |

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|---|---|---|
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 15g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Pevaryl 1% Topical cream by M/s Janssen-Cilag Limited (MHRA Approved) |
| | Me-too Status | ECONAZOLE NITRATE 1% cream by M/s JOHNSON&JOHNSON (Reg#004314) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 932. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Ketozol 2% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39878 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Cream Contains:<br>Ketoconazole…20mg (2% w/w) |
| | Pharmacological Group | Antifungals for topical use (Imidazole and triazole derivatives) |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 10g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Daktarin Gold 2% Cream by M/s McNeil Products Limited (MHRA Approved) |
| | Me-too Status | Myxole Cream 2% by M/s Caraway (Reg#050020) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 933. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Romifin 1% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39877 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Cream Contains:<br>Terbinafine hydrochloride …10mg (1% w/w) |
| | Pharmacological Group | Other antifungals for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack Size & Demanded Price | 10g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | LAMISIL 1% w/w Cream by M/s GlaxoSmithKline Consumer Healthcare (UK) Trading Limited (MHRA Approved) |
| | Me-too Status | Lamisil Cream 1% by M/s Sandoz (Reg.#) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 934. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Rosidic 2% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.#39874 dated 04-12-2018 Rs.20,000/- 04-12-2018 |
| | Composition | Each Gram Contains:<br>Fusidic Acid…20mg (2% w/w) |

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|---|---|---|
| | Pharmacological Group | Other antibiotics for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 15g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fucidin 20 mg/g Cream by M/s LEO Laboratories Limited (MHRA Approved) |
| | Me-too Status | FUCIDIN CREAM by M/s Leo (Reg.#015539) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 935. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Rotrim 1% w/w Topical Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39873 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Cream Contains:<br>Clotrimazole…10mg (1%w/w) |
| | Pharmacological Group | Azole Antifungal |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 5g / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Clotrimazole 1% w/w Cream by M/s Teva UK Limited (MHRA approved) |
| | Me-too Status | Dermofit 1% Cream by M/s Baxter (Reg#073438) |
| | GMP Status | 19-09-2018 amd 03-10-2018; Grant of Additional sections and cGMP certificate. Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 936. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Pirocin 2% w/w Topical Ointment |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39870 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Topical Ointment Contains:<br>Mupirocin Calcium…20mg (2% w/w) |
| | Pharmacological Group | Other antibiotics for topical use |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 15g / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Bactroban 2% Ointment by M/s GlaxoSmithKline (MHRA Approved) |
| | Me-too Status | Bactroban 2% Ointment by M/s GlaxoSmithKline (Reg#010399) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | • Firm has applied as Mupirocin Calcium…20mg where as approved formulation in MHRA, AIFA (Italy) is Mupirocin …20mg. |
| | **Decision: Deferred for submission of correct composition with salt form as per Reference product along with correction fee.** | |
| 937. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Clindacef-V 2% w/w Vaginal Cream |

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|---|---|---|
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39872 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Vaginal Cream Contains:<br>Clindamycin (as phosphate) …20mg (2%w/w) |
| | Pharmacological Group | Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 20g / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Clindamycin 2% w/w Vaginal Cream by M/s Pfizer Inc., USA (MHRA Approved) |
| | Me-too Status | Dalacin Vaginal Cream 2% by M/s UPJOHN PAKISTAN (Reg#018574) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 938. | Name and Address of Manufacturer / Applicant | M/s Roryan Pharmaceuticals Pvt Ltd.<br>85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan |
| | Brand Name + Dosage Form + Strength | Rotrim 10% w/w Vaginal Cream |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 39871 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each Gram Vaginal Cream Contains:<br>Clotrimazole…100mg (10%w/w) |
| | Pharmacological Group | Antifungals for topical use (Imidazole and triazole derivatives) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10g, 20g/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Canestan 10% Vaginal cream of M/s Bayer plc (MHRA Approved) |
| | Me-too Status | Vaginex-1 Cream of M/s Global Pharmaceuticals (Reg#022368) |
| | GMP Status | 19-09-2018 amd 03-10-2018<br>Grant of Additional sections and cGMP certificate<br>Panel recommends Grant of Additional sections and cGMP certificate |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

**Case. No. M/s Maxitech (Pvt.) Ltd, Karachi. (New Section)**

CLB in its 266th meeting held on 24th October, 2018 has considered and granted additional sections to M/s Maxitech Pharma (Pvt.) Ltd. Accordingly, firm has applied for following products for consideration by Drug Registration Board.

| Sr. No | Section | No. of products | No. of molecules |
|---|---|---|---|
| 1 | Oral Dry Powder Suspension (Cephalosporin) Section | 19 | 08 |
| 2 | Dry Powder Vial Injection (Cephalosporin) Section | 26 | 09 |

| **Oral Dry Powder Suspension (Cephalosporin) Section<br>19 Products/ 08 Molecule** | | |
|---|---|---|
| 939. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | CEFUR DRY POWDER SUSPENSION 125mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41899: 07-12-2018<br>PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefuroxime (as axetil) …125 mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |

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|---|---|---|
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Zinnat Suspension 125mg/5ml by M/s Glaxo Wellcome UK Limited (MHRA Approved) |
| | Me-too Status | Razicef 125mg/5ml Suspension of M/s Raazee Therapeutics (Reg.# 068059) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 940. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | CEFUR DRY POWDER SUSPENSION 250mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41900: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains: Cefuroxime (as axetil) …250 mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Zinnat Suspension 250mg/5ml by M/s Glaxo Wellcome UK Limited (MHRA Approved) |
| | Me-too Status | Razicef 250mg/5ml Suspension of M/s Raazee Therapeutics (Reg.# 068066) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 941. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | DINCEF DRY POWDER SUSPENSION 125mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41901: 06-12-2018 PKR 20,000/-: 5-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains: Cefdinir …125 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefdinir 125mg/5ml powder for Suspension by M/s Lupin LTD (USFDA approved) |
| | Me-too Status | Zefnir 125mg/5ml dry Suspension by M/s Genome Pharmaceuticals (Reg. No. 075525) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 942. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | DINCEF DRY POWDER SUSPENSION 250mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41902: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains: Cefdinir …250 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |

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| | Approval Status of Product in Reference Regulatory Authorities. | Cefdinir 250mg/5ml powder for Suspension by M/s Lupin LTD (USFDA approved) |
| | Me-too Status | Zefnir 250mg/5ml dry Suspension by M/s Genome Pharmaceuticals (Reg. No. 075526) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 943. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXLOR DRY POWDER SUSPENSION 125mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41903: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefaclor (as monohydrate) …125 mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefaclor 125mg/5ml Suspension by M/s Strides Pharma UK Ltd (MHRA approved) |
| | Me-too Status | Sac-Lor 125mg/5ml Dry Suspension by M/s Semos Pharma (Reg#081617) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 944. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXLOR DRY POWDER SUSPENSION 187mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41904: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefaclor (as monohydrate) …187 mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefaclor for Oral Suspension 187mg/5ml USP<br>by Yung Shin Pharmaceutical Ind. Co., Ltd. Taiwan<br>(USFDA Approved) |
| | Me-too Status | Ceclor 187mg/ 5ml dry suspension by AGP (Reg#053182) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 945. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXLOR DRY POWDER SUSPENSION 250mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41905: 07-12-2018<br>PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefaclor (as monohydrate) …250 mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefaclor 250mg/5ml Suspension by M/s Strides Pharma UK Ltd (MHRA approved) |
| | Me-too Status | Sac-Lor 250mg/5ml Dry Suspension by M/s Semos Pharma (Reg#081618) |

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| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 946. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXLOR DRY POWDER SUSPENSION 50mg/1ml Drops |
| | Diary No. Date of R & I & fee | Dy No. 41906: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 1ml suspension after reconstitution contains:<br>Cefaclor (as monohydrate) …50mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 15ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefaclor for Oral Suspension 250mg/5ml by Yung Shin Pharmaceutical Ind. Co., Ltd. Taiwan<br>(FDA Approved) |
| | Me-too Status | Ceclor Drops 50mg/1ml by Eli Lilly (Reg#013583) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | The formulation applied by the firm translates to Cefaclor (as monohydrate) 250mg/5ml which the firm has also applied by name of MAXLOR DRY POWDER SUSPENSION 250mg/5ml. |
| | **Decision: Approved** | |
| 947. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MEFIX DRY POWDER SUSPENSION 100mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41907: 07-12-2018<br>PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefixime (as trihydrate) …100 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | SUPRAX® (cefixime) for oral suspension 100mg/5ml by M/ Lupin Pharmaceuticals, Inc. (USFDA Approved) |
| | Me-too Status | Bestar dry Suspension 100mg/5ml by M/s Elko (Reg#073247) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 948. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MEFIX DS DRY POWDER SUSPENSION 200mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41908: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefixime (as trihydrate) …200 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | SUPRAX® (cefixime) for oral suspension 200mg/5ml by M/ Lupin Pharmaceuticals, Inc. (USFDA Approved) |
| | Me-too Status | Bestar DS dry Suspension 200mg/5ml by M/s Elko (Reg#037036) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |

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| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 949. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | OXIMAX DRY POWDER SUSPENSION 40mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41909: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefpodoxime (as proxetil) …40 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 50ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefpodoxime Proxetil 40 mg/5 ml Powder for Oral Suspension by M/s Sandoz GMBH, (MHRA approved) |
| | Me-too Status | Apodox Dry Suspension by M/s Alliance (Reg#054697) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 950. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | OXIMAX DRY POWDER SUSPENSION 100mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41910: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefpodoxime (as proxetil) …100 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 50ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefpodoxime Proxetil 100 mg/5ml Powder for Oral Suspension by M/s Sandoz GMBH, (USFDA approved) |
| | Me-too Status | Qink Dry Suspension 100mg/5ml by Wilshire Laboratories (Pvt) Ltd. (Reg#053636) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 951. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | OZIX DRY POWDER SUSPENSION 125mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41911: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefadroxil (as monohydrate) …125 mg |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | ORACEFAL 125 mg / 5 ml powder for oral suspension by M/s Bristol - Myers Squibb (ANSM Approved) |
| | Me-too Status | Evacef Suspension 125mg/5ml by M/s Highnoon Laboratories, Lahore (Reg#011213) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 952. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | OZIX DRY POWDER SUSPENSION 250mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41912: 07-12-2018 PKR 20,000/-: 7-12-2018 |

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|---|---|---|
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefadroxil (as monohydrate) …250 mg |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 50ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | ORACEFAL 250 mg / 5 ml powder for oral suspension by M/s Bristol - Myers Squibb (ANSM Approved) |
| | Me-too Status | Evacef Suspension 250mg/5ml by M/s Highnoon Laboratories, Lahore (Reg#011214) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 953. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | OZIX DRY POWDER SUSPENSION 100mg/1ml Drops |
| | Diary No. Date of R & I & fee | Dy No. 41913: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 1ml suspension after reconstitution contains:<br>Cefadroxil (as monohydrate) …100 mg |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | ORACEFAL 500 mg / 5 ml powder for oral suspension by M/s Bristol - Myers Squibb (ANSM Approved) |
| | Me-too Status | DROMAX DROPS 100mg/1ml by Bosch (Reg#039441) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of applied pack size.** | |
| 954. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | PRIMICEF DRY POWDER SUSPENSION 125mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41914: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cephalexin (as monohydrate) …125mg |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefalexin 125mg/5ml Powder for Oral Suspension by M/s Milpharm Limited (MHRA approved) |
| | Me-too Status | Vegzin 125mg/5ml by M/s Vega Pharmaceuticals (Reg#078699) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 955. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | PRIMICEF DRY POWDER SUSPENSION 250mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41915: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cephalexin (as monohydrate) …250mg |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |

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| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefalexin 250mg/5ml Powder for Oral Suspension by M/s Milpharm Limited (MHRA approved) |
| | Me-too Status | Vegzin 250mg/5ml by M/s Vega Pharmaceuticals (Reg#078700) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 956. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | PRIMIDIN DRY POWDER SUSPENSION 125mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41917: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cephradine …125 mg |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Velosef Oral Suspension 125mg/5ml<br>by APOTHECON (USFDA Approved) (Discontinued) |
| | Me-too Status | Licef Dry Powder suspension 125mg/5ml by M/s Wisdom Pharmaceuticals (Reg#078532) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | • Approval status of product in Reference Regulatory Authorities not confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 957. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | PRIMIDIN DRY POWDER SUSPENSION 250mg/5ml |
| | Diary No. Date of R & I & fee | Dy No. 41918: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cephradine …250mg |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60ml :As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefradine 250mg/5ml dry powder for syrup by M/s Strides Pharma UK Ltd (MHRA Approved) |
| | Me-too Status | Licef Dry Powder suspension 250mg/5ml by M/s Wisdom Pharmaceuticals (Reg#078531) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| | **Dry Powder Vial Injectable (Cephalosporin) Section<br>27 Products/ 09 Molecule** | |
| 958. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | CEFUR 1.5gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41872: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefuroxime (as sodium) ...1.5gm |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |

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| | Approval Status of Product in Reference Regulatory Authorities. | Cefuroxime 1.5 g powder for solution for injection/infusion by M/s Stragen UK Limited (MHRA Approved) |
| | Me-too Status | Zecef Injection 1.5gm by M/s Bosch Pharmaceuticals (Pvt) Ltd, (Reg#026898) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 959. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | CEFUR 250mg IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41873: 07-12-2018<br>PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefuroxime (as sodium) ...250mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefuroxime 250 mg powder for solution for injection by M/s Stragen UK Limited (MHRA Approved) |
| | Me-too Status | ZINACEF 250MG INJ by M/s GSK Pakistan (Reg#006221) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 960. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | CEFUR 750mg IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41874: 07-12-2018<br>PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefuroxime (as sodium) ...250mg |
| | Pharmacological Group | 2nd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefuroxime 750 mg powder for solution for injection by M/s MIP Pharma GmbH (MHRA Approved) |
| | Me-too Status | ZINACEF 750MG INJ by M/s GSK Pakistan (Reg#006222) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 961. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | FORTEX 1gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41875: 06-12-2018 PKR 20,000/-: 5-12-2018 |
| | Composition | Each Vial contains:<br>Cefotaxime (as sodium) …1gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Claforan Injection 1gm by M/s Aventis Pharma Limited (MHRA Approved) |
| | Me-too Status | Getex Dry powder Injection 1gm by M/s Amarant from Medicaid, Karachi (Reg#080279) |

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| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 962. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | FORTEX 250 IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41876: 07-12-2018<br>PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefotaxime (as sodium) …250mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Claforan Injection 250mg by M/s Aventis Pharma Limited (MHRA Approved) |
| | Me-too Status | Getex Dry Powder Injection 250mg by M/s Amarant from Medicaid, Karachi (Reg#080277). |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 963. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | FORTEX 500mg IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41877: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefotaxime (as sodium) …500mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Claforan Injection 500mg by M/s Aventis Pharma Limited (MHRA Approved) |
| | Me-too Status | Getex Dry powder Injection 500mg by M/s Amarant from Medicaid, Karachi (Reg#080278) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 964. | Name and Address of Manufacturer / Applicant | **M/s Maxitech Pharma (Pvt) Ltd,**<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | **MAROME 1gm IV Injection** |
| | Diary No. Date of R & I & fee | Dy No. 41878: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefpirome (as sulphate) …1gm |
| | Pharmacological Group | 4th Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | CEFROM 1 g / 10 ml, powder and solvent for solution for injection (IV) by M/s SANOFI AVENTIS FRANCE (ANSM Approved) |
| | Me-too Status | IVCEF 1g Injection by Bosch (Reg#027732) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |

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| 965. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZO 1gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41879: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefoperazone (as sodium) …500mg<br>Sulbactam (as sodium) …500mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics/Beta-lactamase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Sulperazon Injection by Pfizer Inc. PMDA Approved |
| | Me-too Status | Cebac Injection 1gm by M/s Bosch (Reg#037630) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 966. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZO 2gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41880: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefoperazone (as sodium) …1000mg<br>Sulbactam (as sodium) …1000mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics/Beta-lactamase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Approved in Europe (Poland, Slovakia, Czech Republic) by EMA |
| | Me-too Status | Cebac Injection 2gm by M/s Bosch (Reg#037631) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 967. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 1gm IM Injection |
| | Diary No. Date of R & I & fee | Dy No. 41881: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …1gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IM 1 g Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 1000mg IM Injection by M/s ROCHE (Reg#008437) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 968. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 1gm IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41882: 07-12-2018 PKR 20,000/-: 7-12-2018 |

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| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …1gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IV 1 g Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 1000mg IV Injection by M/s ROCHE (Reg#008436) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 969. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 2gm IM Injection |
| | Diary No. Date of R & I & fee | Dy No. 41883: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …2gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Ceftriaxone 2 g Powder for Solution for Injection/Infusion (IM) by Sandoz Limited (MHRA Approved) |
| | Me-too Status | Cesod 2000mg IM Injection by M/s Amson (Reg#052404) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 970. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 2gm IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41884: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …2gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Ceftriaxone 2 g Powder for Solution for Injection/Infusion (IV) by Sandoz Limited (MHRA Approved) |
| | Me-too Status | Cesod 2000mg IV Injection by M/s Amson (Reg#052403) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 971. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 250mg IM Injection |
| | Diary No. Date of R & I & fee | Dy No. 41885: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …250mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |

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| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IM 250 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 250mg IM Injection by M/s ROCHE (Reg#008432) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 972. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 250mg IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41886: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …250mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IV 250 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 250mg IV Injection by M/s ROCHE (Reg#008433) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 973. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 500mg IM Injection |
| | Diary No. Date of R & I & fee | Dy No. 41887: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …500mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IM 500 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 500mg IM Injection by M/s ROCHE (Reg#008434) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 974. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAXZON 500mg IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41888: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …500mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IV 500 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 500mg IV Injection by M/s ROCHE (Reg#008435) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

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| 975. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MAZOLIN 1gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41889: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Cefazolin (as sodium) …1gm |
| | Pharmacological Group | 1st Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefazolin 1g Powder for solution for injection/infusion by M/s Noridem Enterprises Ltd (MHRA Approved) |
| | Me-too Status | Safelin Injection 1 gm by M/s Fassgen Pharma (Reg#074513) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 976. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MEZOX 1gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41890: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftizoxime (as sodium) …1gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefizox 1gm Injection by M/s Astellas Pharma US, Inc (USFDA Approved) (Discontinued) |
| | Me-too Status | Tezox 1gm Injection by Bosch (Reg#034853) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | • Applied formulation is discontinued in FDA. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which as adopted by Registration Board in its 275th meeting as Applied formulation is discontinued in FDA**. | |
| 977. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | MEZOX 500mg IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41892: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftizoxime (as sodium) …500mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefizox 1gm Injection by M/s Astellas Pharma US, Inc (USFDA Approved) (Discontinued) |
| | Me-too Status | Tezox 500mg Injection by Bosch (Reg#034852) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | • Applied formulation is discontinued in FDA. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by the Registration Board in its 275th meeting as Applied formulation is discontinued in FDA**. | |
| 978. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd, Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | XADIME 1gm IM/IV Injection |

| | | |
|---|---|---|
| | Diary No. Date of R & I & fee | Dy No. 41893: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftazidime (as pentahydrate) …1gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fortum 1g powder for solution for injection by M/s GlaxoSmithKline UK (MHRA Approved) |
| | Me-too Status | Panacef Injection 1gm by M/s CCL (Reg# 023986) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 979. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | XADIME 250MG IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41894: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftazidime (as pentahydrate) …250mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fortum 250 mg powder for solution for injection by M/s GlaxoSmithKline UK (MHRA Approved) |
| | Me-too Status | Panacef Injection 250mg by M/s CCL (Reg# 023858) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 980. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | XADIME 500MG IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41895: 07-12-2018<br>PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial contains:<br>Ceftazidime (as pentahydrate) …500mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fortum 500 mg powder for solution for injection by M/s GlaxoSmithKline UK (MHRA Approved) |
| | Me-too Status | Panacef Injection 500mg by M/s CCL (Reg# 023859) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 981. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | XPIME 1gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41896: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial Contains:<br>Cefepime (as hydrochloride)…1gm<br>With L-Arginine |
| | Pharmacological Group | 4th Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |

| | | |
|---|---|---|
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefipime hydrochloride 1gm Injection by M/s Hospira, Inc. (USFDA approved) |
| | Me-too Status | Uspime 500mg Injection by Usawa Pharmaceuicals (Reg# 060250) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 982. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | XPIME 2gm IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41897: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial Contains:<br>Cefepime (as hydrochloride)…2gm<br>With L-Arginine |
| | Pharmacological Group | 4th Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefipime hydrochloride 2g Injection by M/s Hospira, Inc. (USFDA approved) |
| | Me-too Status | Pimax Injection 2g by M/s Hilton Pharma (Reg#042114) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 983. | Name and Address of Manufacturer / Applicant | M/s Maxitech Pharma (Pvt) Ltd,<br>Factory, E-178, SITE, Karachi |
| | Brand Name + Dosage Form + Strength | XPIME 500mg IM/IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 41898: 07-12-2018 PKR 20,000/-: 7-12-2018 |
| | Composition | Each Vial Contains:<br>Cefepime (as hydrochloride)…500mg<br>With L-Arginine |
| | Pharmacological Group | 4th Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cefipime hydrochloride 500mg Injection by M/s Hospira, Inc. (USFDA approved) |
| | Me-too Status | Uspime 500mg Injection by Usawa Pharmaceuicals (Reg# 060251) |
| | GMP Status | Last inspection report dated 11-6-2018 confirms satisfactory compliance to GMP |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

**Evaluator PEC-XIII**

| | | |
|---|---|---|
| 984. | Name and address of manufacturer / Applicant | M/s Horizon Healthcare (Pvt.) Ltd, Plot # 35-A Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Vinocare Injection 500mg |
| | Composition | Each vial contains:<br>Vancomycin as Hydrochloride (lyophilized ready-to-fill powder).....500mg |
| | Diary No. Date of R& I & fee | Dy. No. 24744; 17-07-2018; Rs.20,000/- (13-07-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form -5 |
| | Finished product Specification | U.S.P. |

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|---|---|---|
| | Pack size & Demanded Price | 1x 1's vial & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Hisun injection 500mg of M/s Bio- Care Pharma (Reg.# 052214) |
| | GMP status | Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II. |
| | Remarks of the Evaluator | • General Dry powder Vial section is available in the firm as mentioned in the GMP inspection report. |
| | **Decision: Deferred for the confirmation of details of already considered products as priority for new section.** | |
| 985. | Name and address of manufacturer / Applicant | M/s Horizon Healthcare (Pvt.) Ltd, Plot # 35-A Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Vinocare Injection 1g |
| | Composition | Each vial contains:<br>Vancomycin as Hydrochloride (lyophilized ready-to-fill powder).....1g |
| | Diary No. Date of R& I & fee | Dy. No. 24742; 17-07-2018; Rs.20,000/- (13-07-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form -5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | 1x 1's vial & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Vancocin injection 1 g of M/s Biolabs Laboratories (Reg.# 075191) |
| | GMP status | Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II. |
| | Remarks of the Evaluator | • General Dry powder Vial section is available in the firm as mentioned in the GMP inspection report. |
| | **Decision: Deferred for the confirmation of details of already considered products as priority for new section.** | |
| 986. | Name and address of manufacturer / Applicant | M/s Horizon Healthcare (Pvt.) Ltd, Plot # 35-A Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Erynate Injection 30mg |
| | Composition | Each vial contains:<br>Artesunate ……...30mg |
| | Diary No. Date of R& I & fee | Dy. No. 24741; 17-07-2018; Rs.20,000/- (13-07-2018) |
| | Pharmacological Group | Antimalarial |
| | Type of Form | Form -5 |
| | Finished product Specification | Innovator's |
| | Pack size & Demanded Price | Pack of one vial containing Artesunate 30mg + 1 ampoule of w. f. i. 5ml+ 1 ampoule 2ml Lignocaine (1x 1's) & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | WHO recommended formulation |
| | Me-too status | Gen-M Injection by M/s Genix Pharma (Reg#076072) |
| | GMP status | Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II. |
| | Remarks of the Evaluator | • The official monograph for the applied formulation is available in International Pharmacopoeia.<br>• General Dry powder Vial section is available in the firm. |
| | **Decision: Deferred for the confirmation of details of already considered products as priority for new section.** | |

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|---|---|---|
| 987. | Name and address of manufacturer / Applicant | M/s Horizon Healthcare (Pvt.) Ltd, Plot # 35-A Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Erynate Injection 60mg |
| | Composition | Each vial contains:<br>Artesunate ……..60mg |
| | Diary No. Date of R& I & fee | Dy. No. 24743; 17-07-2018; Rs.20,000/- (13-07-2018) |
| | Pharmacological Group | Antimalarial |
| | Type of Form | Form -5 |
| | Finished product Specification | Innovator's |
| | Pack size & Demanded Price | Pack of one vial containing Artesunate 60mg + 1 ampoule of w. f. i. 5ml+ 1 ampoule 2ml Lignocaine (1x 1's) & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | WHO prequalified formulation |
| | Me-too status | Misonate 60mg Injection of M/s Tabros Pharma<br>(Reg. # 057719) |
| | GMP status | Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II. |
| | Remarks of the Evaluator | • The official monograph for the applied formulation is available in International Pharmacopoeia.<br>• General Dry powder Vial section is available in the firm. |
| | **Decision: Deferred for the confirmation of details of already considered products as priority for new section.** | |
| 988. | Name and address of manufacturer / Applicant | M/s Horizon Healthcare (Pvt.) Ltd, Plot # 35-A Small Industrial Estate, Taxilla. |
| | Brand Name +Dosage Form + Strength | Erynate Injection 120mg |
| | Composition | Each vial contains:<br>Artesunate ……..120mg |
| | Diary No. Date of R& I & fee | Dy. No. 24745; 17-07-2018; Rs.20,000/- (13-07-2018) |
| | Pharmacological Group | Antimalarial |
| | Type of Form | Form -5 |
| | Finished product Specification | Innovator's |
| | Pack size & Demanded Price | Pack of one vial containing Artesunate 120mg + 1 ampoule of w. f. i. 5ml + 1 ampoule 2ml Lignocaine (1x 1's) & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | WHO prequalified formulation |
| | Me-too status | Gen-M Injection by M/s Genix Pharma Karachi (Reg. # 076073) |
| | GMP status | Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II. |
| | Remarks of the Evaluator | • The official monograph for the applied formulation is available in International Pharmacopoeia.<br>• General Dry powder Vial section is available in the firm. |
| | **Decision: Deferred for the confirmation of details of already considered products as priority for new section.** | |

## d. Deferred cases

**Evaluator PEC-VIII**

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|---|---|---|
| 989. | Name and address of Manufacturer / Applicant | M/s Winlet Pharmaceuticals 30km Sargodha Road, Lahore. |
| | Brand Name +Dosage Form +Strength | Ciplox750mg tablets |
| | Composition | Each film coated tablet contains:<br>Ciprofloxacin hydrochloride …750mg |
| | Diary No. Date of R&I & fee | DyNo.13639; 12-04-2018; Rs. 20,000/- |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Ciprobid tablet 750mg of Nova pharmaceuticals |
| | GMP status | New License (Issuance Date: 26th Feb 2018) |
| | Remarks of Evaluator | |
| | Previous decision | Registration Board in its 282nd meeting deferred the case for the following reasons:<br>• Clarification of composition as reference product is approved as Ciprofloxacin (as hydrochloride monohydrate) 750 mg film coated tablet which is different from applied formulation i.e ciprofloxacin hydrochloride 750 film coated tablet.<br>• Submission of fee for revision of formulation. |
| | Evaluation by PEC | The firm has now submitted the following:<br>• Revised Form 5, Master Formulation, Manufacturing Method in-Line with reference product so the new composition is as follows:<br>Each film coated tablet contains:<br>Ciprofloxacin (as hydrochloride) …750mg<br>• Applicant further submitted that as it is only correction in equivalency of salt of API which requires no fee. |
| | **Decision:Approved** | |
| 990. | Name and address of Manufacturer / Applicant | M/s Winlet Pharmaceuticals 30km Sargodha Road, Lahore. |
| | Brand Name +Dosage Form +Strength | Ciplox tablet 250mg |
| | Composition | Each film-coated tablet contains:<br>Ciprofloxacin hydrochloride ….....250mg |
| | Diary No. Date of R&I & fee | DyNo.13637; 12-04-2018; Rs. 20,000/- |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP specifications |
| | Pack Size & Demanded Price | 10's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA<br>Ciproxin 250mgFilm-CoatedTablets by Bayer |
| | Me-too status | Ciprobid tablet 250mg of Nova pharmaceuticals |
| | GMP status | New License (Issuance Date: 26th Feb 2018) |
| | Remarks of Evaluator | |
| | Previous decision | Registration Board in its 282nd meeting deferred the case for the following reasons:<br>• Clarification of composition as reference product is approved as Ciprofloxacin (as hydrochloride monohydrate) 250 mg film coated tablet which is different from applied formulation i.e ciprofloxacin hydrochloride 250 film coated<br>• Submission of fee for revision of formulation. |
| | Evaluation by PEC | The firm has now submitted the following:<br>• Revised Form 5, Master Formulation, Manufacturing Method in-Line with reference product so the new composition is as follows: |

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|---|---|---|
| | | Each film coated tablet contains:<br>Ciprofloxacin (as hydrochloride) …250mg<br>• Applicant further submitted that as it is only correction in equivalency of salt of API which requires no fee. |
| | **Decision:Approved** | |
| 991. | Name and address of Manufacturer / Applicant | M/s Winlet Pharmaceuticals 30km Sargodha Road, Lahore. |
| | Brand Name +Dosage Form +Strength | Ciplox tablet 500mg |
| | Composition | Each film coated tablet contains:<br>Ciprofloxacin hydrochloride … 500mg |
| | Diary No. Date of R&I & fee | DyNo.13638; 12-04-2018; Rs. 20,000/- |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP specifications |
| | Pack Size & Demanded Price | 10's, 14's, 28's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status | Ciprobid tablet 500mg of Nova pharmaceuticals |
| | GMP status | New License (Issuance Date: 26th Feb 2018) |
| | Remarks of Evaluator | |
| | Previous decision | Registration Board in its 282nd meeting deferred the case for the following reasons:<br>• Clarification of composition as reference product is approved as Ciprofloxacin (as hydrochloride monohydrate) 500 mg film coated tablet which is different from applied formulation i.e ciprofloxacin hydrochloride 500 film coated<br>• Submission of fee for revision of formulation. |
| | Evaluation by PEC | The firm has now submitted the following:<br>• Revised Form 5, Master Formulation, Manufacturing Method in-Line with reference product so the new composition is as follows:<br>Each film coated tablet contains:<br>Ciprofloxacin (as hydrochloride) …500mg<br>• Applicant further submitted that as it is only correction in equivalency of salt of API which requires no fee. |
| | **Decision:Approved** | |

The firm has requested for withdrawal of their already applied one molecule i.e. Amlodipine as besylate/ Telmisartan Combination tablet having following strengths 10/40, 10/80 ,5/40,5/80, which was considered in 281st RB meeting against New License (Tablet General Section) the applicant further requested to replace the above stated molecule with Nebivolol 5mg, & 10mg.

**APPLICATIONS TO BE CONSIDERED IN REPLACEMENT**

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|---|---|---|
| 992. | Name and address of Manufacturer / Applicant | M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore |
| | Brand Name + Dosage Form+ Strength | Medivolol 5mg Tablet |
| | Composition | Each Tablet Contains:<br>Nebivolol…5mg |
| | Diary No. Date of R&I & fee | Dy No. 12605 ; 05-04-18: Rs.20,000 |
| | Pharmacological Group | Beta blocker |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator |
| | Pack Size & Demanded Price | 10's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Nebil 5mg Tablet of Getz Karachi |
| | GMP status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |

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|---|---|---|
| 993. | Name and address of Manufacturer/Applicant | M/s Medpharm Research Lab 28 km, Ferozepur Road, Lahore |
| | Brand Name + Dosage Form + Strength | Medivolol 2.5mg Tablet |
| | Composition | Each Tablet Contains:<br>Nebivolol…2.5mg |
| | Diary No. D of R & I & Fee | Dy No. 12604 ; 05-04-18: Rs.20,000 |
| | Pharmacological group | Beta blocker |
| | Type of Form | Form 5 |
| | Finished product Specifications | Innovator |
| | Pack Size & demanded price | 10's: As per SRO |
| | Approval status of product in reference regulatory authorities | Approved in US-FDA |
| | Me-too status | Nebil 2.5mg Tablet of Getz Karachi |
| | GMP Status | GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| **PREVIOUSLY DEFERRED APPLICATIONS** | | |
| **1.** | Name and address of manufacturer / Applicant | M/s MedPharm Research Lab.<br>28-Km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Telmo Tablet 10mg/40mg |
| | Diary No. Date of R& I & fee | Diary No: 12612, 05-04-2018, Rs: 20,000/- |
| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …10mg<br>Telmisartan …40mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan and amlodipine tablet 10mg/40mg by M/s Mylan Pharmaceuticals Inc. (USFDAA approved) |
| | Me-too status | Amtas 10mg +40mg Tablet by M/s Getz Pharma (Pvt) Ltd (Reg#066945) |
| | GMP status | 12-01-2018; Grant of new DML,<br>Panel recommends grant of new DML. |
| | Remarks of the Evaluator. | • In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, while the applied drug is single layered tablet. |
| | **Decision: Registration Board acceded the firm's request of withdrawal and decided to reject Telmo Tablet 10mg/40mg tablet which was previously deferred in 281st RB meeting, since firm does not have required manufacturing facility of bi-layer machine.** | |
| **2.** | Name and address of manufacturer / Applicant | M/s MedPharm Research Lab.<br>28-Km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Telmo Tablet 5mg/40mg |
| | Diary No. Date of R& I & fee | Diary No: 12611, 05-04-2018, Rs: 20,000/- |
| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …5mg<br>Telmisartan …40mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan and amlodipine tablet 5mg/40mg by M/s Mylan Pharmaceuticals Inc. (USFDAA approved) |
| | Me-too status | Amtas 5mg +40mg Tablet by M/s Getz Pharma (Pvt) Ltd (Reg#066943) |
| | GMP status | 12-01-2018; Grant of new DML,<br>Panel recommends grant of new DML. |

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|---|---|---|
| | Remarks of the Evaluator. | ● In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, while the applied drug is single layered tablet. |
| | **Decision: Registration Board acceded the firm's request of withdrawal and decided to reject Telmo Tablet 5mg/40mg tablet which was previously deferred in 281st RB meeting, since firm does not have required manufacturing facility of bi-layer machine.** | |
| **3.** | Name and address of manufacturer / Applicant | **M/s MedPharm Research Lab.**<br>28-Km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | **Telmo Tablet 5mg/80mg** |
| | Diary No. Date of R& I & fee | Diary No: 12613, 05-04-2018, Rs: 20,000/- |
| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …5mg<br>Telmisartan …80mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan and amlodipine tablet 5mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDAA approved) |
| | Me-too status | Amtas 5mg +80mg Tablet by M/s Getz Pharma (Pvt) Ltd (Reg#066944) |
| | GMP status | 12-01-2018<br>Grant of new DML,<br>Panel recommends grant of new DML. |
| | Remarks of the Evaluator. | ● In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, while the applied drug is single layered tablet. |
| | **Decision: Registration Board acceded the firm's request of withdrawal and decided to reject Telmo Tablet 5mg/80mg tablet which was previously deferred in 281st RB meeting, since firm does not have required manufacturing facility of bi-layer machine.** | |
| **4.** | Name and address of manufacturer / Applicant | M/s MedPharm Research Lab.<br>28-Km, Ferozepur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Telmo Tablet 10mg/80mg |
| | Diary No. Date of R& I & fee | Diary No: 12614, 05-04-2018, Rs: 20,000/- |
| | Composition | Each tablet contains:<br>Amlodipine (as besylate) …10mg<br>Telmisartan …80mg. |
| | Pharmacological Group | Angiotensin II antagonists and calcium channel blockers |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 14's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Telmisartan and amlodipine tablet 10mg/80mg by M/s Mylan Pharmaceuticals Inc. (USFDAA approved) |
| | Me-too status | Telsarta-A 10/80 Tablet by M/s Pharmevo (Reg#073767) |
| | GMP status | 12-01-2018<br>Grant of new DML,<br>Panel recommends grant of new DML. |
| | Remarks of the Evaluator. | ● In reference regulatory authorities like in EMA and USFDA the applied drug is multi-layered tablet, while the applied drug is single layered tablet. |
| | **Decision: Registration Board acceded the firm's request of withdrawal and decided to reject Telmo Tablet 10mg/80mg tablet which was previously deferred in 281st RB meeting, since firm does not have required manufacturing facility of bi-layer machine.** | |

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| 994. | Name and address of manufacturer / Applicant | Zeta Pharmaceuticals Plot # 494-A, Sunder Industrial Estate, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Sodazet Sachet |
| | Composition | Each sachet contains:<br>Citric Acid (USP)…….0.72g<br>Sodium Citrate (USP)…….0.63g<br>Sodium Bicarbonate (USP) …..1.76g<br>Tartaric Acid (NF)…… 0.89g |
| | Diary No. Date of R& I & fee | Dy No. 28144: 17.08.2018 PKR 20,000/-: 17.08.2018 |
| | Pharmacological Group | Antacid |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed Innovator's specs. |
| | Pack size & Demanded Price | 20's, Rs. 230/- |
| | Approval status of product in Reference Regulatory Authorities. | Ural Effervescent Granules sachets approved by TGA |
| | Me-too status | Citro Soda granules by Abbott Laboratories. Reg. No. 8749 |
| | GMP status | The firm has granted Additional Section (Sachet, General) on the basis of inspection dated 28.05.2018 |
| | Remarks of the Evaluator. | • The firm revised the composition in Form 5 and revised the formulation from Powder to granules with submission of Rs. 5000/- fee. |
| | Previous decision | • The Board in its 285th meeting deferred the case for submission of differential fee of Rs. 15000/- for revision of strength of applied formulation |
| | Evaluation by PEC | The firm submitted differential fee.<br>Dy No. 3610: 25.01.2019 PKR 15,000/-: 25.01.2019 |
| | **Decision: Approved with innovator's specification.** | |
| 995. | Name and address of manufacturer / Applicant | Zeta Pharmaceuticals Plot # 494-A, Sunder Industrial Estate, Multan Road Lahore |
| | Brand Name +Dosage Form + Strength | Osteozet Sachet |
| | Composition | Each sachet contains:<br>Strontium Renelate…….2g |
| | Diary No. Date of R& I & fee | Dy No. 28146: 17.08.2018 PKR 20,000/-: 17.08.2018 |
| | Pharmacological Group | Drugs for treatment of bone diseases |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed Innovator's specs. |
| | Pack size & Demanded Price | 7's, Rs.770/- |
| | Approval status of product in Reference Regulatory Authorities. | Strontium ranelate Aristo 2 g granules for oral suspension by Aristo Pharma GmbH, approved by MHRA |
| | Me-too status | Strate 2g Sachet by Platinum Pharmaceuticals, Karachi Reg. No. 70841 |
| | GMP status | The firm has granted Additional Section (Sachet, General) on the basis of inspection dated 28.05.2018 |
| | Remarks of the Evaluator. | • The firm revised Strontium Renelate 2mg to Strontium Renelate 2g and from Powder to granule with submission of Rs. 5000/- fee. |
| | Previous decision | • The Board in its 285th meeting deferred the case for submission of differential fee of Rs. 15000/- for revision of strength of applied formulation |
| | Evaluation by PEC | The firm submitted differential fee.<br>Dy No. 3609: 25.01.2019 PKR 15,000/-: 25.01.2019 |
| | **Decision: Approved with innovator's specification.** | |
| 996. | Name and address of manufacturer / Applicant | Trillium Pharmaceuticals (Pvt) Ltd. Plot No. C-3 & C-4 Value Addition City, Faisalabad |
| | Brand Name +Dosage Form + Strength | Triquin Cream 4% |
| | Composition | Each gram contains:<br>Hydroquinone…….4% (w/w) |
| | Diary No. Date of R& I & fee | Dy No. 36206: 31.10.2017 PKR 20,000/-: 31.10.2017 |

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| | Pharmacological Group | Other dermatologicals |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Safoquin Cream 4% by Saffron Pharmaceuticals.Reg. No. 46440 |
| | GMP status | The firm has been granted DML on the basis of inspection dated 03.07.2018 |
| | Remarks of the Evaluator. | • |
| | Previous decision | The board in its 287th meeting, deferred the case for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting. |
| | Evaluation by PEC | • CORRECTOR 4 (hydroquinone 4% w/w) cream. **Health Canada** approved |
| | **Decision: Approved** | |

**Evaluator PEC-XII**

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| 997. | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd.<br>Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | Dylox 30mg Capsule |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43971 dated 27-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each hard gelatin Contains:<br>Enteric coated Pellets of Duloxetine hydrochloride equivalent to Duloxetine (20%w/w)…30 mg |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Duloxetine 30 mg gastro-resistant capsules By Tillomed Laboratories Ltd. (MHRA Approved.) |
| | Me-too Status | SYMPTA Capsules by M/s Polyfine Chempharma (Pvt,) Ltd. (Reg.# 078462) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | • Source of pellets:<br>Alphamed formulations Private Limited,<br>Address: Survey no. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District-500 078, Telangana, India.<br>• Firm has not submitted differential fee for import of pellets. |
| | Previous decision | Registration Board in its 287th meeting deferred the case for the following reason:<br>Deferred for submission of differential fee of Rs. 80,000/- for import of pellets. |
| | Evaluation by PEC | • Firm has submitted COA of pellets from manufacturer.<br>• Firm has submitted stability study data of pellets conducted as per Zone IV-A conditions.<br>• Firm has submitted differential fee of Rs. 80,000/- for import of pellets.(Challan#0810758) |
| | **Decision: Approved** | |
| 998. | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd.<br>Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | Dylox 20mg Capsule |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43970 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018 |
| | Composition | Each hard gelatin Contains:<br>Enteric coated Pellets (17%) of Duloxetine hydrochloride equivalent to Duloxetine…20 mg |

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| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cymbalta (Duloxetine 20 mg capsule) by M/s Eli Lilly, (USFDA Approved) |
| | Me-too Status | Dulan (Duloxetine 20 mg capsule) by M/s Hilton Pharma.(Reg#055446) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | • Source of pellets:<br>Alphamed formulations Private Limited,<br>Address: Survey no. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District-500 078, Telangana, India.<br>• Firm has not submitted differential fee for import of pellets. |
| | Previous decision | Registration Board in its 287th meeting deferred the case for the following reason:<br>Deferred for submission of differential fee of Rs. 80,000/- for import of pellets. |
| | Evaluation by PEC | • Firm has submitted COA of pellets from manufacturer.<br>• Firm has submitted stability study data of pellets conducted as per Zone IV-A conditions.<br>• Firm has submitted differential fee of Rs. 80,000/- for import of pellets.(Challan#0810759) |
| | **Decision: Approved** | |
| 999. | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd.<br>Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | Temolin 0.4mg Capsule |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43975 dated 27-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each hard gelatin Contains:<br>Tamsulosin hydrochloride (as extended release pellets 0.2%w/w)……. 0.4mg |
| | Pharmacological Group | Drugs used in benign prostatic hypertrophy (Alpha-adrenoreceptor antagonists) |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Galebon 0.4 mg prolonged-release hard capsules of M/s Consilient Health Limited (MHRA Approved) |
| | Me-too Status | M-Sol 0.4mg Capsule of M/s Regal Pharmaceuticals (Reg.#081977) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | • Source of pellets:<br>Alphamed formulations Private Limited,<br>Address: Survey no. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District-500 078, Telangana, India.<br>• Firm has not submitted differential fee for import of pellets. |
| | Previous decision | Registration Board in its 287th meeting deferred the case for the following reason:<br>Deferred for submission of differential fee of Rs. 80,000/- for import of pellets. |
| | Evaluation by PEC | • Firm has submitted COA of pellets from manufacturer.<br>• Firm has submitted stability study data of pellets conducted as per Zone IV-A conditions.<br>• Firm has submitted differential fee of Rs. 80,000/- for import of pellets.(Challan#0810755) |
| | **Decision: Approved** | |

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| 1000. | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd.<br>Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | Dylox 60mg Capsule |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43972 (27-12-2018) Rs.20,000/- 27-12-2018 |
| | Composition | Each hard gelatin Contains:<br>Enteric coated Pellets (17%) of Duloxetine hydrochloride equivalent to Duloxetine…60 mg |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Cymbalta (Duloxetine 60 mg capsule) by M/s Eli Lilly, (USFDA Approved) |
| | Me-too Status | Swenta 60mg Capsule by M/s Martin Dow (Reg#070784) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | • Source of pellets:<br>Alphamed formulations Private Limited,<br>Address: Survey no. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District-500 078, Telangana, India.<br>• Firm has not submitted differential fee for import of pellets. |
| | Previous decision | Registration Board in its 287th meeting deferred the case for the following reason:<br>Deferred for submission of differential fee of Rs. 80,000/- for import of pellets. |
| | Evaluation by PEC | • Firm has submitted COA of pellets from manufacturer.<br>• Firm has submitted stability study data of pellets conducted as per Zone IV-A conditions.<br>• Firm has submitted differential fee of Rs. 80,000/- for import of pellets.(Challan#0810757) |
| | **Decision: Approved** | |
| 1001. | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd.<br>Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | O-Fit 120mg Capsule |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43973 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018 |
| | Composition | Each hard gelatin Contains:<br>Orlistat (IR Pellets 50%) ……120mg |
| | Pharmacological Group | Peripherally acting antiobesity products |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Orlistat 120 mg capsules, hard by M/s TEVA UK Limited (MHRA Approved) |
| | Me-too Status | Osker 120mg Capsule by M/s Genix (Reg#066788) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | • Registration board deferred the formulation for clarification of the composition of pellets in its 284th meeting.<br>• Source of pellets not submitted by the firm. |
| | Previous decision | Registration Board in its 287th meeting deferred the case for the following reason:<br>Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. |
| | Evaluation by PEC | • Source of pellets:<br>Alphamed formulations Private Limited,<br>Address: Survey no. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District-500 078, Telangana, India.<br>• Firm has submitted COA of pellets from manufacturer. |

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| | | • Firm has submitted stability study data of pellets conducted as per Zone IV-A conditions.<br>• Firm has submitted differential fee of Rs. 80,000/- for import of pellets.(Challan#0810754) |
| | **Decision: Registration Board deferred the case for further deliberation stability profile of orlistat pellets at accelerated conditions i.e., 40ºC+ 2ºC/ 75%RH+5%.** | |
| 1002. | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd.<br>Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | Xolim 40mg Sachet |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 44147 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018 |
| | Composition | Each Sachet Contains:<br>Esomeprazole as Esomeprazole magnesium trihydrate (enteric coated pellets 22.5%w/w) …40mg |
| | Pharmacological Group | Proton pump inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer specifications |
| | Pack Size & Demanded Price | 5's, 10's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | NEXIUM (esomeprazole magnesium) for delayed-release oral suspension (unit dose packet) by AstraZeneca Pharmaceuticals LP (USFDA Approved) |
| | Me-too Status | Esowin Plus 40mg Sachet of M/s Winthrox Pharmaceuticals, Karachi. (Reg.# 081519) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | • Source of pellets:<br>Alphamed formulations Private Limited,<br>Address: Survey no. 225, Sampanbole Village, Shamirpet Mandal, Medchal-Malkajgiri District-500 078, Telangana, India.<br>• Firm has not submitted differential fee for import of pellets. |
| | Previous decision | Registration Board in its 287th meeting deferred the case for the following reason:<br>Deferred for submission of differential fee of Rs. 80,000/- for import of pellets. |
| | Evaluation by PEC | • Firm has submitted COA of pellets from manufacturer.<br>• Firm has submitted stability study data of pellets conducted as per Zone IV-A conditions.<br>• Firm has submitted differential fee of Rs. 80,000/- for import of pellets.(Challan#0810756) |
| | **Decision: Approved with innovator's specification.** | |

**M/s Hamaz Pharmaceuticals (Pvt.) Ltd,** 13-km, Lutafabad, Bosan Road, Multan

Firm applied for registration of 19 products against their Liquid Injectable (Ampoule/Vial) (General and General Antibiotics section). In the inspection report of the firm, ampoule and vials filling rooms and equipment being mentioned but Licensing Division issued letter for one section for the two separate sections.

As per policy, registration Board considered only 10 products per new section. The 19 applications were placed before the board and the board deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials.

On 17th November 2015, the firm has submitted a request for consideration of their case again in and given priority of 10 products out of 19.

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| 1003. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | Spizole IV Infusion 500mg/100ml |
| | Composition | Each 100 ml vial contains<br>Metronidazole …500mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4810 dated 04-08-2015 |
| | Pharmacological Group | Quinolone Antibiotics |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | Pack of 1 x 100 ml/ price 78. |
| | Approval status of product in Reference | METROZINE metronidazole 500mg in 100mL injection vial by |

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| | Regulatory Authorities | M/s Proqualix Pty Ltd (TGA Approved) |
| | Me-too status | Anarob Injection 500mg/100ml by M/s Global (Reg#026985) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics) |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1004. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | Flikz IV Infusion 100mg/50ml |
| | Composition | Each 50 ml vial contains<br>Fluconazole …100mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4840 dated 04-08-2015 |
| | Pharmacological Group | Antifungal Trizole |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | Pack of 1 x 50 ml/ price 560. |
| | Approval status of product in Reference Regulatory Authorities | DIFLUCAN fluconazole 100mg/50mL injection vial by M/s Pfizer (TGA Approved_ |
| | Me-too status | Syncon Infusion IV 100mg/50ml by M/s Synchro (Reg#083374) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics) |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1005. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | Flacin IV Injection 600 mg/2ml |
| | Composition | Each Vial 02 ml contains<br>Lincomycin (as hydrochloride) …600mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4837 dated 04-08-2015 |
| | Pharmacological Group | Lincosamide |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | Pack of 1 x 02 ml vials / price 55. |
| | Approval status of product in Reference Regulatory Authorities | LINCOCIN 600mg/2mL injection vial by M/s Pfizer Australia Pty Ltd (TGA Approved) |
| | Me-too status | LINCOMYCIN 600MG INJ (vial) by M/s Conagent (Reg#006065) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |

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| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics) |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1006. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | I-MOX IV Infusion 400 mg/250ml |
| | Composition | Each 250 ml vial contains<br>Moxifloxacin (as hydrochloride) …400 mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4830 dated 04-08-2015 |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | Pack of 1 x 250 ml vials / price 1250. |
| | Approval status of product in Reference Regulatory Authorities | AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle by M/s Bayer Australia Ltd (TGA Approved) |
| | Me-too status | Izilon I.V Infusion 400mg/250ml by Bosch (Reg#030074) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics)<br>• **Firm does not have relevant section to manufacture applied product** |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1007. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | Gastid Injection 50mg/2ml |
| | Composition | Each ampoule (2 ml) contains<br>Ranitidine (as hydrochloride) …50 mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4811 dated 04-08-2015 |
| | Pharmacological Group | H2 Blocker |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | MRP. Rs 110.56 for 05 Ampoule |
| | Approval status of product in Reference Regulatory Authorities | ZANTAC 50mg/2mL injection ampoule by M/s Aspen Pharmacare Australia Pty Ltd (TGA Approved) |
| | Me-too status | ULCEMED I.M / I.V INJECTION 50MG / 2ML by M/s MEDICEENA (Reg#023104) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |
| | Remarks of Evaluator | |

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| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics) |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1008. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | Nitid Injection 50mg/2ml |
| | Composition | Each ampoule (2ml) contains<br>Pheniramine Maleate 50 mg equivalent to Pheniramine Salicylate 45.4 mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4823 dated 04-08-2015 |
| | Pharmacological Group | Arylakylamine |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | MRP. Rs 500 for 50 x 02 ml Ampoule<br>MRP Rs 1211 per 100 x 02 ml |
| | Approval status of product in Reference Regulatory Authorities | International availability not confirmed |
| | Me-too status | Not confirmed |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics)<br>• Approval status of product in Reference Regulatory Authorities **not** confirmed<br>• Me-too status **not** confirmed from available database. |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1009. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | M.B Vit Injection 500 mcg/ml |
| | Composition | Each ampoule (1 ml) contains<br>Mecobalamin…500 mcg |
| | Diary No. Date of R&I & fee | Coenzyme Type Vitamin B12 |
| | Pharmacological Group | Rs. 20,000/- vide Dy. No. 4836 dated 04-08-2015 |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacture Specification |
| | Pack Size & Demanded Price | MRP Rs 814 per 10 Ampoules |
| | Approval status of product in Reference Regulatory Authorities | Methycobal (ampoule)of M/s Eisai Company Ltd (PMDA Japan Approved) |
| | Me-too status | METHYCOBAL INJECTION 0.5mg/ml of M/s PROGRESSIVE ASSOCIATE (Reg#010313) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |

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| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics) |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1010. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | Vialox IV Infusion 200mg/100ml |
| | Composition | Each 100 ml vial contains<br>Ofloxacin hydrochloride 220 mg eq to Ofloxacin 200 mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4808 dated 04-08-2015 |
| | Pharmacological Group | Quinolone Antibiotics |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | Pack of 1 x 100 ml/ price 768. |
| | Approval status of product in Reference Regulatory Authorities | Tarivid® 200mg/100ml Solution for Infusion (Vial) by M/s Sanofi-Aventis (MHRA approved) |
| | Me-too status | Adios Injection 200mg/100ml by M/s Wilshire (Reg#032350) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |
| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics)<br>• Firm has applied as Ofloxacin (as hydrochloride) …200 mg ,whereas, formulation approved in MHRA is Ofloxacin …200 mg |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |
| 1011. | Name and address of Manufacturer / Applicant | M/s. Hamaz Pharmaceuticals (Pvt.) Ltd;<br>13 km, Bosan road, Lutfabad, Multan |
| | Brand Name +Dosage Form +Strength | Linor IV Injection 200 mg/100ml |
| | Composition | Each 100 ml contains<br>Linezolid …200mg |
| | Diary No. Date of R&I & fee | Rs. 20,000/- vide Dy. No. 4831 dated 04-08-2015 |
| | Pharmacological Group | Oxazolidinone, Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacture Specification |
| | Pack Size & Demanded Price | Pack of 1 x 100 ml vial /price 346.<br>1 x 200 ml vial/ price 400<br>1 x 300 ml vial / Price 600 |
| | Approval status of product in Reference Regulatory Authorities | FDA approved Linezolid (Sandoz) |
| | Me-too status | Zolrest 200mg / 100ml Infusion by M/s Bosch (Reg#055914) |
| | GMP status | Certificate of last, GMP Inspection dated 01.08.2017 with cGMP compliance. |

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| | Remarks of Evaluator | |
| | Previous Decision | Registration Board in its 253rd meeting deferred the case for the following reason:<br>Deferred for clarification from Central Licensing Board regarding separate section for ampoule and vials. |
| | Evaluation by PEC | • The firm has requested Registration board to consider the applied formulations on its turn basis.<br>• Firm has the following section:<br>Liquid Injectable (Ampoule/Vial) (General and General Antibiotics) |
| | **Decision: Registration Board deferred the case for confirmation of details of approved manufacturing facility, whether it is for Small Volume Parentrals or Large Volume Parentrals.** | |

**Case No. 04: Registration Applications for Local Manufacturing of (Veterinary) Drugs.**

**a. New cases**

**Evaluator PEC-IV**

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| 1012. | Name and address of manufacturer / Applicant | M/S Intervac (Pvt) Ltd., 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Oxytofas- DS Injection |
| | Composition | Each 100ml contains:<br>Oxytocin ( Synthetic)…….2000IU |
| | Diary No. Date of R& I & fee | Dy.No.8143; 10-07-2017; Rs.20,000/- (10-07-2017) |
| | Pharmacological Group | Hormone |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 50ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Oxytovet Injection Of M/S International Pharma Labs. |
| | GMP status | Last inspection conducted on 28-02-2017 & 17-03-2017 and report concludes that panel recommend the renewal of injectable section (veterinary) and vaccines section (veterinary). |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for further deliberation regarding applied fill volume.** | |
| 1013. | Name and address of manufacturer / Applicant | M/S Intervac (Pvt) Ltd., 18-Km, Lahore Sheikhupura Road, Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | Oxytofas- DS Injection |
| | Composition | Each 100ml contains:<br>Oxytocin ( Synthetic)…….2000IU |
| | Diary No. Date of R& I & fee | Dy.No.8144; 10-07-2017; Rs.20,000/- (10-07-2017) |
| | Pharmacological Group | Hormone |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 100ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Oxytovet Injection Of M/S International Pharma Labs. |
| | GMP status | Last inspection conducted on 28-02-2017 & 17-03-2017 and report concludes that panel recommend the renewal of injectable section (veterinary) and vaccines section (veterinary). |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for further deliberation regarding applied fill volume.** | |
| 1014. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Multi-Wal Injection |

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|---|---|---|
| | Composition | Each ml contains:<br>Vitamin B1…5mg<br>Vitamin B2…2.5mg<br>Vitamin B6…2.5mg<br>Nicotinamide…37.5mg |
| | Diary No. Date of R& I & fee | Dy.No 5296 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Pharmacological Group | Multivitamin |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 50ml,Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Vitamin B Complex Of M/S Amros Pharmaceuticals |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |
| 1015. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Keto-Wal Injection |
| | Composition | Each ml contains:<br>Ketprofen BP…100mg |
| | Diary No. Date of R& I & fee | Dy.No 5304 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specification |
| | Pack size & Demanded Price | 50ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Ketoshell Injection Of M/S. Inshal Pharmaceutical |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |
| 1016. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | GCD-Wal Injection |
| | Composition | Each 100ml contains:<br>Gentamicin suplhate BP…5g<br>Colistin Sulpahte BP…50 MIU<br>Dihydrostreptomycin Sulphate BP…10g |
| | Diary No. Date of R& I & fee | Dy.No 5303 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specificaton |
| | Pack size & Demanded Price | 100ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Tg-65 Injection Of M/S Attabak Pharmaceutical |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications.** | |

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| 1017. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | GTS-MIX Injection |
| | Composition | Each ml contains:<br>Gentamicin Sulpahte BP…30mg<br>Trimethoprim BP…25mg<br>Sulfadimidine…125mg |
| | Diary No. Date of R& I & fee | Dy.No 5293 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specificaton |
| | Pack size & Demanded Price | 100ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Alfacin Plus Injection. Of M/S Alina Combine Pharmaceuticals |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |
| 1018. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Bersen-Wal Injection |
| | Composition | Each ml contains:<br>Trimethoprim BP…80mg<br>Sulfadiazine BP…400mg |
| | Diary No. Date of R& I & fee | Dy.No 5294 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specifications | BP |
| | Pack size & Demanded Price | 100ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Trimdiazine Injection Of M/S Elko Organisation |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |
| 1019. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Nitrox-200 Injection |
| | Composition | Each ml contains:<br>Nitroxynil BP…200mg |
| | Diary No. Date of R& I & fee | Dy.No 5302 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacuture specification |
| | Pack size & Demanded Price | 100ml:Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Nitoxil-20% Injection Of M/S Star Laboratories |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |

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| 1020. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Meloxi-Wal Injection |
| | Composition | Each ml contains:<br>Meloxicam BP…10mg |
| | Diary No. Date of R& I & fee | Dy.No 5301 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specifications | BP |
| | Pack size & Demanded Price | 50ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Meloxi-10 Injection Of M/S Selmore Pharmaceuticals |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |
| 1021. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Davo Injection |
| | Composition | Each ml contains:<br>Diminazene aceturate…105mg<br>Antipyrine BP…131mg<br>Vitamin B12 BP…4mg |
| | Diary No. Date of R& I & fee | Dy.No 5292 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antihelmentic, vitamin |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufactures specification |
| | Pack size & Demanded Price | 50ml,:Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Dipyrene Plus Injection Of M/ Breeze Pharma |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |
| 1022. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Nitrox-340 Injection |
| | Composition | Each ml contains:<br>Nitroxynil BP…340mg |
| | Diary No. Date of R& I & fee | Dy.No 5297 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacuture specification |
| | Pack size & Demanded Price | 100ml:Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Nixil Injection. Of M/S Hilton Pharma (Pvt) Ltd. Karachi. . |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |

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| 1023. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Dipyrine Injection |
| | Composition | Each ml contains:<br>Diminazene aceturate…105mg<br>Antipyrine BP…131mg |
| | Diary No. Date of R& I & fee | Dy.No 5291 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Anthelmentic, Vitamin |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml,; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Diamin Plus Injection. Of M/S Alina Combine Pharmaceutical |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Registration Board referred the case to Expert Committee for Veterinary Drugs.** | |
| 1024. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | IVO-Super Injection |
| | Composition | Each ml contains:<br>Ivermectin (USP)…10mg<br>Clorsulon (USP)…100mg |
| | Diary No. Date of R& I & fee | Dy.No 5290 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 50ml,: Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | Ivoron Super Injection Of M/S Breeze Pharma Islamabad |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |
| 1025. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Floxacin-10% Injection |
| | Composition | Each ml contains:<br>Enrofloxacin BP…100mg |
| | Diary No. Date of R& I & fee | Dy.No 5295 dated 14-02-2018 Rs. 20,000/- 13-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | 50ml, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status (with strength and dosage form) | El-Floxacin Injection Of M/S Elko Organisation Karachi |
| | GMP status | Last inspection conducted on 10-10-2017 report concludes that overall evalution of the inspection report is good |
| | Remarks of the Evaluator | |
| | **Decision: Approved with Innovator's specifications** | |

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| 1026. | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | LICOSON Oral W/S Powder |
| | Composition | Each g contains:-<br>Lincomycin HCl……100mg<br>Colistin sulphate ……. 800,000IU |
| | Diary No., Date of R & I & Fee | Dy.6438, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotics |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 016204; Lincocol-W/S Powder<br>M/S International Champharma Lahore |
| | GMP Status | GMP Inspection conducted on 14/12/2017. Good |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1027. | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | FON-MAARS Oral W/S Powder |
| | Composition | Each 100g contains:-<br>Oxytetracycline HCl ……. 300mg<br>Florfenicol ……. 100mg<br>Neomycin Sulphate ……. 150mg |
| | Diary No., Date of R & I & Fee | Dy.6449, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotics |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 081733; E-Col Water Soluble Powder<br>M/s. Evergreen Pharmaceuticals, Lahore. |
| | GMP Status | GMP Inspection conducted on 14/12/2017. Good |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1028. | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | DT-60 Oral W/S Powder |
| | Composition | Each 100g contains:-<br>Doxycycline HCl ……..…… 40g<br>Tylosin tartrate ……..…….. 20g |
| | Diary No., Date of R & I & Fee | Dy.6441, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotics |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 063807; M Kill-TD Water Soluble Powder<br>M/s Biogen Pharma, Rawat Chak Beli Road, Rawat. |
| | GMP Status | GMP Inspection conducted on 14/12/2017. Good |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |

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| 1029. | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | D-ZINE Oral W/S Powder |
| | Composition | Each g contains:-<br>Piperazine Citrate …… 1000mg |
| | Diary No., Date of R & I & Fee | Dy.6440, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antiparasitics |
| | Type Of Form | Form 5 |
| | Finished product Specification | BP |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 034530<br>Piperapure-1000 Water Soluble Powder.<br>By Attabak Pharmaceutical Industries, Islamabad. |
| | GMP Status | GMP Inspection conducted on 14/12/2017. Good |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1030. | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | DINESON Oral W/S Powder |
| | Composition | Each 100g contains:-<br>Amantadine HCl ……98g |
| | Diary No., Date of R & I & Fee | Dy.6442, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Anti-Viral |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 081735; EMANTA-98 ORAL POWDER<br>M/s. Evergreen Pharmaceuticals,<br>69-70/B, Main Glaxo Town, Industrial Area, 20th Km Ferozpur Road, Lahore. |
| | GMP Status | GMP Inspection conducted on 14/12/2017. Good |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1031. | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | ECIDINE 10% Oral W/S Powder |
| | Composition | Each 100g contains:-<br>Amantadine HCl ……10g |
| | Diary No., Date of R & I & Fee | Dy.6443, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Anti-Viral |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 075697<br>Amantabak 10% Powder<br>"M/S. Attabak Pharmaceuticals,<br>Plot # 5c, I-10/3, Industrial Area, Islamabad." |
| | GMP Status | GMP Inspection conducted on 14/12/2017. Good |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |

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| 1032. | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | NEO-MAARS Oral W/S Powder |
| | Composition | Each 100g contains:-<br>Neomycin Sulphate ……72g |
| | Diary No., Date of R & I & Fee | Dy.6447, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotics |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 043588; Velle Neomycin W.S. Powder.<br>By M.S K&K PHARMACEUTICALS, LAHORE |
| | GMP Status | GMP Inspection conducted on 14/12/2017. Good |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |

**Evaluator PEC-I**

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| 1033. | Name and address of manufacturer | M/s RAS Pharmaceutical (pvt) ltd. Qadirpir Raan Bypass Near Shalimar Petrolium 25km, Multan. |
| | Brand Name +Dosage Form + Strength | AMPRO C-50 Oral Powder |
| | Diary No. Date of R& I & fee | Diary No:19403, 30-10-2017 , Rs: 20,000/- |
| | Composition | Each gram contains: -<br>Amprolium HCl……..…500mg |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per policy of DRAP. |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | BIO-AMP 50% POWDER (Reg.# 023410) |
| | GMP status | Date of Inspection: 16-10-2018<br>The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for submission of correct pharmacological group** | |
| 1034. | Name and address of man | **M/s RAS Pharmaceutical (pvt) ltd. Qadirpir Raan Bypass Near Shalimar Petrolium 25km, Multan** |
| | Brand Name +Dosage Form + Strength | **DIANIL Oral Suspension** |
| | Diary No. Date of R& I & fee | Diary No:16963, 04-10-2017 , Rs: 20,000/- |
| | Composition | Each 1ml contains: -<br>Sulphadiazine …….35.5mg<br>Sulphadimidine ……...28.4mg<br>Neomycin Sulphate……..…...1.8mg<br>Hyoscine Methylbromide ……...0.04mg<br>Kaolin…….……103.3mg<br>Pectin ……..…… 7.10mg<br>Vitamin B1 ……..0.15mg<br>Vitamin B2 ……..0.22mg |
| | Pharmacological Group | Anti-biotic + Vitamins |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specs. |
| | Pack size & Demanded Price | As per policy of DRAP. |
| | Approval status of product in Reference Regulatory Authorities. | NA |

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| | Me-too status | Peclin-S Oral Suspension. (Reg.# 035132) |
| | GMP status | Date of Inspection: 16-10-2018<br>The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of composition.** | |
| 1035. | Name and address of man | M/s RAS Pharmaceutical (pvt) ltd. Qadirpir Raan Bypass Near Shalimar Petrolium 25km, Multan |
| | Brand Name +Dosage Form + Strength | LINCORAS 11 Feed Premix Powder |
| | Diary No. Date of R& I & fee | Diary No:16962, 04-10-2017 , Rs: 20,000/- |
| | Composition | Each 1kg powder contains: -<br>Lincomycin HCl…….….. 11gm |
| | Pharmacological Group | Anti-biotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per policy of DRAP. |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | JFLINCON ORAL POWDER. (Reg.# 043245) |
| | GMP status | Date of Inspection: 16-10-2018<br>The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| 1036. | Name and address of man | M/s RAS Pharmaceutical (pvt) ltd. Qadirpir Raan Bypass Near Shalimar Petrolium 25km, Multan |
| | Brand Name +Dosage Form + Strength | RENOTON Powder |
| | Diary No. Date of R& I & fee | Diary No:16961, 04-10-2017 , Rs: 20,000/- |
| | Composition | Each 100g contains: -<br>Ammonium Chloride……. .45gm<br>Magnesium Sulphate……25gm<br>Sodium Sulphate……...25gm<br>Sorbitol…….5.0gm |
| | Pharmacological Group | Feed Supplements as Diuretic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specs. |
| | Pack size & Demanded Price | As per policy of DRAP. |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | RENAL PLUS POWDER (Reg.# 043174) |
| | GMP status | Date of Inspection: 16-10-2018<br>The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications** | |
| 1037. | Name and address of man | M/s RAS Pharmaceutical (pvt) ltd. Qadirpir Raan Bypass Near Shalimar Petrolium 25km, Multan |
| | Brand Name +Dosage Form + Strength | DIGESTON Feed Premix Oral Powder |
| | Diary No. Date of R& I & fee | Diary No:16959, 04-10-2017 , Rs: 20,000/- |
| | Composition | Each 100g powder contains: -<br>Olaquindox……..…. 10gm |
| | Pharmacological Group | Anti microbial |

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| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specs. |
| | Pack size & Demanded Price | As per policy of DRAP. |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | OLANDOX POWDER (Reg.# 022151) |
| | GMP status | Date of Inspection: 16-10-2018<br>The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications** | |

**Evaluator PEC-VI**

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| 1038. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Florowan-25 Oral Liquid |
| | Composition | Each 100ml contains:<br>Florfenicol ……25gm |
| | Diary No. Date of R& I & fee | Dy. No. 54; 29-4-2016; Rs.20,000/- (29-4-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacurer's Specification |
| | Pack size & Demanded Price | 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | NOBIFLOR 25% LIQUID Reg # 063639 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1039. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Coliran 25% Oral Solution |
| | Composition | Each 100ml contains:<br>Colistin Sulphate……25gm |
| | Diary No. Date of R& I & fee | Dy. No. 54; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | Mfg |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Colisulph Liquid by Lexicon Karachi (Could not be confirmed) |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached.<br>Me-too status could not be confirmed. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1040. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Coliwan Oral Solution |

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| | Composition | Each 100ml contains:<br>Colistin Sulphate……20gm |
| | Diary No. Date of R& I & fee | Dy. No. 54; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | **Colibiotic by Guytton Pharma Reg no # 034573** |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1041. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Quinocin 25% Oral Liquid |
| | Composition | Each 100ml contains:<br>Enrofloxacin……25gm |
| | Diary No. Date of R& I & fee | Dy. No. 54; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Flunix Liquid by Lead Pharma Islamabad Reg # 046657 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1042. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Bromowan 5% Oral Liquid |
| | Composition | Each 100ml contains:<br>Bromhexine HCl……5gm |
| | Diary No. Date of R& I & fee | Dy. No. 51; 29-4-2016; Rs.20,000/- (29-4-2016) |
| | Pharmacological Group | Mucolytic |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Bromofos by Intervac Pharma Reg # 057108 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |

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| 1043. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | R-Encoras Oral Solution |
| | Composition | Each 100ml contains:<br>Enrofloxacin……10gm<br>Colistin Sulphate…..50 M IU |
| | Diary No. Date of R& I & fee | Dy. No. 56; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Encoras Oral Solution by Zakfas Pharma Multan Reg # 057067 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1044. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Hepavit Super Oral Liquid |
| | Composition | Each 100ml contains:<br>Carnitine…..2500mg<br>Methionine…..1000mg<br>Choline Chloride….1900mg<br>Magnesium Sulphate….1000mg<br>Sorbitol…..20,000mg |
| | Diary No. Date of R& I & fee | Dy. No. 57; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Hepasol Liquid by Intervac Reg # 069657 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1045. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Florax -C Oral Liquid |
| | Composition | Each 100ml contains:<br>Florfenicol ..……10gm<br>Colistin Sulphate……50MIU |
| | Diary No. Date of R& I & fee | Dy. No. 51; 29-4-2016; Rs.20,000/- (29-4-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |

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| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | FLORO-C ORAL LIQUID Reg # '074079 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1046. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Enro-C Oral Solution |
| | Composition | Each 100ml contains:<br>Enrofloxacin….20gm<br>Colistin Sulphate….50 MIU |
| | Diary No. Date of R& I & fee | Dy. No. 57; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 100ml, 200ml, 500ml, 1 Liter, 5 Liter, 25Liter Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | COL-EN 70 LIQUID Reg # 075691 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1047. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | Coli T-30 Oral Powder |
| | Composition | Each 100gm contains:<br>Colistin Sulphate….30gm |
| | Diary No. Date of R& I & fee | Dy. No. 57; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Coli-cure 30% by Westmont Pharma Reg # 071002 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1048. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | RZL-150 Fee Premix Powder |
| | Composition | Each 1kg contains:<br>Zinc Bacitracin……100gm<br>Lincomycin (Lincomycin as HCl)…..50gm |

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| | Diary No. Date of R& I & fee | Dy. No. 57; 29-4-2016; Rs.20,000/- (29-4-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | ZL-150 by Intervac Reg # 069663 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Registration Board referred the applied formulation to Expert Working Group on Veterinary Drugs for review.** | |
| 1049. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | SS-30 Oral Powder |
| | Composition | Each 100gm contains:<br>Sulphaclozine Sodium……30% w/w |
| | Diary No. Date of R& I & fee | Dy. No. 57; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | E-COX ORAL POWDER of M/s Biogen pharma (Reg.# 057033) |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached.<br>Me-too status could not be confirmed. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1050. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | R ONC-154 Oral Powder |
| | Composition | Each 100gm contains:<br>Oxytetracycline HCl…..8gm<br>Neomycin Sulphate….7gm<br>Colistin Sulphate….0.4gm |
| | Diary No. Date of R& I & fee | Dy. No. 57; 29-5-2016; Rs.20,000/- (29-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | ONC-154 by Intervac Pharma Reg # 071035 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |

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| 1051. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | D-50 Oral Powder |
| | Composition | Each 100gm contains:<br>Doxycycline HCl…..50gm |
| | Diary No. Date of R& I & fee | Dy. No. 57; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Seldox Powder by Selmore Reg # 058717 |
| | GMP status | i. 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached.<br>Me-too product contains Doxycycline Hyclate. |
| | **Decision: Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1052. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | TCD-35 Oral Powder |
| | Composition | Each 100gm contains:<br>Tylosin tartrate……10gm<br>Doxycycline HCl….20gm<br>Colistine Sulphate….45 MIU<br>Bromhexine HCl….4gm |
| | Diary No. Date of R& I & fee | Dy. No. 57; 29-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | CD Ras Powder by Zakfas Pharmaceuticals(Could not be confirmed) |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached.<br>Me-too status could not be confirmed. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1053. | Name and address of manufacturer / Applicant | M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, multan |
| | Brand Name +Dosage Form + Strength | RCD-RAS Oral Powder |
| | Composition | Each 100gm contains:<br>Tylosin tartrate……10gm<br>Doxycycline HCl….20gm<br>Colistine Sulphate….5gm<br>Bromhexine HCl…..0.5gm |
| | Diary No. Date of R& I & fee | Dy. No. 57; 25-5-2016; Rs.20,000/- (25-5-2016) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled |

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| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | CD Raas Powder by Zakfas Pharmaceuticals Reg # 057072 |
| | GMP status | 16-10-2018 Firm was operating at the fair level of GMP Compliance. |
| | Remarks of Evaluator | Fee challan Photocopy attached.<br>Me-too product contains Doxycycline Hyclate. |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1054. | Name and address of manufacturer / Applicant | M/s Sanna laboratories, 1019-B, Sargodha road, Faisalabad |
| | Brand Name +Dosage Form + Strength | Broncodox-Forte (Oral Water Soluble Powder) |
| | Composition | Each 100gm contains:<br>Tylosin Tartarate….20gm<br>Doxycycline HCl……40gm<br>Colistin Sulphate…..10gm<br>Bromhexine HCl…..2gm |
| | Diary No. Date of R& I & fee | Dy. No. 51; 11-07-2017 ; Rs.20,000/- (10-07-2017) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovators Specification |
| | Pack size & Demanded Price | 100gm, 300gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Brocotyd by Univet Pharmaceutical, Rawalpindi Reg # 058962 |
| | GMP status | Panel inspection report conducted on 04-07-2017 for grant of GMP certificate concluding fair level of compliance with GMP guidelines. |
| | Remarks of Evaluator | Me-too product contains Doxycycline Hyclate |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1055. | Name and address of manufacturer / Applicant | M/s Star laboratories, 23 KM- Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | Kolivet Injection 50ml |
| | Composition | Each ml contains:<br>Amoxcillin as Trihydrate….100mg<br>Colistin Sulphate……250,000 IU |
| | Diary No. Date of R& I & fee | Dy. No. 18837; 24-10-2017 ; Rs.20,000/- (24-10-2017) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovators Specification |
| | Pack size & Demanded Price | 50ml, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Colimoxin BY Selmore reg # 034576 |
| | GMP status | 27-10-2016 In general GMP Compliance was found good as per guidelines laid down under schedule B and B-II. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| 1056. | **Name and address of manufacturer / Applicant** | **M/s Star laboratories, 23 KM- Multan road, Lahore.** |
| | Brand Name +Dosage Form + Strength | TYZ injection 50ml |
| | Composition | Each ml contains:<br>Gentamycin Sulphate…..100mg<br>Tylosin Tartarate….50mg |
| | Diary No. Date of R& I & fee | Dy. No. 18838; 24-10-2017 ; Rs.20,000/- (24-10-2017) |

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|---|---|---|
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovators Specification |
| | Pack size & Demanded Price | 50ml, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | B.G. GENTA INJECTION Reg # 075624 |
| | GMP status | 27-10-2016 In general GMP Compliance was found good as per guidelines laid down under schedule B and B-II. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| 1057. | Name and address of manufacturer / Applicant | M/s Star laboratories, 23 KM- Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | Ktex injection 50ml |
| | Composition | Each ml contains:<br>Amoxicillin (as Amoxicillin trihydrate)….140mg<br>Clavulanic acid (as Potassium Clavulanate)…35mg |
| | Diary No. Date of R& I & fee | Dy. No. 18836; 24-10-2017 ; Rs.20,000/- (24-10-2017) |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 50ml, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | Clavet Injection Reg # 046519 |
| | GMP status | 27-10-2016 In general GMP Compliance was found good as per guidelines laid down under schedule B and B-II. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| 1058. | Name and address of manufacturer / Applicant | M/s Star laboratories, 23 KM- Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | Ivotek DS injection 50ml |
| | Composition | Each ml contains:<br>Ivermectin…20mg |
| | Diary No. Date of R& I & fee | Dy. No. 18840; 24-10-2017 ; Rs.20,000/- (24-10-2017) |
| | Pharmacological Group | Antiparasitic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 50ml, Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | ZAMEC INJECTION. Reg # 046535 |
| | GMP status | 27-10-2016 In general GMP Compliance was found good as per guidelines laid down under schedule B and B-II. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| 1059. | Name and address of manufacturer / Applicant | M/s Star laboratories, 23 KM- Multan road, Lahore. |
| | Brand Name +Dosage Form + Strength | Ivotek DS injection 10ml |
| | Composition | Each ml contains:<br>Ivermectin…20mg |
| | Diary No. Date of R& I & fee | Dy. No. 18839; 24-10-2017 ; Rs.20,000/- (24-10-2017) |
| | Pharmacological Group | Antiparasitic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 50ml, Decontrolled |

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| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | ZAMEC INJECTION. Reg # 046535 |
| | GMP status | 27-10-2016 In general GMP Compliance was found good as per guidelines laid down under schedule B and B-II. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-VII**

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| 1060. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Quinak Bolus |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3680 dated 29-01-2018 Rs. 20,000 Dated 29-01-2018 |
| | Composition | Each Bolus Contains:<br>Flumiquine…0.35 grams |
| | Pharmacological Group | Antibiotic<br>Cattle, sheep and goat |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 5's, 10's,20's, 50's,100's<br>Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | FLUMIQUIN BOLUS by leads (043585) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1061. | Name and address of manufacturer / Applicant | M/sA & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Moxis-20 Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3691 dated 29-01-2018 Rs. 20,000 Dated 29-01-2018 |
| | Composition | Each 100 gm ontains:<br>Amoxicillin Trihydrate…20 g |
| | Pharmacological Group | Antibiotic<br>Cattle, sheep and goat |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 28 gm,100 gm, 200 gm, Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | AMOXICILLIN 20% SUSPENSION (057155) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1062. | Name and address of manufacturer / Applicant | M/sA & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Colmox-23 powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3690 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each 100 gm contains:<br>Ampicillin as Trihydrate…23 g<br>Colstin Sulphate…100 MIU |
| | Pharmacological Group | Antibiotic |

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| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 28 gm,100 gm, 200 gm,<br>Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | COLI-A POWDER by Gutoyn (044941) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1063. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industrial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Levanew- 300 bolus |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3696 dated 29-01-2018 Rs. 20,000 Dated 29-01-2018 |
| | Composition | Each bolus contains:<br>Levamisole HCL…0.3 grams |
| | Pharmacological Group | Antibiotic<br>Live stock |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 5, 10,20,50 and 100's (4.90 gm bolus) Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | Leva 300 Bolus (Intervac) 073987 |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1064. | Name and address of manufacturer / Applicant | M/sA & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Zisco-AK Bolus |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3679 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each bolus contains:<br>Copper…0.1604 grams<br>Cobalt…0.0032 grams<br>Selenium…0.0032 grams<br>Zinc…0.1443 grams<br>Iodine…0.0171 grams |
| | Pharmacological Group | Antibiotic<br>Dairy cattles |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 5, 10,20,50 and 100's Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | NA |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | Me too not available |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority and evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

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| 1065. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Clopinol-500 Bolus |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3677 dated 29-01-2018 Rs. 20,000 Dated 29-01-2018 |
| | Composition | Each bolus ontains:<br>Closantel…0.5 grams |
| | Pharmacological Group | Antibiotic<br>Dairy cattles |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 5, 10,20,50 and 100's (5.1 gm bolus) Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | FLUKINIL BOLUS (046571) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1066. | Name and address of manufacturer / Applicant | M/sA & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Levoxazole Bolus |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3678 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each bolus contains:<br>Oxyclozanide…2.25 grams<br>Levamisole HCL…1.125 grams |
| | Pharmacological Group | Anthelmentic<br>Cattle, Sheep and goat |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 10, 20,50 and 100's (8.025 gm bolus weight) Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | VERMICIDE BOLUS by Biolabs (034565) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1067. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Parazole-200 Granules |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3686 dated 29-01-2018 Rs. 20,000 Dated 29-01-2018 |
| | Composition | Each gram contains:<br>Albendazole…200 mg |
| | Pharmacological Group | Anthelmentic<br>Cattle, Sheep and goat |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 10, 20,50 and 100's Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | ALVENAX GRANULES by star labs (026581) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |

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| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1068. | Name and address of manufacturer / Applicant | M/sA & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | LS-Amoxi Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3685 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each gram contains:<br>Amoxicillin Trihydrate…0.2kg<br>Spectinomycin 2HCL…0.08kg<br>Lincomycin HCL…0.08kg<br>Vitamin E Acetate…0.03kg |
| | Pharmacological Group | Antibiotic/ Poultry |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | ASLE WATER SOLUBLE POWDER (079840) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1069. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Strepen ZC-AK Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3695 dated 29-01-2018 Rs.20,000/- 29-01-2018 |
| | Composition | Each kg contains:<br>Procaine Penicillin…0.012kg<br>Zinc Bacitracin…0.052kg<br>Streptomycin Sulphate…0.036kg<br>Colistin Sulphate…0.003kg |
| | Pharmacological Group | Antibiotic<br>Poultry |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | PRO SB-PLUS POWDER (028508) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1070. | Name and address of manufacturer / Applicant | M/sA & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Strepen Z-AK Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3694 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each gram contains:<br>Procaine Penicillin…24 g<br>Zinc Bacitracin…104 g<br>Streptomycin Sulphate…72 g |
| | Pharmacological Group | Antibiotic<br>Poultry |

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| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | Polymycin Plus Powder By Star Labs (027493) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.** | |
| 1071. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Ampicolist-AK Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3681 dated 29-01-2018 Rs. 20,000/-29-01-2018 |
| | Composition | Each gram Contains:<br>Ampicillin as Trihydrate…200mg<br>Colstin Sulphate…600,000 IU |
| | Pharmacological Group | Antibiotic / Calves and lambs |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | NA |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | Me too evidence missing |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority and evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 1072. | Name and address of manufacturer / Applicant | M/sA & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Pro-AK Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3682 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each kg Contains:<br>Procaine Penicillin…12 g<br>Zinc Bacitracin…52 g<br>Streptomycin Sulphate…36 g |
| | Pharmacological Group | Antibiotic<br>Poultry |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | NA |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | 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 referred the case to QA & LT Division to conduct GMP inspection of Firm on priority and evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |

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| 1073. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Tydox 30-BD Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3683 dated 29-01-2018 Rs. 20,000 Dated 29-01-2018 |
| | Composition | Each Kg Contains:<br>Tylosin Tartrate…0.1kg<br>Doxycycline HCL…0.2kg<br>Bromhexine HCL…0.005kg<br>Dihydrostreptomycin…0.02kg |
| | Pharmacological Group | Antibiotic<br>Poultry |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | NA |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | 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 referred the case to QA & LT Division to conduct GMP inspection of Firm on priority and evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |
| 1074. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industrial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Amoxiclave-200 Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3684 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each g Contains:<br>Amoxicillin Trihydrate…160 mg<br>Clavulanic Acid…40 mg |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | CLAVET POWDER of salmore (034582) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority** | |
| 1075. | Name and address of manufacturer / Applicant | M/s A & K pharmaceuticals 94-A Punjab small industraial estae Sargodha road Faisalabad. |
| | Brand Name +Dosage Form + Strength | Moxis-50 Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 3692 dated 29-01-2018 Rs. 20,000/- 29-01-2018 |
| | Composition | Each 1000 gm contains:<br>Amoxicillin Trihydrate…500 g |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 200, 250, 500, 1000, 5kg, 2.5 kg, 15 kg, 10 kg, 25 kg Decontrolled |

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| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | Rymox-50 Water Soluble Powder. (069665) |
| | GMP status | Last GMP inspection conducted on 11-2-2016 and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority** | |

**Evaluator PEC-XII**

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| 1076. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Bromo-Wal 50 Liquid** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5527 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each ml contains:<br>Bromhexine hydrochloride …50mg |
| | Pharmacological Group | Mucolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Bromomont Oral Liquid 5gm/100ml by M/s Westmont Pharmaceutical (Reg#063742) |
| | GMP status | 10-10-2017<br>Renewal of DML<br>Firm is compliant to cGMP requirements. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1077. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Nor-Col Oral Liquid** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5528 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each 100ml contains:<br>Norfloxacin …20g<br>Colistin sulphate …60 MIU |
| | Pharmacological Group | Fluoroquinolone + Polymyxin (antibacterials) |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Coli-Nor Liquid by M/s LEADS PHARMA (PVT) LTD (Reg#049501) |
| | GMP status | 10-10-2017; Renewal of DML<br>Firm is compliant to cGMP requirements. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1078. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Bromo-Wal 10 Liquid |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5529 dated 15-02-2018 Rs. 20,000/- Dated 15-02-201 |

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| | Composition | Each ml Liquid Contains:<br>Bromhexine hydrochloride…10mg |
| | Pharmacological Group | Mucolytics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Brombak Oral Liquid by M/s Attabak Pharmaceutical (Reg#058904) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1079. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Nor-TS Oral Liquid** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5530 dated 15-02-2018 Rs. 20,000/- 15-02-2018 |
| | Composition | Each 100ml contains:<br>Norfloxacin …10g<br>Sulfamethoxypyridazine …15g<br>Trimethoprim …3g |
| | Pharmacological Group | Combinations of antibacterials |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Norplus Liquid by M/s Attabak Pharmaceutical (Reg#034534) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1080. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Sulpha-Wal Liquid** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5526 dated 15-02-2018 Rs. 20,000/- 15-02-2018 |
| | Composition | Each ml contains:<br>Sulfadiazine …35.50mg<br>Sulfadimidine …28.40mg<br>Neomycin sulpahte …1.80mg<br>Hyoscine methylbromide…0.04mg<br>Pectin…7.10mg<br>Kaolin …103.30mg<br>Vitamin B1 …0.15mg<br>Vitamin B2 …0.22mg |
| | Pharmacological Group | Antidiarrheal combination / multivitamin |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Ever-X Suspension by M/s Evergreen Pharmaceuticals (Reg#072691) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |

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| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1081. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Tri-Wal SC Oral Suspension |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5525 dated 15-02-2018 Rs. 20,000/- 15-02-2018 |
| | Composition | Each ml contains:<br>Triclabendazole…50mg<br>Levamisole hydrochloride …37.5mg<br>Cobalt sulphate…0.075g<br>Sodium selenite …0.035g |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | FASINIL PLUS DRENCH by M/s SELMORE PHARMCEUTICALS (PVT) LTD (Reg#035011) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1082. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Gumbo-Wal Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5537 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each 100g contains:<br>Ammonium Chloride …70g<br>DL-Methionine …10g<br>Sorbitol …5g<br>Vitamin A …1,50,000 IU<br>Vitamin C …10g |
| | Pharmacological Group | Diuretic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | PERPHRON-N POWDER by M/s FARIM AID GROUP (Reg#026513) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1083. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Colistin-50% Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5538 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each 100g contains:<br>Colistin sulphate …500 MIU |
| | Pharmacological Group | Antibiotics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg /Decontrolled |

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| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | VELLE COLISTIN W.S. POWDER by M/s K&K PHARMACEUTICALS (Reg#043590) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1084. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Amantadine 10% Powder** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5539 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each 100g contains:<br>Amantadine hydrochloride …10g |
| | Pharmacological Group | Anti-parkinson drugs |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | ANTAMITS WATER SOLUBLE POWDER by M/s WIMITS PHARMACEUTICALS (Reg#078316) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for submission of correct pharmacological group.** | |
| 1085. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Pipera-Wal Powder** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5540 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each gram contains:<br>Piperazine citrate …1000mg |
| | Pharmacological Group | Anthelmintics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Pipra-Fa Powder by M/s Farm Aid Group (Reg#026568) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1086. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | Levamisole-50 Powder |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5541 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each 100gm Powder contains:<br>Levamisole hydrochloride …50g |
| | Pharmacological Group | Anthelmintics |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg /Decontrolled |

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| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | DEWORM WS POWDER by M/s ATTABAK PHARMACEUTICALS (Reg#053927) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1087. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **EN-Flox Powder** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5542 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018 |
| | Composition | Each 100gm powder contains:<br>Enrofloxacin hydrochloride …20g |
| | Pharmacological Group | Fluoroquinolone antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | ENROCIN POWDER by M/s ATTABAK PHARMACEUTICALS (Reg#053919) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1088. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Wal-Fone-C injection** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5305 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Composition | Each 100ml contains:<br>Calcium gluconate…20.83g<br>Magnesium hypophosphate…5.33g<br>Magnesium chloride…2.0g<br>Calcium D-Saccharate…1.0g<br>Boric Acid…4.33g<br>Dextrose anhydrous…20g |
| | Pharmacological Group | Minerals |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 300ml /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Dicalfon-C Injection by M/s Mylabs (Reg#073912) |
| | GMP status | 10-10-2017<br>Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1089. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **LS-Wal Injection** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5289 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |

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| | Composition | Each ml contains:<br>Spectinomycin (as hydrochloride) …100mg<br>Lincomycin (as hydrochloride) …50mg |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100ml /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | SPECTRAL INJECTION. by M/s BREEZE PHARMA (Reg#059120) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1090. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Nixin-Wal Injection** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5299 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Composition | Each ml contains:<br>Flunixin meglumin …50mg |
| | Pharmacological Group | Antiinflammatory and antirheumatic products, non-steroids |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | FLUMEG INJECTION by M/s Elko Organization (Pvt) Ltd (Reg#029631) |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1091. | Name and address of manufacturer / Applicant | M/s Nawal Pahrmaceuticals.<br>Plot No. 11-A, Punjab Small Industrial Estate,Taxila |
| | Brand Name +Dosage Form + Strength | **Wal-D Injection** |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 5300 dated 14-02-2018 Rs. 20,000/- Dated 13-02-2018 |
| | Composition | Each 100 ml contains:<br>Calcium gluconate…20.83g<br>Magnesium hypophosphate…5.33g<br>Magnesium chloride…2.0<br>Calcium D-Saccharate…1g<br>Boric Acid…4.33g<br>Dextrose…20g<br>Vitamin B1…100mg<br>Vitamin B2…70mg<br>Vitamin B12…3000mcg<br>Nicotinamide…200mg |
| | Pharmacological Group | Mineral supplements |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 500ml /Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Not confirmed |
| | GMP status | 10-10-2017; Renewal of DML<br>Panel recommends renewal of DML. |

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| | Remarks of the Evaluator. | • Me-too status not confirmed from available database. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

**Evaluator PEC-XIII**

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| 1092. | Name and address of manufacturer / Applicant | M/s Biolabs (Pvt.) Limited, Plot # 145- Industrial Triangle, Kahutta Road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Biocolistin injection 20% (100ml) |
| | Composition | Each ml contains:<br>Tylosin Tartrate …….200mg |
| | Diary No. Date of R& I & fee | Dy. No. 25507; 21-12-2017; Rs.20,000/- (21-12-2017) |
| | Pharmacological Group | Macrolide Antibiotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1x1 Vial of 100ml & As per PRC |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status | Tysin-200 Injection of M/s Epla Laboratories (Reg. # 026566) |
| | GMP status | GMP certificate granted based on inspection conducted on 5th and 6th Dec, 2017. |
| | Remarks of the Evaluator | • Firm has liquid injection general (Vet) section as is mentioned in the submitted section approval letter. |
| | **Decision: Approved** | |
| 1093. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Cyanoriq 1000 Injection |
| | Composition | Each ml contains:<br>Cyanocobalamin…….1000mcg |
| | Diary No. Date of R& I & fee | Dy. No.7407 (27-02-2018) Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Vitamin |
| | Type of Form | Form 5 |
| | Finished Product Specification | In-house |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Cyanocob-1000 injection of M/s Prix Pharma (Reg. # 074021) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1094. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Tylobar 20 Injection |
| | Composition | Each ml contains:<br>Tylosin tartrate…200mg |
| | Diary No. Date of R& I & fee | Dy. No. 7411 (27-02-2018) Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Tylosan-20 injection of M/s Sanna Lab (Reg.# 027416) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |

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| 1095. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dine-98 Water Soluble Powder |
| | Composition | Each kg Powder contains:<br>Amantadine HCl…0.980KG |
| | Diary No. Date of R& I & fee | Dy. No. 7417 (27-02-2018) Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Anti- Parkinson drug |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100gm, 250gm, 500gm, 1000gm, 2500gm, 5000gm, 10000gm, 25000gm |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Emanta-98 oral powder by Evergreen Pharma Reg.#081735 |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Deferred for submission of correct pharmacological group.** | |
| 1096. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Seleriq Injection |
| | Composition | Each ml contains:<br>Vitamin E as Acetate…50mg<br>Sodium Selenite……...0.5mg |
| | Diary No. Date of R& I & fee | Dy. No 7413 (27-02-2018) Rs. 20,000/- (27-02-2018) |
| | Pharmacological Group | Vitamin with mineral |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Pri-tolevit Plus SE injection by Prix Pharma (Reg.# 080760) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1097. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Ketoriq Injection |
| | Composition | Each ml Contains:<br>Ketoprofen…100mg |
| | Diary No. Date of R& I & fee | Dy.No 7414 dated 27-02-2018 Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Ketoflame-10 injection by Prix Pharma (Reg.# 080747) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1098. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | GTRIQ Injection |
| | Composition | Each ml contains:<br>Gentamycin sulphate…50mg<br>Tylosin tartrate…100mg |

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| | Diary No. Date of R& I & fee | Dy.No 7401 dated 27-02-2018<br>Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | G-Tylo injection by Vetz Pharma (Reg.# 079291) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1099. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Iverclor Injection |
| | Composition | Each ml contains:<br>Ivermectin…10mg<br>Clorsulon…100mg |
| | Diary No. Date of R& I & fee | Dy.No 7406 dated 27-02-2018 Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Ivoshell super injection by Inshall Pharma (Reg.# 080523) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1100. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Hepariq Injection |
| | Composition | Each ml contains:<br>Phenoxy-2 Methyl-2 Propionic Acid…100mg |
| | Diary No. Date of R& I & fee | Dy. No. 7405 dated 27-02-2018 Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Appetizer |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 50ml |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Hepasel injection by Selmore Pharma (Reg.#046518) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Deferred for submission of correct pharmacological group.** | |
| 1101. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dorariq Injection |
| | Composition | Each ml Contains:<br>Doramectin…10mg |
| | Diary No. Date of R& I & fee | Dy. No. 7403 (27-02-2018) Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference | N.A |

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| | Regulatory Authorities. | |
| | Me-too status | Doramec injection by Leads Pharma (Reg.# 043580) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1102. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Enrobar-10 Injection |
| | Composition | Each ml Contains:<br>Enrofloxacin…100mg |
| | Diary No. Date of R& I & fee | Dy. No.7404 (27-02-2018) Rs. 20,000/-(27-02-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Encure-10 injection by Nawan Lab (Reg.# 020803) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1103. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Mecclose Injection |
| | Composition | Each ml contains:<br>Ivermectin…10mg<br>Closantel…125mg |
| | Diary No. Date of R& I & fee | Dy. No. 7408 (27-02-2018) Rs. 20,000/- Dated 27-02-2018 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Ectin- C injection of M/s Decent Pharma (Reg.# 079170) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1104. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Oxfendbar Suspension |
| | Composition | Each ml contains:<br>Oxfendazole……..22.65mg |
| | Diary No. Date of R& I & fee | Dy. No. 7409 (27-02-2018) Rs. 20,000/-(27-02-2018) |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100 ml,250ml,450ml,500ml,1000ml,2500ml,5000ml |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Oxasel Drench by SelmorePharma (Reg.# 071084) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | Finished product monograph is available in USP. |
| | **Decision: Approved** | |
| 1105. | Name and address of manufacturer / | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial |

| | | |
|---|---|---|
| | Applicant | Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Trimobar-S Injection |
| | Composition | Each ml Contains:<br>Sulphadiazine …400mg<br>Trimethoprim…80mg |
| | Diary No. Date of R& I & fee | Dy. No. 7410 (27-02-2018) Rs. 20,000/- (27-02-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Santrin-50 injection by Sanna Lab (Reg.# 033270) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1106. | Name and address of manufacturer / Applicant | M/s Baariq Pharmaceuticals. Plot # 600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Florbar-30 Injection |
| | Composition | Each ml contains:<br>Florfenicol…300mg |
| | Diary No. Date of R& I & fee | Dy. No. 7402 (27-02-2018) Rs. 20,000/- (27-02-2018) |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In- house |
| | Pack size | 100ml |
| | Approval status of product in Reference Regulatory Authorities. | N.A |
| | Me-too status | Florofen injection of M/s Leads Pharma (Reg.# 043160) |
| | GMP status | Last GMP inspection was conducted on 28-08-2018 and the report concludes a satisfactory level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-XIV**

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| 1107. | Name and address of manufacturer / Applicant | M/s Elko Organization Pvt Ltd. Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Elko Cox Oral Liquid |
| | Composition | Each gm contains:<br>Toltrazuril…2.5% (25mg/ml) |
| | Diary No. Date of R& I & fee | Dy.No 4475, 07-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Antiprotozoal agent |
| | Type of Form | Form-5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | 100ml, 250ml, 450ml, 500ml,1L,5L; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Toltragen Oral Solution.by M/s Biogen Pharma (Reg#049715) |
| | GMP status | Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1108. | Name and address of manufacturer / Applicant | M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Elkoflor Oral Solution |

| | | |
|---|---|---|
| | Composition | Each ml contains:<br>Florfenicol…….300mg |
| | Diary No. Date of R& I & fee | Dy.No 4474, 07-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | 100ml, 250ml, 450ml, 500ml,1L,5L; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | MEDIFLOR 30% Oral Solution (Not confirmed) |
| | GMP status | Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1109. | Name and address of manufacturer / Applicant | M/s Elko Organization Pvt Ltd., Plot No.27 & 28, Sector 12-B, North Karachi, Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Elvomec-Tri Drench |
| | Composition | Each ml contains:<br>Triclabendzole……..120mg<br>Ivermectin……2mg |
| | Diary No. Date of R& I & fee | Dy.No 4476, 07-02-2018, Rs. 20,000/-, 06-02-2018 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | 100ml, 250ml, 450ml, 500ml, 1 L, 5 L; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Thunder Drench of Star labs |
| | GMP status | Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1110. | Name and address of manufacturer / Applicant | M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th Km Ferozpur Road, Lahore |
| | Brand Name +Dosage Form + Strength | Lincopec WS Powder |
| | Composition | Each Kg contains:<br>Lincomycin Hydrochloride……0.222Kg<br>Spectinomycin Hydrochloride……0.4447Kg |
| | Diary No. Date of R& I & fee | Dy.No 6818, 21-06-2017, Rs. 20,000/-, 19-06-2017 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | 100gm, 250gm, 500gm, 1000gm, 2500gm; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Spectolin 100 of Baariq Pharma |
| | GMP status | Last inspection report 03-01-2018, panel decided to recommend the renewal of DML. |
| | Remarks of the Evaluator. | The submitted me-too reference could not be verified from available database. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1111. | Name and address of manufacturer / Applicant | M/s Biogen Pharma, 8-Km Rawat Chak Beli Road, Rawat |
| | Brand Name +Dosage Form + Strength | Selectozik IB Water Soluble Powder |

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| | Composition | Each 1000gm contains:-<br>Tylosin Tartrate……100gm<br>Doxycycline HCI……..200gm<br>Amantadione HCI……...40gm<br>Erythrocin……...10gm |
| | Diary No. Date of R& I & fee | 364, 18-01-2011, 8000/-, 17-01-2011, 12000/-, 12-01-2015 |
| | Pharmacological Group | Antibiotic/ Antiviral |
| | Type of Form | Form-5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | 100ml, 250ml, 500ml, 1000ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Biosin TD of Leads Pharma |
| | GMP status | The firm has provided its latest inspection report which was conducted on 18-08-2017 and it concludes good level of GMP Compliance. |
| | Remarks of the Evaluator. | The submitted me-too reference could not be verified from available database. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1112. | Name and address of manufacturer / Applicant | M/s Biogen Pharma, 8-Km Rawat Chak Beli Road, Rawat |
| | Brand Name +Dosage Form + Strength | B.G. Neo Oxyclor Oral Solution |
| | Composition | Each 1000ml contains:-<br>Neomycin Sulphate……150gm<br>Oxytetracycline ……..300gm<br>Chloramphenicol…….300gm<br>Salicylic Acid……..50gm<br>Ascorbic acid……100gm |
| | Diary No. Date of R& I & fee | 422, 20-01-2011, 8000/-, 19-01-2011, 12000/-, 12-01-2015 |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In-house |
| | Pack size & Demanded Price | 100ml, 250ml, 500ml, 1000ml; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Not confirmed. |
| | GMP status | The firm has provided its latest inspection report which was conducted on 18-08-2017 and it concludes good level of GMP Compliance. |
| | Remarks of the Evaluator. | Me-too reference could not be verified. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

**b. Deferred cases**

**Evaluator PEC-VIII**

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| 1113. | Name and address of manufacturer / Applicant | M/s. Decent Pharma plot # 30 Street St 3 National Industrial Zone Rawat - Islamabad. |
| | Brand Name +Dosage Form + Strength | Evomec Super Injection |
| | Composition | Each 1ml contains:-<br>Ivermectin ....10mg<br>Clorsulon…..100mg |
| | Diary No. Date of R& I & fee | Dy. No.1189,02-05-2017, 20,000/-, 28-04-2017 |
| | Pharmacological Group | Anti-parasitic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 50ml(i.m, subcut); Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Actimec plus injection of Selmore Pharmaceuticals (10ML.50ML.100ML.) |
| | GMP status | Panel inspection conducted on 31-08-2018 & 05-09-2018 recommends resumption of production to M/s decent Pharmaceuticals by the competent forum of CLB subject to the following conditions:<br>• The management has agreed not to manufacture sterile products prior to the installation of distillation assembly during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) & retained samples.<br>• The management shall submit monthly progress report to the office of concerned Federal inspector of Drugs on the updated progress on all the undertakings submitted alongside this report.<br>• The management has also undertaken to purchase FTIR within Two months.<br>*(Report by Area FID dated 05-09-2018 verified purchase of FTIR, So the QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production).* |
| | Remarks of the Evaluator | Firm has Liquid injection Vet (general section).<br>Firm is not carrying out Terminal sterilization with this justification that applied drug product is heat sensitive.<br>Firm is using Type II glass with this justification that as it is recommended for acidic, aqueous, & alkaline parenteral preparation by USP. Furthermore product does not contain any ingredients which could react with USP type II glass. USP article 660.<br>*However, The USP article 660 to which the applicant is referring for the choice of container closure system, states following:*<br>*The following recommendations can be made as to the suitability of the glass type for containers for pharmaceutical products, based on the tests for hydrolytic resistance. Type I glass containers are suitable for most products for parenteral and nonparenteral uses. Type II glass containers are suitable for most acidic and neutral aqueous products for parenteral and nonparenteral uses. Type II glass containers may be used for alkaline parenteral products where stability data* |

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| | | *demonstrate their suitability. Type III glass containers usually are not used for parenteral products or for powders for parenteral use, except where suitable stability test data indicate that Type III glass is satisfactory.* |
| | Previous Decision | Registration Board in its 286th Meeting deferred the case for the following reasons:<br>• Rectification of above stated observation in the distillation plant made by Panel during the inspection.<br>• Justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.<br>• Justification on scientific basis for not performing terminal sterilization during manufacturing of applied formulation. |
| | Evaluation By PEC | Now the applicant has submitted the following:<br>• Letter of CLB dated 22nd of January, 2019 confirming resumption of production in the sterile area.<br>• No information is available in B.P (Vet) for use of either type I or type II glass for products containing Ivermectin& brands containing Ivermectin are available in market in type II glass, however, we may opt for type I glass, if recommended by the Registration Board.<br>*(Evaluation By PEC:As monograph for test/analysis of this drug product is not present in BP so referring to B.P for this formulation is not logical, instead, it is present in USP & initially they were also referring to USP, which states following: Preserve in single-dose or multidose containers, preferably of Type I glass or plastic. Store at a temperature not higher than 30°).*<br>• Ivermectin is heat sensitive with melting point of 150C. Terminal sterilization requires pressure 15 pounds & temperature of 121C which is close to the melting point of Ivermectin. So, the terminal sterilization will result in loss of contents of Ivermectin. Further, Pharmacopoeial monographs both in B.P/USP do not mention terminal sterilization for finished product containing Ivermectinhowever, we may opt for terminal sterilization if recommended by the Registration Board.<br>*(Evaluation By PEC: Official books/ Official monographsdon't actually mention any specific method for sterilization of a drug product instead, these states that product should comply to the test for sterility.)* |
| | **Decision: Deferred for justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.** | |
| 1114. | Name and address of manufacturer / Applicant | M/s. Decent Pharma plot # 30Street SS 3 National Industrial Zone Rawat - Islamabad. |
| | Brand Name +Dosage Form + Strength | Clozamax oral suspension 110mg/ml |
| | Composition | Each 1ml contains:-<br>Closantal…. 110mg |
| | Diary No. Date of R& I & fee | Dy. No.1195,02-05-2017, 20,000/-, 28-04-2017 |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form-5 |
| | Finished Product Specification | B.P Specifications |
| | Pack size & Demanded Price | 100ml, 500ml, 1 Litre; Decontrolled |

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| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Closenmall of mallard Pharmaceuticals, Multan (Reg # 046690) (not verifiable) |
| | GMP status | Panel inspection conducted on 31-08-2018 & 05-09-2018 recommends resumption of production to M/s decent Pharmaceuticals by the competent forum of CLB subject to the following conditions:<br>• The management has agreed not to manufacture sterile products prior to the installation of distillation assembly during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) & retained samples.<br>• The management shall submit monthly progress report to the office of concerned Federal inspector of Drugs on the updated progress on all the undertakings submitted alongside this report.<br>• The management has also undertaken to purchase FTIR within Two months.<br>*(Report by Area FID dated 05-09-2018 verified purchase of FTIR, So the QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production).* |
| | Remarks of the Evaluator. | Firm has Liquid Vet (general section).<br>Evidence of Me Too provided by the firm is not verifiable. |
| | Previous Decision | Registration Board in its 286th Meeting deferred the case for the following:<br>• For evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | Evaluation By PEC | Now the firm has submitted Me Too of applied drug product: Closenmall 11% Liquid (Reg No. 046690) Of Mallard Pharmaceuticals, Multan. |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1115. | Name and address of manufacturer / Applicant | M/s. Decent Pharma plot # 30Street SS 3 National Industrial Zone Rawat - Islamabad. |
| | Brand Name +Dosage Form + Strength | Biomectin LA injection |
| | Composition | Each 1ml contains:-<br>Ivermectin…. 20mg |
| | Diary No. Date of R& I & fee | Dy No.1193;02-05-2017 : 20,000/-, 28-04-2017 |
| | Pharmacological Group | Anti-parasitic |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 50ml (i.m, subcut); Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Elvomec D/S. Injection 2% Of Elko Organization (Pvt) Ltd., Karachi (50ML, 100ML) |
| | GMP status | Panel inspection conducted on 31-08-2018 & 05-09-2018 recommends resumption of production to M/s decent Pharmaceuticals by the competent forum of CLB subject to the following conditions:<br>• The management has agreed not to manufacture sterile |

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| | | products prior to the installation of distillation assembly during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) & retained samples.<br>• The management shall submit monthly progress report to the office of concerned Federal inspector of Drugs on the updated progress on all the undertakings submitted alongside this report.<br>• The management has also undertaken to purchase FTIR within Two months.<br>*(Report by Area FID dated 05-09-2018 verified purchase of FTIR, So the QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production).* |
| | Remarks of the Evaluator. | Firm has Liquid injection Vet (general section).<br>Firm is not carrying out Terminal sterilization with this justification that applied drug product is heat sensitive.<br>Firm is using Type II glass with this justification that as it is recommended for acidic, aqueous, & alkaline parenteral preparation by USP. Furthermore product does not contain any ingredients which could react with USP type II glass. USP article 660.<br>*However, The USP article 660 to which the applicant is referring for the choice of container closure system, states following:*<br>*The following recommendations can be made as to the suitability of the glass type for containers for pharmaceutical products, based on the tests for hydrolytic resistance. Type I glass containers are suitable for most products for parenteral and nonparenteral uses. Type II glass containers are suitable for most acidic and neutral aqueous products for parenteral and nonparenteral uses. Type II glass containers may be used for alkaline parenteral products where stability data demonstrate their suitability. Type III glass containers usually are not used for parenteral products or for powders for parenteral use, except where suitable stability test data indicate that Type III glass is satisfactory.* |
| | Previous Decision | Registration Board in its 286th Meeting deferred the case for the following reasons:<br>• Rectification of above stated observation in the distillation plant made by Panel during the inspection.<br>• Justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.<br>• Justification on scientific basis for not performing terminal sterilization during manufacturing of applied formulation. |
| | Evaluation By PEC | Now the applicant has submitted the following:<br>• Letter of CLB dated 22nd of January, 2019 confirming resumption of production in the sterile area.<br>• No information is available in B.P (Vet) for use of either type I or type II glass for products containing Ivermectin& brands containing Ivermectin are available in market in type II glass, however, we may |

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| | | opt for type I glass, if recommended by the Registration Board.<br>• Ivermectin is heat sensitive with melting point of 150C. Terminal sterilization requires pressure 15 pounds & temperature of 121C which is close to the melting point of Ivermectin. So, the terminal sterilization will result in loss of contents of Ivermectin. Further, Pharmacopoeial monographs both in B.P/USP do not mention terminal sterilization for finished product containing Ivermectinhowever; we may opt for terminal sterilization if recommended by the Registration Board.<br>*(Evaluation By PEC: Official books/ Official monographsdon't actually mention any specific method for sterilization of a drug product instead, these states that product should comply to the test for sterility.)* |
| | **Decision: Deffered for justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.** | |
| 1116. | Name and address of manufacturer / Applicant | M/s. Decent Pharma plot # 30Street SS 3 National Industrial Zone Rawat - Islamabad. |
| | Brand Name +Dosage Form + Strength | Solofos Injection |
| | Composition | Each 1ml contains:-<br>Toldfimos sodium …. 100mg |
| | Diary No. Date of R& I & fee | Dy No.1192;02-05-2017 : 20,000/-, 28-04-2017 |
| | Pharmacological Group | Immune booster |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 50ml (i.m, subcut); Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Fosfan Injection Of Selmone Agencies Lahore (20ml, 50ml) |
| | GMP status | Panel inspection conducted on 31-08-2018 & 05-09-2018 recommends resumption of production to M/s decent Pharmaceuticals by the competent forum of CLB subject to the following conditions:<br>• The management has agreed not to manufacture sterile products prior to the installation of distillation assembly during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) & retained samples.<br>• The management shall submit monthly progress report to the office of concerned Federal inspector of Drugs on the updated progress on all the undertakings submitted alongside this report.<br>• The management has also undertaken to purchase FTIR within Two months.<br>*(Report by Area FID dated 05-09-2018 verified purchase of FTIR, So the QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production).* |
| | Remarks of the Evaluator. | Firm has Liquid injection Vet (general section).<br>Firm is not carrying out Terminal sterilization with this justification that applied drug product is heat sensitive.<br>Firm is using Type II glass with this justification that as it is |

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| | | recommended for acidic, aqueous, & alkaline parenteral preparation by USP. Furthermore product does not contain any ingredients which could react with USP type II glass. USP article 660.<br>*However, The USP article 660 to which the applicant is referring for the choice of container closure system, states following:*<br>*The following recommendations can be made as to the suitability of the glass type for containers for pharmaceutical products, based on the tests for hydrolytic resistance. Type I glass containers are suitable for most products for parenteral and nonparenteral uses. Type II glass containers are suitable for most acidic and neutral aqueous products for parenteral and nonparenteral uses. Type II glass containers may be used for alkaline parenteral products where stability data demonstrate their suitability. Type III glass containers usually are not used for parenteral products or for powders for parenteral use, except where suitable stability test data indicate that Type III glass is satisfactory.* |
| | Previous Decision | Registration Board in its 286th Meeting deferred the case for the following reasons:<br>• Rectification of above stated observation in the distillation plant made by Panel during the inspection.<br>• Justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.<br>• Justification on scientific basis for not performing terminal sterilization during manufacturing of applied formulation. |
| | Evaluation By PEC | Now the applicant has submitted the following:<br>• Letter of CLB dated 22nd of January, 2019 confirming resumption of production in the sterile area.<br>• No information is available in B.P (Vet) for use of either type I or type II glass for products containing Ivermectin& brands containing Ivermectin are available in market in type II glass, however, we may opt for type I glass, if recommended by the Registration Board.<br>*(Evaluation By PEC:As monograph for test/analysis of this drug product is not present in BP (vet), so referring to BP (vet), for this formulation is not logical;rather the guidelines given in USP article 660 (stated above) may be used as reference for the choice of container closure system.*<br>• It is heat sensitive with melting point of 150C. Terminal sterilization requires pressure 15 pounds & temperature of 121C which is close to the melting point of Ivermectin. So, the terminal sterilization will result in loss of contents of Ivermectin. Further, Pharmacopoeial monographs both in B.P/USP do not mention terminal sterilization for finished product containing Ivermectinhowever; we may opt for terminal sterilization if recommended by the Registration Board.<br>*(Evaluation By PEC: Official books/ Official monographsdon't actually mention any specific method for sterilization of a drug product instead, these states that product should comply to the test for sterility.)* |
| | **Decision: Deferred for justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.** | |

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| 1117. | Name and address of manufacturer / Applicant | M/s. Decent Pharma plot # 30Street SS 3 National Industrial Zone Rawat - Islamabad. |
| | Brand Name +Dosage Form + Strength | Doramax Injection |
| | Composition | Each 1ml contains:-<br>Doramectin…. 10mg |
| | Diary No. Date of R& I & fee | Dy No.1190;02-05-2017 : 20,000/-, 28-04-2017 |
| | Pharmacological Group | Anti-parasitic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | 50ml (i.m, subcut); Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Dectomax Injectable Solution Of Ghazi Brothers, Karachi. ( 10ml, 20ml, 25ml, 50ml, 200ml, 500ml) |
| | GMP status | Panel inspection conducted on 31-08-2018 & 05-09-2018 recommends resumption of production to M/s decent Pharmaceuticals by the competent forum of CLB subject to the following conditions:<br>• The management has agreed not to manufacture sterile products prior to the installation of distillation assembly during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) & retained samples.<br>• The management shall submit monthly progress report to the office of concerned Federal inspector of Drugs on the updated progress on all the undertakings submitted alongside this report.<br>• The management has also undertaken to purchase FTIR within Two months.<br>*(Report by Area FID dated 05-09-2018 verified purchase of FTIR, So the QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production).* |
| | Remarks of the Evaluator. | Firm has Liquid injection Vet (general section).<br>Firm is not carrying out Terminal sterilization with this justification that applied drug product is heat sensitive.<br>Firm is using Type II glass with this justification that as it is recommended for acidic, aqueous, & alkaline parenteral preparation by USP. Furthermore product does not contain any ingredients which could react with USP type II glass. USP article 660.<br>*However, The USP article 660 to which the applicant is referring for the choice of container closure system, states following:*<br>*The following recommendations can be made as to the suitability of the glass type for containers for pharmaceutical products, based on the tests for hydrolytic resistance. Type I glass containers are suitable for most products for parenteral and nonparenteral uses. Type II glass containers are suitable for most acidic and neutral aqueous products for parenteral and nonparenteral uses. Type II glass containers may be used for alkaline parenteral products where stability data demonstrate their suitability. Type III glass containers usually are not used for parenteral products or for powders for parenteral use, except where suitable stability test data indicate that Type III glass is satisfactory.* |

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| | Previous Decision | Registration Board in its 286th Meeting deferred the case for the following reasons:<br>• Rectification of above stated observation in the distillation plant made by Panel during the inspection.<br>• Justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.<br>• Justification on scientific basis for not performing terminal sterilization during manufacturing of applied formulation. |
| | Evaluation By PEC | Now the applicant has submitted the following:<br>• Letter of CLB dated 22nd of January, 2019 confirming resumption of production in the sterile area.<br>• No information is available in B.P (Vet) for use of either type I or type II glass for products containing Ivermectin& brands containing Ivermectin are available in market in type II glass, however, we may opt for type I glass, if recommended by the Registration Board.<br>*(Evaluation By PEC:As monograph for test/analysis of this drug product is not present in BP (vet), so referring to BP (vet), for this formulation is not logical; rather the guidelines given in USP article 660 (stated above) may be used as reference for the choice of container closure system.*<br>• Doramectin belongs to group Ivermectinwhich is heat sensitive with melting point of 150C. Terminal sterilization requires pressure 15 pounds & temperature of 121C which is close to the melting point of Ivermectin. So, the terminal sterilization will result in loss of contents of Ivermectin. Further, Pharmacopoeial monographs both in B.P/USP do not mention terminal sterilization for finished product containing Ivermectinhowever, we may opt for terminal sterilization if recommended by the Registration Board.<br>*(Evaluation By PEC: Official books/ Official monographsdon't actually mention any specific method for sterilization of a drug product instead, these states that product should comply to the test for sterility.)* |
| | **Decision: Deferred for justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.** | |
| 1118. | Name and address of manufacturer / Applicant | M/s. Decent Pharma plot # 30Street SS 3 National Industrial Zone Rawat - Islamabad. |
| | Brand Name +Dosage Form + Strength | Evomec LA Injection |
| | Composition | Each 1ml contains:-<br>Ivermectin ....10mg |
| | Diary No. Date of R& I & fee | Dy. No.1194,02-05-2017, 20,000/-, 28-04-2017 |
| | Pharmacological Group | Anti-parasitic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack size & Demanded Price | 50ml (i.m, subcut); Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Actimec injection of Selmore Pharmaceuticals (10ML.20ml 50ML.100ML.) |

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| | GMP status | Panel inspection conducted on 31-08-2018 & 05-09-2018 recommends resumption of production to M/s decent Pharmaceuticals by the competent forum of CLB subject to the following conditions:<br>• The management has agreed not to manufacture sterile products prior to the installation of distillation assembly during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) & retained samples.<br>• The management shall submit monthly progress report to the office of concerned Federal inspector of Drugs on the updated progress on all the undertakings submitted alongside this report.<br>• The management has also undertaken to purchase FTIR within Two months.<br>*(Report by Area FID dated 05-09-2018 verified purchase of FTIR, So the QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production).* |
| | Remarks of the Evaluator. | Firm has Liquid injection Vet (general section).<br>Firm is not carrying out Terminal sterilization with this justification that applied drug product is heat sensitive.<br>Firm is using Type II glass with this justification that as it is recommended for acidic, aqueous, & alkaline parenteral preparation by USP. Furthermore product does not contain any ingredients which could react with USP type II glass. USP article 660.<br>*However, The USP article 660 to which the applicant is referring for the choice of container closure system, states following:*<br>*The following recommendations can be made as to the suitability of the glass type for containers for pharmaceutical products, based on the tests for hydrolytic resistance. Type I glass containers are suitable for most products for parenteral and non-parenteral uses. Type II glass containers are suitable for most acidic and neutral aqueous products for parenteral and non-parenteral uses. Type II glass containers may be used for alkaline parenteral products where stability data demonstrate their suitability. Type III glass containers usually are not used for parenteral products or for powders for parenteral use, except where suitable stability test data indicate that Type III glass is satisfactory.* |
| | Previous Decision | Registration Board in its 286th Meeting deferred the case for the following reasons:<br>• Rectification of above stated observation in the distillation plant made by Panel during the inspection.<br>• Justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.<br>• Justification on scientific basis for not performing terminal sterilization during manufacturing of applied formulation. |
| | Evaluation By PEC | Now the applicant has submitted the following:<br>• Letter of CLB dated 22nd of January, 2019 confirming |

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| | | resumption of production in the sterile area.<br>• No information is available in B.P (Vet) for use of either type I or type II glass for products containing Ivermectin& brands containing Ivermectin are available in market in type II glass, however, we may opt for type I glass, if recommended by the Registration Board.<br>• Ivermectin is heat sensitive with melting point of 150C. Terminal sterilization requires pressure 15 pounds & temperature of 121C which is close to the melting point of Ivermectin. So, the terminal sterilization will result in loss of contents of Ivermectin. Further, Pharmacopoeial monographs both in B.P/USP do not mention terminal sterilization for finished product containing Ivermectinhowever, we may opt for terminal sterilization if recommended by the Registration Board.<br>*(Evaluation By PEC: Official books/ Official monographsdon't actually mention any specific method for sterilization of a drug product instead, these states that product should comply to the test for sterility.)* |
| | **Decision: Deferred for justification on scientific basis for preferring Type II glass over Type I glass as a container closure system for applied formulation or otherwise for use of Type I glass container for the applied formulation.** | |
| 1119. | Name and address of manufacturer / Applicant | M/s. Decent Pharma plot # 30Street SS 3 National Industrial Zone Rawat - Islamabad. |
| | Brand Name +Dosage Form + Strength | Choice Oral Powder |
| | Composition | Each kg powder contains:-<br>Doxycycline HCl....400gm<br>Tylosin tartrate….200gm<br>Colistin Sulphate…. 500MIU<br>Bromhexine HCl…. 10gm |
| | Diary No. Date of R& I & fee | Dy. No.1191,02-05-2017, 20,000/-, 28-04-2017 |
| | Pharmacological Group | Anti-bacterial/mucolytic agent |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 100gm, 500gm, 01kg, 2.5kg, 5kg, 10kg, 20kg, 25kg;<br>Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Respi 100 W/S Powder of Dmaarson Pharmaceuticals Rawat. (not verifiable) |
| | GMP status | Panel inspection conducted on 31-08-2018 & 05-09-2018 recommends resumption of production to M/s decent Pharmaceuticals by the competent forum of CLB subject to the following conditions:<br>• The management has agreed not to manufacture sterile products prior to the installation of distillation assembly during this tenure the management has been advised to conduct BET testing on market samples (post market surveillance) & retained samples.<br>• The management shall submit monthly progress report to the office of concerned Federal inspector of Drugs on the updated progress on all the undertakings submitted alongside this report.<br>• The management has also undertaken to purchase FTIR within Two months.<br>*(Report by Area FID dated 05-09-2018 verified purchase of FTIR, So the QA Division vide letter No.F.8-6/2018-QA dated* |

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| | | *18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production).* |
| | Remarks of the Evaluator. | Evidence of Me Too provide by the firm is not verifiable.<br>Firm has submitted letter of CLB dated 12th March, 2013 verifying manufacturing facility "Oral dry Powder Section (vet)". |
| | Previous Decision | Registration Board in its 286th Meeting deferred the case for the following reasons:<br>• For evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. |
| | Evaluation By PEC | Now the firm has submitted Me Too of applied drug product: Fit Respi Water Soluble Powder (Reg No.078268) Of D-Maarson Pharmaceuticals |
| | **Decision: Approved with innovator's specification and change of brand name.** | |

**Evaluator PEC-XIV**

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| 1120. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | FENLOR PLUS ORAL SOLUTION |
| | Composition | Each ml contains:<br>Florfenicol ……100mg |
| | Diary No. Date of R& I & fee | 21-10-2016, Dy. No.2119, Rs.20,000/-, 19-10-2016 |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 150ml, 200ml, 450ml,500ml, 1Litre, 2.5Litre, 5Litre, 10Litre, 20Litre; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Maxi-Flor Liquid of M/s.Biogen Pharma (Reg#075612) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for correction of pharmacological group **(M-286)**. |
| | Evaluation by PEC | The firm has now submitted Pharmacological group as "*Antibacterial/ Amphenicol*". |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1121. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | AQUAFLOR Oral Solution |
| | Composition | Each ml contains:<br>Florfenicol……..…….230mg |
| | Diary No. Date of R& I & fee | 21-10-2016, Dy. No.2116, Rs.20,000/-, 19-10-2016 |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |

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| | Pack size & Demanded Price | 50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Litre, 2.5Litre, 5Litre, 10Litre, 20Litre;Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Neflox solution of Selmore Pharma (Reg # 049647) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for correction of pharmacological group **(M-286)**. |
| | Evaluation by PEC | The firm has now submitted Pharmacological group as "*Antibacterial/ Amphenicol*". |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1122. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | AMCO DOX Water Soluble Powder |
| | Composition | Each Kg powder contains:<br>Doxycycline Hyclate…….. 500g |
| | Diary No. Date of R& I & fee | 21-10-2016, Dy. No.2118, Rs.20,000/-, 19-10-2016 |
| | Pharmacological Group | Antibacterial |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50g, 100g, 500g, 1kg, 5Kg, 10Kg,20Kg; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Riz wan-S W/S Powder of Nawal Pharma |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.<br>QA division vide letter No. F.8-9/2018-QA (M-267-CLB) informed that the firm is directed to resume production activity in sterile area. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm **(M-286)**. |
| | Evaluation by PEC | The firm has submitted me-too reference "Doxyveto-50S Soluble Powder of M/s Orient Traders (Reg#023470)" which has been verified from database. |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1123. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | CTD Oral Powder |
| | Composition | Each Kg powder contains:<br>Colistin Sulphate……500MIU<br>Tylosin Tartrate……..100gm<br>Doxycycline HCl……200gm |
| | Diary No. Date of R& I & fee | 06-03-2017, Dy. No.3443, Rs.20,000/-, 24-02-2017 |

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| | Pharmacological Group | Antibacterial & Bronchodilator |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50g, 100g, 500g, 1kg, 5Kg, 10Kg, 20Kg, 25kg; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | CT-DOX WSP of M/s Inshal Pharma (Reg#048172) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.<br>QA division vide letter No.F.8-9/2018-QA (M-267-CLB) informed that the firm is directed to resume production activity in sterile area. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for correction of Pharmacological group. **(M-286)**. |
| | Evaluation by PEC | The firm has now submitted pharmacological group as "*Antibacterial*". |
| | **Decision: Approved with innovator's specification with change in brand name. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1124. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | PRIDE Oral Powder |
| | Composition | Each Kg powder contains:<br>Doxycycline HCl……200gm<br>Tylosin Tartrate……..100gm<br>Colistin Sulphate……480MIU<br>Bromhexine HCl…….5gm |
| | Diary No. Date of R& I & fee | 06-03-2017, Dy. No.3447, Rs.20,000/-, 24-02-2017 |
| | Pharmacological Group | Antibacterial and Bronchodilator |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 500g, 1kg, 5Kg, 10Kg, 20Kg, 25kg; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | PULMOMATS WSP of M/s. Nawal Pharma (Reg#074093) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.<br>QA division vide letter No. F.8-9/2018-QA (M-267-CLB) informed that the firm is directed to resume production activity in sterile area. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for correction of Pharmacological group. **(M-286)**. |
| | Evaluation by PEC | The firm has now submitted pharmacological group as "*Antibacterial/Mucolytic*". |
| | **Decision: Approved with innovator's specification with change in brand name. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1125. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | KLIK Oral Powder |
| | Composition | Each Kg contains: |

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| | | Doxycycline HCl……400gm<br>Tylosin Tartrate……..200gm<br>Colistin Sulphate……60gm<br>Bromhexine HCl…….20gm |
| | Diary No. Date of R& I & fee | 06-03-2017, Dy. No.3444, Rs.20,000/-, 24-02-2017 |
| | Pharmacological Group | Antibacterial and Bronchodilator |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 100g, 500g, 1kg, 5Kg, 10Kg, 20Kg, 25kg; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | NOBI TDC 680 of M/s. Noble Pharma (Reg#074093) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.<br>QA division vide letter No. F.8-9/2018-QA (M-267-CLB) informed that the firm is directed to resume production activity in sterile area. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for correction of Pharmacological group.<br>**(M-286)**. |
| | Evaluation by PEC | The firm has now submitted pharmacological group as "*Antibacterial/Mucolytic*". |
| | **Decision: Approved with innovator's specification with change in brand name. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |
| 1126. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | ZESEL ORAL SOLUTION |
| | Composition | Each Liter contains:<br>Vitamin E……..200,000mg<br>Sorbitol…….50,000 mg<br>Choline Chloride……50,000 mg<br>Vitamin C……...20,000 mg<br>Selenium as sodium selenite……..150 mg<br>Zinc as Zinc Sulphate……4000 mg |
| | Diary No. Date of R& I & fee | 06-03-2017, Dy. No.3448, Rs.20,000/-, 24-02-2017 |
| | Pharmacological Group | Multivitamin/Nutritional Supplement |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Litre, 2.5Litre, 5Litre, 10Litre, 20Litre;Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Vestol-Forte oral liquid of M/s Sanna (Reg#078272) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.<br>QA division vide letter No. F.8-9/2018-QA (M-267-CLB) informed that the firm is directed to resume production activity in sterile area. |
| | Previous remarks of the Evaluator. | |

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| | Previous decision | Deferred for rationale of quantities of APIs in applied formulation **(M-286)**. |
| | Evaluation by PEC | The firm has submitted label of already registered product Vestol-Forte which describes that it is a proven combination of Selenium and Vitamin E with added qualities of Vitamin C, Zinc, choline and sorbitol, which are inevitable for combating low fertility and hatchability. |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by RB for generic / me-too product will be given.** | |
| 1127. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | U FLOR ORAL SOLUTION |
| | Composition | Each ml contains:<br>Florfenicol…….200mg |
| | Diary No. Date of R& I & fee | 06-03-2017, Dy. No.3446, Rs.20,000/-, 24-02-2017 |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Litre, 2.5Litre, 5Litre, 10Litre, 20Litre; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | FLUROTIN LIQUID of M/s Elegance (Reg#075751) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.<br>QA division vide letter No. F.8-9/2018-QA (M-267-CLB) informed that the firm is directed to resume production activity in sterile area. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for correction of pharmacological group **(M-286)**. |
| | Evaluation by PEC | The firm has now submitted pharmacological group as "*Antibacterial/Amphenicol*". |
| | **Decision: Approved with innovator's specification.Only the pack sizes, already approved by DRAP for generic / me-too product will be given** | |
| 1128. | Name and address of manufacturer / Applicant | M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | MYCOFLOR ORAL LIQUID |
| | Composition | Each liter contains:<br>Florfenicol……110gm<br>Colistin Sulphate……..500MIU |
| | Diary No. Date of R& I & fee | 06-03-2017, Dy. No.3440, Rs.20,000/-, 24-02-2017 |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 150ml, 200ml, 450ml, 500ml, 1Litre, 2.5Litre, 5Litre, 10Litre, 20Litre; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | F-COL Liquid of M/s D-Maarson (Reg#072679) |
| | GMP status | QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the |

| | | |
|---|---|---|
| | | panel of experts and subsequent approval for resumption of production.<br>QA division vide letter No. F.8-9/2018-QA (M-267-CLB) informed that the firm is directed to resume production activity in sterile area. |
| | Previous remarks of the Evaluator. | |
| | Previous decision | Deferred for correction of pharmacological group **(M-286)**. |
| | Evaluation by PEC | The firm has now submitted pharmacological group as "*Antibacterial/Amphenicol*". |
| | **Decision: Approved with innovator's specification.Only the pack sizes, already approved by DRAP for generic / me-tooproduct will be given** | |
| 1129. | Name and address of manufacturer / Applicant | M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar industrial Estate, Haripur |
| | Brand Name +Dosage Form + Strength | THIACOL ORAL LIQUID |
| | Composition | Each ml contains:<br>Thiamphenicol……200mg |
| | Diary No. Date of R& I & fee | Dy. No. 233; 22-11-2017 ; Rs.20,000/- (20-11-2017) |
| | Pharmacological Group | Amphenicols (Broad spectrum Antimicrobial) |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 50ml, 100ml, 200ml, 250ml, 500ml, 1L, 2.5 L, 5L, 10L, 15L, 20L, 25L; Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | TRISAN 200 Liquid of M/s prix Pharma |
| | GMP status | Routine GMP inspection dated 07-09-2017 showed that the firm was working under satisfactory level of GMP. |
| | Remarks of the Evaluator. | The firm has submitted revised Form-5 with following label claim:<br>Each 100ml of solution contains:<br>Thiamphenicol……25g<br>Firm has submitted fee challan of Rs. 5000/- (deposit slip#0757431) dated 18-09-2018 and fee challan of Rs.15,000/- (deposit slip#0816906) dated 03-01-2019. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

## Case No. 05: Registration applications of newly granted DML or New section (Veterinary)

### a. New DML/secton

**Evaluator PEC-VII**

**Case of M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.**

CLB in its 266 meeting held on 24 October, 2018 has considered the approval of seven additional sections grant. Accordingly, firm has applied for following products for consideration by Drug Registration Board.

| Sr. No | Section | No. of products | No. of molecules |
|---|---|---|---|
| 1 | Aerosol (Vet) | 10 | 9 |

| | | |
|---|---|---|
| 1130. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Tetramide Spray |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 2024 dated 16-01-2018 Rs. 20,000 Dated 15-01-2018 |
| | Composition | Each 100gm Contains:<br>Chlotetracycline…367000IU<br>Sulphanilamide…5.963mg |
| | Pharmacological Group | Insecticide/hormonal analogue |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 150, 210 ml, 250 ml<br>As per SRO (10% less then brand leader |

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|---|---|---|
| | Approval Status of Product in Reference Regulatory Authorities. | Oro-spray vetoquinol Ireland |
| | Me-too Status | Orospray External Spray (027453) |
| | GMP status | Last GMP inspection conducted on 13-9-2018 to 14-9-2018 for grant of additional section |
| | Remarks of the Evaluator [VII] | • Aerosol vet section present (can solid spray manufactured in this facility) |
| | **Decision: Deferred for clarification of manufacturing of powder formulation in aerosol section.** | |
| 1131. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Roximax Topical Spray |
| | Diary No. Date of R& I & fee | Dy.No 2008 dated 16-01-2018 Rs. 20,000 Dated 15-01-2018 |
| | Composition | Each 170 gm Bottle Contains:<br>Rifaximin…0.5gm |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 10ml, 20 ml, 30 ml, 50 ml and 100 ml<br>As per SRO (10% less then brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | FATROXIMIN TOPIC SPRAY (021263) |
| | GMP status | Last GMP inspection conducted on 13-9-2018 to 14-9-2018 for grant of additional section |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Deferred for clarification of manufacturing of powder formulation in aerosol section.** | |
| 1132. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Hydrocort Spray |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 2007 dated 16-01-2018 Rs. 20,000/- 15-01-2018 |
| | Composition | Each ml Contains:<br>Oxytetracycline…5mg<br>Hydrocortisone…1.6mg |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 10ml, 20 ml, 30 ml, 50 ml and 100 ml<br>As per SRO (10% less then brand leader) |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | CORTISEL SPRAY (071079) |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Approved with innovator's specification.** | |
| 1133. | **Name and address of manufacturer / Applicant** | **M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur** |
| | Brand Name +Dosage Form + Strength | Anti-Mastitis Spray |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 2006 dated 16-01-2018 Rs. 20,000/- 15-01-2018 |
| | Composition | Each 15gm Contains:<br>Rifaximin…0.100gm<br>Cefacetrile Sodium…0.200gm |
| | Pharmacological Group | Anti-Mastitis |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |

| | | |
|---|---|---|
| | Pack Size & Demanded Price | 10ml, 20 ml, 30 ml, 50 ml and 100 ml<br>As per SRO (10% less then brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | CEFAXIMIN-L ANTI MASTITIS SPRAY (019906) |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Deferred for clarification of manufacturing of powder formulation in aerosol section.** | |
| 1134. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Alspray |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 2005 dated 16-01-2018 Rs. 20,000/- 15-01-2018 |
| | Composition | Each gm Contains:<br>Aluminium Powder…40mg |
| | Pharmacological Group | Antiseptic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 210<br>As per brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | ALUSPRAY PRESSURIZED SUSPENSION (028560) |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Deferred for clarification of manufacturing of powder formulation in aerosol section.** | |
| 1135. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Pink spray |
| | Diary No. Date of R& I & fee | Dy.No 44227 dated 28-12-2018 Rs. 20,000 (26/12/2018) |
| | Composition | Each 150 ml Contains:<br>Chloramphenicol….. 7.5 gm<br>Cetrimide……...1.5 gm<br>Phthalate ……1.5 gm<br>Crystal violet …….0.75gm |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 250 ml<br>As per brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | PINKSPRAY (020078) |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Approved with innovator's specification with change of brand name.** | |
| 1136. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Oxycart spray |
| | Diary No. Date of R& I & fee | Dy.No 44228 dated 28-12-2018 Rs. 20,000 (26/12/2018) |
| | Composition | Each ml Contains:<br>Oxytetracyclin….. 750 mg<br>Oxycartisone……..240 mg |
| | Pharmacological Group | Antibiotic/steroidal solution |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |

| | | |
|---|---|---|
| | Pack Size & Demanded Price | 250 ml / As per brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | NA |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | Me too not available |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1137. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Tetragen spray |
| | Diary No. Date of R& I & fee | Dy.No 44229 dated 28-12-2018 Rs. 20,000 (26/12/2018) |
| | Composition | Each ml Contains:<br>Oxytetracyclin HCl….. 40 mg<br>Gentian violet……..04 mg<br>Permethrine……..10 mg<br>Citronella oil……..20 mg |
| | Pharmacological Group | Antibacterial/fly repellent |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 125 ml<br>As per brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | TERAGEN PLUS AEROSOL SPRAY (063623) |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Approved with innovator's specification** | |
| 1138. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Roximax Intrauterine Foam |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 2009 dated 16-01-2018 Rs.20,000/- 15-01-2018 |
| | Composition | Each 13.4gm Bottle Contains:<br>Rifaximin…0.10gm |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 100, 500, 1kg, 10 kg, 25 kg<br>As per SRO (10% less then brand leader) |
| | Approval Status of Product in Reference Regulatory Authorities. | Itlay |
| | Me-too Status | FATROXIMIN INTRAUTERINE FOAM. ('048129) |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | |
| | **Decision: Deferred for clarification of manufacturing of powder formulation in aerosol section.** | |
| 1139. | Name and address of manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name +Dosage Form + Strength | Liberty Vet Spray |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 2024 dated 16-01-2018 Rs. 20,000/- 15-01-2018 |
| | Composition | Each Liter Contains:<br>Permethrin…15.44gm<br>(S)-Methoprene…0.34gm |
| | Pharmacological Group | Insecticide/hormonal analogue |
| | Type of Form | Form-5 |

| | | |
|---|---|---|
| | Finished Product Specification | In house |
| | Pack Size & Demanded Price | 50, 100, 150, 210 ml<br>As per SRO (10% less then brand leader |
| | Approval Status of Product in Reference Regulatory Authorities. | NA |
| | Me-too Status | NA |
| | GMP status | Last GMP inspection conducted on and operating at satisfactory compliance with GMP guidelines as of today |
| | Remarks of the Evaluator [VII] | Proof of me-too product (name and registration number) with same dosage form, same salt form, same strength and same volume/pack size (as demanded) is required. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

**Evaluator PEC-XII**

**Case. No. M/s Mylab Pvt Ltd.** Bahawalpur**. (New Section)**

The Central Licensing Board in its 266th meeting held on 24th Oct, 2018 has considered and approved the grant of 7 additional section of firm M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur Pakistan (DML:000747) as under:-

| Sr. No | Section | No. of products | No. of molecules |
|---|---|---|---|
| 1 | Liquid injectable (Penicillin) Veterinary | 20 | 10 |
| 2 | Oral liquid (General) Veterinary | 10 | 10 |
| 3 | Dry powder injectable (Penicillin) Veterinary | - | - |
| 4 | Liquid Injectable (Hormone) Veterinary | - | - |
| 5 | Liquid Injectable (Steroid) Veterinary | - | - |
| 6 | Aerosol Veterinary | - | - |
| 7 | Oral powder (Penicillin) Veterinary | - | - |

**Liquid injectable (Penicillin) Veterinary**
**20 products / 10 molecules**

| | | |
|---|---|---|
| 1140. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Propen-300 Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 2017 dated 16-01-2018 Rs. 20,000 Dated 15-01-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin…300mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | NAWAPEN-30 by M/s NAWAN LABORATORIES (Reg#053996) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 1141. | Name and Address of Manufacturer / Applicant | **M/s Mylab Pvt Ltd.**<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | **LA Durapen Injection** |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 2016 dated 16-01-2018 Rs. 20,000/- 15-1-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin G…100000IU<br>Benzathine Penicillin G…150000IU<br>Dihydrostreptomycin sulphate…200mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |

| | | |
|---|---|---|
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | BPS-LA INJECTION by M/s SELMORE PHARMACEUTICALS (Reg#080951) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 1142. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Bactillin Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 2011 dated 16-01-2018 Rs. 20,000/- 15-1-2018 |
| | Composition | Each 100ml Contains:<br>Amoxcillin (as trihydrate) …10gm<br>Colistin sulphate…25,000,000IU |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | AMOXILIST LA INJECTION. by M/s BREEZE PHARMA (PVT.) LTD (Reg#063550) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 1143. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Dorapen Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 2012 (16-01-2018) Rs. 20,000/- 15-01-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin...200,000IU<br>Dihydrostreptomycin sulphate…250mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | ORIPEN-S INJECTION. by M/s ORIENT LABORATORIES (Reg#035016) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 1144. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Duramox Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 2013 dated 16-01-2018 Rs.20,000/- 15-1-2018 |
| | Composition | Each ml Contains:<br>Amoxcillin trihydrate…150mg<br>Gentamycin as sulphate…40mg |
| | Pharmacological Group | Broad spectrum antibiotic |

| | | |
|---|---|---|
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml/Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | GENTAMOX INJECTION by M/s MARUSH (PVT) LIMITED (Reg#080160) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 1145. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Selmox LA Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40605 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each ml Contains:<br>Amoxicillin as trihydrate…200mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | NOVAMOX 20% LA INJECTION. by M/s SELMORE PHARMACEUTICALS (Reg#043145) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 1146. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Streptomet Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40603 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin G…200,000 IU<br>Dihydrostreptomycin Sulphate…200mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | STREPTOMET INJECTION by M/s SELMORE PHARMACEUTICALS (Reg#080954) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification** | |
| 1147. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Clavet Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40602 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |

| | | |
|---|---|---|
| | Composition | Each ml Contains:<br>Amoxicillin as Trihydrate…140mg<br>Clavulanic Acid (as potassium clavulanate) …35mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | CLAVET INJECTION by M/s SELMORE PHARMACEUTICALS ( (Reg#046519) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | • Brand name resemblance |
| | **Decision: Approved with innovator's specification** | |
| 1148. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Mybiotic LA Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40607 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin…100,000 IU<br>Benzyl Penicillin…150,000 IU |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml/Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | Not confirmed |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | • Me-too Status not confirmed from available database. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1149. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Maxivet-LA Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 44146 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018 |
| | Composition | Each ml Contains:<br>Amoxicillin trihydrate…150mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | Amoxy LA Injection by M/s Inshal Pharmaceutical Industries (Reg#073932) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |

| | | |
|---|---|---|
| 1150. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Bactillin Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43831 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each 100ml Contains:<br>Amoxcillin (as trihydrate) …10gm<br>Colistin sulphate…25,000,000IU |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml/Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | AMOXILIST LA INJECTION. by M/s BREEZE PHARMA (PVT.) LTD (Reg#063550) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1151. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Propen-300 Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43832 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin…300mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | NAWAPEN-30 by M/s NAWAN LABORATORIES (Reg#053996) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1152. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Streptomet Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43833 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin G…200,000 IU<br>Dihydrostreptomycin Sulphate…200mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | STREPTOMET INJECTION by M/s SELMORE PHARMACEUTICALS (Reg#080954) |

| | | |
|---|---|---|
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1153. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Dorapen Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43834 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin…200,000 IU<br>Dihydrostreptomycin sulphate…250mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml/Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | ORIPEN-S INJECTION. by M/s ORIENT LABORATORIES (Reg#035016) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1154. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Duramox Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43828 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each ml Contains:<br>Amoxicillin trihydrate…150mg<br>Gentamicin as sulphate…40mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml/Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | GENTAMOX INJECTION by M/s MARUSH (PVT) LIMITED (Reg#080160) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1155. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Clavet Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43829 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each ml Contains:<br>Amoxicillin as Trihydrate…140mg<br>Clavulanic Acid (as potassium clavulanate) …35mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |

| | | |
|---|---|---|
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml/Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | CLAVET INJECTION by M/s SELMORE PHARMACEUTICALS ( (Reg#046519) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | • Brand name resemblance |
| | **Decision: Approved with innovator's specification and change** | |
| 1156. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | LA Durapen Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 43830 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin G…100,000 IU<br>Benzathine Penicillin G…150,000 IU<br>Dihydrostreptomycin Sulphate…200mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | BPS-LA INJECTION by M/s SELMORE PHARMACEUTICALS (Reg#080951) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1157. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Mybiotic LA Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 44143 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018 |
| | Composition | Each ml Contains:<br>Procaine Penicillin…150,000 IU<br>Benzyl Penicillin…100,000 IU |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | Not confirmed |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | • Me-too Status not confirmed from available database. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| 1158. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Maxivet-LA Injection |

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|---|---|---|
| | Diary No. Date of R & I & fee | Form-5 Dy.No 44145 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018 |
| | Composition | Each ml Contains:<br>Amoxicillin as Trihydrate…150mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | Amoxy LA Injection by M/s Inshal Pharmaceutical Industries (Reg#073932) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1159. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Selmox-LA Injection |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 44144 dated 27-12-2018 Rs.20,000/- Dated 27-12-2018 |
| | Composition | Each ml Contains:<br>Amoxicillin as trihydrate…200mg |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml/Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | NOVAMOX 20% LA INJECTION. by M/s SELMORE PHARMACEUTICALS (Reg#043145) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| | **Oral liquid (General) Veterinary<br>10products / 10 molecules** | |
| 1160. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Vitaking-E Liquid |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 13015 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018 |
| | Composition | Each ml Contains:<br>Alpha-Tocopherol Acetate (Vitamin E)…150mg |
| | Pharmacological Group | Vitamin |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml, 500ml, 1L, 5L, 10L, 20L, 25L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | HOKOSAN E LIQUID by M/s U.M.ENTER PRISES (Reg#021446) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |

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| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1161. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Timpavax Liquid |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 13041 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018 |
| | Composition | Each ml Contains:<br>Di (Ethyl-Hexyl) Sulphosuccinate…200mg<br>Polydimethyl Siloxane…3.5mg |
| | Pharmacological Group | Stool softner, laxative and lubricant |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml, 500ml, 1L, 5L, 10L, 20L, 25L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | TIMPAVEEX by M/s AIMS TRADER (Reg#008315) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | Brand name resemblance. |
| | **Decision: Approved with innovator's specification with change of brand name.** | |
| 1162. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Doxisol Oral Solution |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 13040 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018 |
| | Composition | Each ml Contains:<br>Doxycycline Hycalate…200mg |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 100ml, 500ml, 1L, 5L, 10L, 20L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | DOXY 20% ORAL LIQUID by M/s ATTABAK PHARMACEUTICAL (Reg#058911) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | Firm has applied as Doxycycline Hycalate…200mg/ml, whereas, formulation approved by DRAP is Doxycycline hydrochloride…200mg/ml. |
| | **Decision: Approved with innovator's specification.** | |
| 1163. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Sulbectra Oral Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.# 13007 dated 06-04-2018 Rs.20,000/- 27-2-2018 |
| | Composition | Each ml Contains:<br>Trimethoprim…80mg (8%w/v)<br>Sulphadiazine…400mg (40%w/v) |
| | Pharmacological Group | Combinations of sulfonamides and trimethoprim, incl. derivatives |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 500ml, 1L, 5L, 10L, 20L, 25L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |

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| | Me-too Status | TRYTON SOLUTION by M/s GUYTON PHARMACEUTICAL (Reg#032225) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1164. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Curbex Liquid |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 13025 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018 |
| | Composition | Each litre Contains:<br>Ammonium Propionate…65%<br>Mono and Diglycerides…1.25%<br>Phosphoric Acid…0.50%<br>Sorbic Acid…0.25% |
| | Pharmacological Group | Acidifiers |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 1L, 5L, 10L, 20L, 25L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | MYCO CURB LIQUID by M/s VET PHARMA TRADING (Reg#)020146 |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1165. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Levadox Drench |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40633 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each 100ml Contains:<br>Levamisole hydrochloride…1.5gm<br>Cobalt Sulphate…0.382gm<br>Sodium Selenite…0.050gm |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 250ml, 500ml, 1L, 5L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | VERNIL S.C. DRENCH by M/s STAR LABORATORIES (PVT) LTD (Reg#033261) |
| | GMP Status | 14-09-2018; Renewal of DML and Grant of additional sections. Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1166. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Combiox Drench |
| | Diary No. Date of R & I & fee | Form-5 Dy.#40628 dated 06-12-2018 Rs.20,000/- 04-12-2018 |
| | Composition | Each ml Contains:<br>Oxyclozanide…94mg |

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|---|---|---|
| | | Oxfendazole…34mg<br>Cobalt Sulphate…3.82mg<br>Sodium Selenite…0.50mg |
| | Pharmacological Group | Anthelmintic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | COMBIOX DRENCH by M/s SELMORE PHARMACEUTICALS (PVT) LTD (Reg#057004) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | • Brand name resemblance. |
| | **Decision: Approved with innovator's specification with change of brand name** | |
| 1167. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | I-Tolodox-C Oral Solution |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40631 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each 100ml Contains:<br>Tylosin tartrate…14gm<br>Doxycycline hydrochloride…16gm<br>Colistin sulphate…120 MIU |
| | Pharmacological Group | Broad spectrum antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 250ml, 500ml, 1L, 5L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | I-TYLODOX-C ORAL SOLUTION by M/s INTERNATIONAL PHARMA LABS (Reg#079847) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1168. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Interfenicol 25% Oral Solution |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40634 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each 100ml Contains:<br>Florfenicol…25gm |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 250ml, 500ml, 1L, 5L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | FLORFENICOL ORAL LIQUID by M/s ATTABAK PHARMACEUTICALS (Reg#075707) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |

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| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| 1169. | Name and Address of Manufacturer / Applicant | M/s Mylab Pvt Ltd.<br>Khankah Sharif Bahawalpur |
| | Brand Name + Dosage Form + Strength | Scournil Oral Suspension |
| | Diary No. Date of R & I & fee | Form-5 Dy.No 40636 dated 06-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each 100ml Contains:<br>Sulphadiazine…3.550gm<br>Sulphadimidine…2.840gm<br>Kaolin…10.33gm<br>Pectin…0.710gm<br>Hyoseine Butyl Bromide…0.004gm<br>Neomycin Sulphate…0.180gm<br>Vitamin B1…0.015gm<br>Vitamin B2…0.022gm |
| | Pharmacological Group | Combinations of antibiotics, anti-toxins, antispasmodic and minerals |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 250ml, 500ml, 1L, 5L /Decontrolled |
| | Approval Status of Product in Reference Regulatory Authorities. | N/A |
| | Me-too Status | SCOUR-X ORAL SUSPENSION by M/s SELMORE PHARMACEUTICALS (PVT) LTD. (Reg#023661) |
| | GMP Status | 14-09-2018<br>Renewal of DML and Grant of additional sections.<br>Panel recommends Renewal of DML and Grant of additional sections. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |

## Case No. 06: Registration applications of categories to be considered on priority

### a. Export Facilitation

**Evaluator PEC-IV**

| Export Facilitation: Applications were received through letter No.F.11-1/2014-DD(R-IV)(Pt), The firm claimed 4 molecules to be considered on priority". | | |
|---|---|---|
| 1170. | Name and address of manufacturer / Applicant | M/S Genome Pharmaceuticals (Pvt) Ltd, Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Hesdimine 450mg/50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Diosmin……..…450mg<br>Hesperidine…….50mg |
| | Diary No. Date of R& I & fee | Dy.No 27401 dated 09-08-2018 Rs. 20,000/- 09-08-2018 |
| | Pharmacological Group | Bioflavonoids |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Daflon 500mg Tablets of ( ANSM approved) |
| | Me-too status (with strength and dosage form) | Diflon 500mg Tablets Et M/S Hoover Pharma |
| | GMP status | Last GMP inspection was conducted on 12-05-2017 and report concludes that overall the firm was operating under good level of GMP. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 1171. | Name and address of manufacturer / Applicant | M/S Genome Pharmaceuticals (Pvt) Ltd, Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK, Pakistan |

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|---|---|---|
| | Brand Name +Dosage Form + Strength | Hesdimine 450mg/50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Diosmin……..…900mg<br>Hesperidine…….100mg |
| | Diary No. Date of R& I & fee | Dy.No 27402 dated 09-08-2018 Rs. 20,000/- 09-08-2018 |
| | Pharmacological Group | Bioflavonoids |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Daflon Tablets of ( ANSM approved) |
| | Me-too status (with strength and dosage form) | Daflon Tablets 1000mg M/s Serveir Research and Pharmaceuticals |
| | GMP status | t GMP inspection was conducted on 12-05-2017 and report concludes that overall the firm was operating under good level of GMP. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 1172. | Name and address of manufacturer / Applicant | M/S Genome Pharmaceuticals (Pvt) Ltd, Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Clopid-S 75mg/75mg Tablet |
| | Composition | Each film coated tablet contains:<br>Aspirin……..…75mg<br>Clopidogrel (as bisulphate)…….75mg |
| | Diary No. Date of R& I & fee | Dy.No 28138 dated 17-08-2018 Rs. 20,000/- 17-08-2018 |
| | Pharmacological Group | Antiplatelet drug |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | CoPlavix Tablet Of (TGA Approved) |
| | Me-too status (with strength and dosage form) | Clodril Plus Tablet M/s Macter International |
| | GMP status | Last GMP inspection was conducted on 12-05-2017 and report concludes that overall the firm was operating under good level of GMP. |
| | Remarks of the Evaluator[4] | As per the Inspection conducted on 12-05-2018, the report states that the firm has recently installed a double hopper ZP 41 Rotary tablet press machine to strengthen their tablet manufacturing capacity. The firm informed that the double hopper rotary press has the ability to compress the tablets as double layered. |
| | **Decision: Approved with innovator's specification** | |
| 1173. | Name and address of manufacturer / Applicant | M/S Genome Pharmaceuticals (Pvt) Ltd, Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Agolet 25mg Tablet |
| | Composition | Each film coated tablet contains:<br>Agomelatine……..…25mg |
| | Diary No. Date of R& I & fee | Dy.No 31409 dated 18-09-2018 Rs. 20,000/- 18-09-2018 |
| | Pharmacological Group | Antidepressant |
| | Type of Form | Form 5 |
| | Finished product Specifications | Manufacturer specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Agomelatine of (MHRA Approved) |
| | Me-too status (with strength and dosage form) | Valdoxan tablet by Servier |

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| | GMP status | Last GMP inspection was conducted on 12-05-2017 and report concludes that overall the firm was operating under good level of GMP. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved with innovator's specification.** | |
| 1174. | Name and address of manufacturer / Applicant | M/S Genome Pharmaceuticals (Pvt) Ltd, Plot # 16/I-Phase IV, Industrial Estate Hattar, KPK, Pakistan |
| | Brand Name +Dosage Form + Strength | Rebam 100mg Tablet |
| | Composition | Each film coated tablet contains:<br>Rebamipide…….100mg |
| | Diary No. Date of R& I & fee | Dy.No 32570 dated 01-10-2018 Rs. 20,000/- Dated 28-09-2018 |
| | Pharmacological Group | Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD) |
| | Type of Form | Form 5 |
| | Finished product Specifications | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Mucosta 100mg of (MHRA Approved) |
| | Me-too status (with strength and dosage form) | MUCOSTA TABLET 100MG tablet of M/S. OTSUKA (Reg#078129) (Import product) Reg on 22-09-2014 |
| | GMP status | Last GMP inspection was conducted on 12-05-2017 and report concludes that overall the firm was operating under good level of GMP. |
| | Remarks of the Evaluator[4] | |
| | **Decision: Registration Board deferred for deliberation with approval status of innovator product.** | |

**Evaluator PEC-III**

| | | |
|---|---|---|
| Following applications were received from section R-V Products can be granted priority registration under Export Facilitation | | |
| 1175. | Name and address of manufacturer / Applicant | M/s Schazoo Zaka (Pvt) Ltd 20Km Lahore Jaranwala Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Vilag Tablet 50mg |
| | Composition | Each tablet contains:<br>Vildagliptin……50mg |
| | Diary No. Date of R& I & fee | Dy. No 931: 08-01-2019 Rs. 20,000/-: 07-01-2019 |
| | Pharmacological Group | Anti diabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 4x7's: Rs. 25/Tablet |
| | Approval status of product in Reference Regulatory Authorities. | GALVUS vildagliptin 50 mg tablets un-coated by Novartis Pharmaceuticals Australia Pty Ltd. **TGA** approved |
| | Me-too status | Glavil 50mg Tablet by Atco Laboratories. |
| | GMP status | GMP Certificate issued on the basis of inspection dated 26-06-2018 & 27-06-2018 with following sections:<br>1- Tablet (Gen, Anti TB)<br>2- Capsule (Gen)<br>3- Dry Powder suspension (Gen, Anti TB)<br>4- Sachet (Gen, Anti TB). |
| | Remarks of the Evaluator[3]. | • |
| | **Decision: Approved with innovator's specification.** | |
| 1176. | Name and address of manufacturer / Applicant | M/s Schazoo Zaka (Pvt) Ltd 20Km Lahore Jaranwala Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Vilag-M Tablet |
| | Composition | Each film coated tablet contains:<br>Vildagliptin……50mg<br>Metformin hydrochloride……500mg |
| | Diary No. Date of R& I & fee | Dy. No 932: 08-01-2019 Rs. 20,000/-: 07-01-2019 |

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| | Pharmacological Group | Anti diabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 2x7's: Rs. 26.07/Tablet |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/500 film coated tablet by Novartis Pharmaceuticals (**TGA** Australia Approved) |
| | Me-too status | Galvus Met 50/500mg Tablets by Novartis. |
| | GMP status | GMP Certificate issued on the basis of inspection dated 26-06-2018 & 27-06-2018 with following sections:<br>1- Tablet (Gen, Anti TB)<br>2- Capsule (Gen)<br>3- Dry Powder suspension (Gen, Anti TB)<br>4- Sachet (Gen, Anti TB). |
| | Remarks of the Evaluator[3]. | • |
| | **Decision: Approved with innovator's specification.** | |
| 1177. | Name and address of manufacturer / Applicant | M/s Schazoo Zaka (Pvt) Ltd 20Km Lahore Jaranwala Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Vilag-M Tablet |
| | Composition | Each film coated tablet contains:<br>Vildagliptin……50mg<br>Metformin hydrochloride……850mg |
| | Diary No. Date of R& I & fee | Dy. No 933: 08-01-2019 Rs. 20,000/-: 07-01-2019 |
| | Pharmacological Group | Anti diabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 2x7's: Rs. 26.07/Tablet |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/850 film coated tablet by Novartis Pharmaceuticals (**TGA** Australia Approved) |
| | Me-too status | Galvus Met 50/850mg Tablets by Novartis. |
| | GMP status | GMP Certificate issued on the basis of inspection dated 26-06-2018 & 27-06-2018 with following sections:<br>1- Tablet (Gen, Anti TB)<br>2- Capsule (Gen)<br>3- Dry Powder suspension (Gen, Anti TB)<br>4- Sachet (Gen, Anti TB). |
| | Remarks of the Evaluator[3]. | • |
| | **Decision: Approved with innovator's specification.** | |
| 1178. | Name and address of manufacturer / Applicant | M/s Schazoo Zaka (Pvt) Ltd 20Km Lahore Jaranwala Road Sheikhupura |
| | Brand Name +Dosage Form + Strength | Vilag-M Tablet |
| | Composition | Each film coated tablet contains:<br>Vildagliptin……50mg<br>Metformin hydrochloride……1000mg |
| | Diary No. Date of R& I & fee | Dy. No 932: 08-01-2019 Rs. 20,000/-: 07-01-2019 |
| | Pharmacological Group | Anti diabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size | 2x7's: Rs. 26.07/Tablet |
| | Approval status of product in Reference Regulatory Authorities. | GALVUMET 50/1000 film coated tablet by Novartis Pharmaceuticals (**TGA** Australia Approved) |
| | Me-too status | Galvus Met 50/1000mg Tablets by Novartis. |
| | GMP status | GMP Certificate issued on the basis of inspection dated 26-06-2018 & 27-06-2018 with following sections:<br>1- Tablet (Gen, Anti TB)<br>2- Capsule (Gen)<br>3- Dry Powder suspension (Gen, Anti TB)<br>4- Sachet (Gen, Anti TB). |
| | Remarks of the Evaluator[3]. | • |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-II**

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| Registration section-V vide its letter No. F.8-6/2013-Reg-V dated 21-12-2018, has stated to consider following two applications on priority as per decision of 263rd meeting of Registration Board.<br>The said letter mentions following details:<br>"The firm claimed one molecule to be considered on priority against USD 974044 (fiscal year Jan-Dec, 2017) duly verified from submitted documents (Form E GD form and shipment/invoices) as per decision of Registration Board. Two molecules already considered against above mentioned claim." | | |
| 1179. | Name and address of manufacturer / Applicant | M/s Schazoo Pharmaceutical Laboratories Pvt Ltd., 20 Jaranwala Road, Kalwala Stop, Tehsil Ferozewala, District Sheikhupura. |
| | Brand Name +Dosage Form + Strength | Velam Tablets5/80mg |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine as besylate …… 5mg<br>Valsartan ….. 80mg |
| | Diary No. Date of R& I & fee | Dy. No 55 dated 01-01-2019 Rs.20,000/- 01-01-2019 |
| | Pharmacological Group | Calcium channel blocker/Angiotensin-II receptor antagonists |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 2 x 7's: Rs. 22.86/tablet Rs. 320/pack |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Exforge Tablet of M/s Novartis Pharma (Reg.#047569) |
| | GMP status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 1180. | Name and address of manufacturer / Applicant | M/s Schazoo Pharmaceutical Laboratories Pvt Ltd., 20 Jaranwala Road, Kalwala Stop, Tehsil Ferozewala, District Sheikhupura. |
| | Brand Name +Dosage Form + Strength | Velam Tablets5/160mg |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine as besylate …… 5mg<br>Valsartan ….. 160mg |
| | Diary No. Date of R& I & fee | Dy. No 56 dated 01-01-2019 Rs.20,000/- 01-01-2019 |
| | Pharmacological Group | Calcium channel blocker/Angiotensin-II receptor antagonists |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 2 x 7's: Rs. 22.86/tablet Rs. 320/pack |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Exforge Tablet of M/s Novartis Pharma (Reg.#047570) |
| | GMP status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

Following three cases were received from section R-V vide letter No. F.8-6/2013-Reg-V dated 28th December, 2018. According to the contents of the letter the firm has claimed two molecules to be considered on priority against export worth USD 974044 which is duly verified from submitted documents (Form E GD and shipment invoices) as per the decision of Registration Board.

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| 1181. | Name and Address of Manufacturer / Applicant | **M/s Schazoo Pharmaceutical Laboratories (Pvt) Limited,** 20km Lahore-jaranwala road, District Sheikhupura. |
| | Brand Name + Dosage Form + Strength | **Letrose Tablet 2.5mg** |
| | Diary No. Date of R & I & fee | Dy.No 43934 dated 26-12-2018 Rs.20,000/- Dated 26-12-2018 |
| | Composition | Each film-coated tablet Contains:<br>Letrozole …2.5mg |
| | Pharmacological Group | Aromatase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1x10's/Rs.2470 |
| | Approval Status of Product in Reference Regulatory Authorities. | LETROZOLE APOTEX letrozole 2.5 mg film-coated tablet by M/s Cipla Australia Pty Ltd (TGA Approved) |
| | Me-too Status | Aromek film coated tablet 2.5mg by M/s Glaxy Pharma (Reg#052258) |
| | GMP Status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| 1182. | Name and Address of Manufacturer / Applicant | **M/s Schazoo Pharmaceutical Laboratories (Pvt) Limited,** 20km Lahore-jaranwala road, District Sheikhupura. |
| | Brand Name + Dosage Form + Strength | **Decalc Plus Tablet (Orange flavor)** |
| | Diary No. Date of R & I & fee | Dy.No 40077 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each chewable tablet Contains:<br>Calcium carbonate …1250mg eq. to elemental calcium …500mg<br>Vitamin D …125I.U |
| | Pharmacological Group | Calcium supplement with vitamin |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 3x10's/Rs.86.79 |
| | Approval Status of Product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too Status | Qalsan D Chewable Tablet by M/s Novartis Pharma (Reg#055081) |
| | GMP Status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | • Approval status of applied formulation in Reference Regulatory Authorities could not be confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| 1183. | Name and Address of Manufacturer / Applicant | **M/s Schazoo Pharmaceutical Laboratories (Pvt) Limited,** 20km Lahore-jaranwala road, District Sheikhupura. |
| | Brand Name + Dosage Form + Strength | **Decalc Plus Tablet (Mix fruit flavor)** |
| | Diary No. Date of R & I & fee | Dy.No 40076 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018 |
| | Composition | Each chewable tablet Contains:<br>Calcium carbonate …1250mg eq. to elemental calcium …500mg<br>Vitamin D …125I.U |
| | Pharmacological Group | Calcium supplement with vitamin |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 3x10's/Rs.86.79 |
| | Approval Status of Product in Reference Regulatory Authorities. | Not confirmed |

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| | Me-too Status | Qalsan D Chewable Tablet by M/s Novartis Pharma (Reg#055081) |
| | GMP Status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | • Approval status of applied formulation in Reference Regulatory Authorities could not be confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| Following one case was received from section R-III vide letter No. F.6-2/2016-Reg-III dated 17th December, 2018. According to the contents of the letter the firm has claimed one molecule to be considered on priority as per the decision of Registration Board. | | |
| 1184. | Name and Address of Manufacturer / Applicant | **M/s Ambrosia Pharmaceuticals**<br>Plot#18, Street#9, National Industrail Zone, Rawat-Islamabad.. |
| | Brand Name + Dosage Form + Strength | **Infacol Plus Gel Suspension** |
| | Diary No. Date of R & I & fee | Dy.No 29131 dated 31-08-2018 Rs.20,000/- Dated 31-08-2018 |
| | Composition | Each 5ml Contains:<br>Dicyclomine hydrochloride …2..5mg,<br>Aluminium hydroxide …200mg<br>Light magnesium oxide …100mg<br>Simethicone …20mg |
| | Pharmacological Group | Antacid, antiflatulannt, antispasmodic, demulcent |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 60ml/Rs.93.33 |
| | Approval Status of Product in Reference Regulatory Authorities. | Kolanticon Gel Suspension by M/sPeckforton Pharmaceuticals (MHRA Approved) |
| | Me-too Status | Peptogel Suspension by M/s Mediways (Reg#030280) |
| | GMP Status | **08-10-2018**<br>During the follow up inspection of M/s Ambrosia Pharmaceuticals Rawat, it is observed, that majority of the observations noted in the previous inspection i.e. conducted on 16-07-2018 have been rectified and the firm was found working in compliance to GMP as of the date of inspection. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification and change of brand name.** | |

## b. Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting

**Evaluator PEC-V**

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| 1185. | Name and address of Manufacturer / Applicant | "M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore" |
| | Diary No. Date of R&I & fee | Dy.No 27078 dated 07-08-2018 Rs.20,000/- Dated 07-08-2018 |
| | Brand Name+Dosage Form+Strength | Lefimide 10mg Tablet |
| | Composition | "Each Film Coated Tablet Contains:<br>Leflunomide…10mg" |
| | Pharmacological Group | Selective immunosuppressant |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's. As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved. |
| | Me-too status | 066488; Zefora Tablets 10mg<br>M/s Global Pharmaceuticals, Plot No 204-205, Kahuta Triangle, Industrial Area, Islamabad. |
| | GMP status | 03/11/17. Conclusion:<br>"The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the |

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| | | manufacturing and Quality control operations on the day of inspection."<br>GMP Certificate issued on 10-12-2018. |
| | Remarks of Evaluator | |
| | **Decision:Approved** | |
| 1186. | Name and address of Manufacturer / Applicant | "M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore" |
| | Diary No. Date of R&I & fee | Dy.No 27079 dated 07-08-2018 Rs.20,000/- Dated 07-08-2018 |
| | Brand Name+Dosage Form+Strength | Lefimide 20mg Tablet |
| | Composition | "Each Film Coated Tablet Contains:<br>Leflunomide…20mg" |
| | Pharmacological Group | Selective immunosuppressant |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's. As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved. |
| | Me-too status | 066489; Zefora Tablets 20mg<br>M/s Global Pharmaceuticals, Plot No 204-205, Kahuta Triangle, Industrial Area, Islamabad. |
| | GMP status | 03/11/17. Conclusion:<br>"The panel of inspectors was of the opinion, that the firm M/s Wimits Pharmaceuticals Lahore had maintained satisfactory conformance to GMP Compliance in the manufacturing and Quality control operations on the day of inspection."<br>GMP Certificate issued on 10-12-2018. |
| | Remarks of Evaluator | |
| | **Decision:Approved** | |
| 1187. | Name and address of Manufacturer / Applicant | "M/s Briell Pharmaceutical (Pvt) Ltd.<br>538C Sundar Industrial Estate Multan Road, Lahore." |
| | Diary No. Date of R&I & fee | Dy.No 27077 dated 07-08-2018 Rs.20,000/- 07-08-2018 |
| | Brand Name+Dosage Form+Strength | Famera 2.5mg Tablet |
| | Composition | "Each Film Coated Tablet Contains:<br>Letrozole…2.5mg" |
| | Pharmacological Group | Hormone antagonists and related agents,<br>Aromatase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 3x10's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | Femara<br>USFDA Approved. |
| | Me-too status | 075805<br>Letzole 2.5mg Tablet M/s Opal Labs, Karachi. |
| | GMP status | Last inspection report dated 25-04-2017, the panel recommended the grant of New DML. |
| | Remarks of Evaluator | Form 5 not signed by applicant and undertaking also not signed. |
| | **Decision: Deferred for clarification as Form 5 and undertaking were not signed by applicant.** | |
| 1188. | Name and address of Manufacturer / Applicant | "M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi" |
| | Diary No. Date of R&I & fee | Dy.No 28141 dated 17-08-2018 Rs.20,000/- 17-08-2018 |
| | Brand Name+Dosage Form+Strength | Letram 2.5mg Tablet |
| | Composition | "Each Film Coated Tablet Contains:<br>Letrozole…2.5mg" |
| | Pharmacological Group | Hormone antagonists and related agents, Aromatase inhibitors |

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| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's,20's,30's, As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Femara<br>USFDA Approved. |
| | Me-too status | 075805<br>Letzole 2.5mg Tablet<br>M/s Opal Labs, Karachi . |
| | GMP status | Last inspection conducted on 28-09-2017 and report concludes that firm is found at good level of GMP compliance. |
| | Remarks of Evaluator | |
| | **Decision:Approved** | |
| 1189. | Name and address of Manufacturer / Applicant | "M/s Kaizen Pharmaceuticals Pvt Ltd.<br>E-127-129, North Western Industrial Zone, Bin Qasim, Karachi" |
| | Diary No. Date of R&I & fee | Dy.No 26605 dated 02-08-2018 Rs.20,000/- 31-07-2018 |
| | Brand Name+Dosage Form+Strength | Deferox 125mg Tablet |
| | Composition | "Each Dispersible Tablet Contains:<br>Deferasirox…125mg" |
| | Pharmacological Group | Iron chelating agents |
| | Type of Form | Form 5 |
| | Finished Product Specification | Innovator |
| | Pack Size & Demanded Price | 10's, 20's, 30's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | 062244; "Osveral 125mg Dispersible<br>M/s Osvah Pharmaceutical Company, Iran.Nextar Pharma, Karachi |
| | GMP status | 02/08/18. Conclusion:<br>"The building facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis." |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-XIII**

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| 1190. | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals (Pvt.) Limited, Plot # 129, Sundar Industrial Estate (P.I.E.) Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Roxwin tablet 250mg |
| | Composition | Each dispersible tablet contains:<br>Deferasirox ……....250mg |
| | Diary No. Date of R& I & fee | Dy. No. 29716; 05-09-2018; Rs.20,000/- (05-09-2018) |
| | Pharmacological Group | Iron chelating agent |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10's, 30's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Exjade 250mg dispersible tablet of M/s Novartis Pharma (USFDA Approved) |
| | Me-too status | Oderox-250mg dispersible tablet of M/s A.J. Mirza Pharma (Reg. # 078115) |
| | GMP status | Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator | • Firm has General tablet section as mentioned in the GMP inspection report.<br>• No official monograph is available in USP, BP, IP |

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| | | or JP for the applied formulation. |
| | **Decision: Approved with innovator's specification.** | |
| 1191. | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals (Pvt.) Limited, Plot # 129, Sundar Industrial Estate (P.I.E.) Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Roxwin tablet 500mg |
| | Composition | Each dispersible tablet contains:<br>Deferasirox ……..…….500mg |
| | Diary No. Date of R& I & fee | Dy. No.29717; 05-09-2018; Rs.20,000/- (05-09-2018) |
| | Pharmacological Group | Iron chelating agent |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10's, 30's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Exjade 500mg dispersible tablet of M/s Novartis Pharma (USFDA Approved) |
| | Me-too status | Oderox -500 dispersible tablet of M/s A.J. Mirza Pharma (Pvt.) Ltd (Reg.# 078116) |
| | GMP status | Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator | • Firm has General tablet section as mentioned in the GMP inspection report.<br>• No official monograph is available in USP, BP, IP or JP for the applied formulation. |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-XIV**

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|---|---|---|
| 1192. | Name and address of manufacturer / Applicant | M/s Pacific Pharmaceuticals Ltd, 30th Kilometer, Multan Road, P.O. Box 399, Lahore, Pakistan |
| | Brand Name +Dosage Form + Strength | TAMOXIDEX 10mg TABLET |
| | Composition | Each tablet contains:<br>Tamoxifen citrate equivalent to Tamoxifen……10mg |
| | Diary No. Date of R& I & fee | 30423, 10-09-2018, 20,000/-, 10-09-2018 |
| | Pharmacological Group | Anti-Oestrogens, hormone antagonist |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Nolvadex Tablet of Astrazeneca **(USFDA approved)** |
| | Me-too status | Tamoxifen Sandoz 10mg Tablet by Novartis Pharma (Reg no.047670) |
| | GMP status | The firm was granted GMP certificate based on inspection conducted on 22-02-2018. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product with reference to decision of 286th meeting of Registration Board regarding "Manufacturing facility for steroidal and non-steroidal hormones".** | |
| 1193. | Name and address of manufacturer / Applicant | M/s Pacific Pharmaceuticals Ltd, 30th Kilometer, Multan Road, P.O. Box 399, Lahore, Pakistan |
| | Brand Name +Dosage Form + Strength | TAMOXIDEX 20mg TABLET |
| | Composition | Each tablet contains:<br>Tamoxifen citrate equivalent to Tamoxifen……20mg |
| | Diary No. Date of R& I & fee | 30424, 10-09-2018, 20,000/-, 10-09-2018 |
| | Pharmacological Group | Nonsteroidal Anti-oestrogen |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | Pack of 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Nolvadex Tablet of Astrazeneca **(USFDA approved)** |
| | Me-too status | Tamoxifen Sandoz 20mg Tablet by Novartis Pharma (Reg no.047671) |

| | | |
|---|---|---|
| | GMP status | The firm was granted GMP certificate based on inspection conducted on 22-02-2018. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for confirmation of requisite section for the applied product with reference to decision of 286th meeting of Registration Board regarding "Manufacturing facility for steroidal and non-steroidal hormones".** | |

## c. Applications submitted on CTD format

**Evaluator PEC-III**

| | | |
|---|---|---|
| Firm has been communicated the shortcomings for following two cases along with reminder on following dates:<br>Letter: 16th July, 2018<br>Reminder: 3rd September, 2018<br>Regardless of reminder firm has not yet replied to any letter and the case is still pending in PEC. The case is presented before the Board for its consideration. | | |
| 1194. | Name, address of Applicant / Marketing Authorization Holder | M/s Bosch Pharmaceuticals (Pvt) Ltd., Bosch House 221, Sector 23, Korangi Industrial Area, Karachi. |
| | Name, address of Manufacturing site. | M/s Bosch Pharmaceuticals (Pvt) Ltd., Bosch House 221, Sector 23, Korangi Industrial Area, Karachi. |
| | Status of the applicant | ✓ **Manufacturer**<br>□ Importer<br>□ Is involved in none of the above (contract giver) |
| | Dy No. and date of submission | Dy No. 21270: 13-06-2018 |
| | Details of fee submitted | PKR 20,000/-: 13-06-2018 |
| | Valid drug manufacturing license | DML issued on 16-02-2015 is submitted by the firm. |
| | Evidence of approval of manufacturing facility / approved section from licensing authority | Copy of approval letter dated 17-3-2015 of Oral dry powder suspension (General) section is submitted. |
| | List of registered drugs in this section | Firm has submitted list of 11 products registered in this section. |
| | Manufacturer's site master file and credentials (for importers) | N.A |
| | Type of Application | □ New Drug Product (NDP)<br>✓ **Generic Drug Product (GDP)** |
| | Intended purpose of pharmaceutical product | □ Domestic sale<br>□ Export sale<br>✓ **Domestic and Export sales** |
| | For imported products, please specify one of following: | NA |
| | Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976 | NA |
| | The proposed proprietary name / brand name | **Prelox 100mg/5ml Granules for oral suspension** |
| | Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit | Each 5ml contains:<br>Cefpodoxime (as proxetil)…….100mg |
| | Proposed Pack size | 50ml (HDPE bottle) |
| | Proposed unit price | As per SRO |
| | Pharmacotherapeutic Group of (API) | Cephalosporin |
| | Pharmacopoeial reference | USP |
| | Route of administration | Oral |
| | Dosage form of applied drug | **Granules for oral suspension** |

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|---|---|---|
| | For generic drugs (me-too status) | Qink Dry Suspension by Wilshire Laboratories (Reg # 053636) |
| | The status in reference regulatory authorities | Cefpodoxime proxetil for suspension by Sandoz (**USFDA** Approved) |
| | Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens | Yes |
| | Description of Batch numbering system | Yes |
| | Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form). | Not provided |
| | Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). | Yes but clinical indications are different |
| | Commitments | Yes |
| | Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer. | Yes |
| | Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company. | **Not provided** |
| | Information on Prior-related Applications | Not provided |
| | Electronic Review Package | Not provided |
| | QIS (Quality Information Summary) | Yes |
| | **Drug Substance related Document including following:** | |
| | a. Name and address of API manufacturer. | Nectar Lifesciences Limited Vill Saidpura, The. Dera Bassi, Distt. Mohali, Punjab. India |
| | b. Approval of manufacturing facility of API by regulatory body of country and validity. | Not provided. |
| | c. Vendor qualification / audit is | □ **Document based**<br>□ Site inspection based |
| | d. Reason for above point (c) | GMP status and DMF |
| | **MODULE 2: OVERVIEWS & SUMMARIES** | |
| | Drug Substance | Firm has submitted details of drug substance from DMF from the manufacturer of API |
| | Drug Product | Firm has submitted details of drug product |
| | **MODULE 3: QULITY / CMC** | |
| | **3.2.S: Drug substance** | |
| | Manufacturer of API | Nectar Lifesciences Limited Vill Saidpura, The. Dera Bassi, Distt. Mohali, Punjab. India |
| | API Lot No. | |
| | Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin. | |
| | Documents confirming import of API | |
| | 3.2.S.1 General Information | Attached DMF provides details of nomenclature, structure and general properties. |
| | 3.2.S.2 Manufacture | Firm has submitted description of manufacturing process and process controls and control of materials |
| | 3.2.S.3 Characterization | Firm has provided details regarding elucidation of structure and other characteristics and impurities. |

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|---|---|---|
| | 3.2.S.4 Control of drug substance | Firm has submitted details of specification, analytical procedures, validation, batch analysis and justification of specification. |
| | 3.2.S.5 Reference standards or materials | The DMF provided by firm has not submitted any details regarding reference standard or materials. |
| | 3.2.S.6 Container closure system | Firm has provided DMF which specify that material is packed in LDPE bag. |
| | 3.2.S.7 Stability | The real time stability data of API has been conducted at 25ºC ±2ºC and 60% ± 5% RH, which is not as per the requirement of zone IV-A. Accelerated stability data of API is submitted. |
| | **3.2.P: Drug Product** | |
| | 3.2.P.1 Description and composition of drug product | Firm has submitted description and composition of drug product. |
| | 3.2.P.2 Pharmaceutical development | Firm has submitted details of components of drug products, formulation, overages, and properties, manufacturing process development, container closure system, microbiological attributes and compatibility. |
| | 3.2.P.3 Manufacture | Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates.<br>Firm has not submitted process validation and or evaluation. |
| | 3.2.P.4 Control of excipients | Firm has provided details of specifications (excipients and finished product), analytical procedures, batch analysis and justification of specifications.<br>Firm has not submitted data for validation of analytical procedure and impurities characterization. |
| | 3.2.P.5 Control of drug product | Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification. |
| | 3.2.P.6 Reference standard or materials | Firm has provided COA of working standard |
| | 3.2.P.7 Container closure system | Amber glass round bottle 90ml. |
| | 3.2.P.8 Stability | Firm has submitted stability commitment only.<br>**Firm has not submitted stability study data** |
| | Comparative dissolution profile | |
| | **MODULE 4: NON-CLINICAL / SAFETY** | |
| | 4.2.1 Pharmacology | Not provided |
| | 4.2.2 Pharmacokinetics | Not provided |
| | 4.2.3 Toxicology | Not provided |
| | **MODULE 5: CLINICAL / EFFICACY** | |
| | NA. | |
| | **REMARKS OF EVALUATOR** | |
| | • Training evidence of technical staff with respect of manufacturing of applied drug (1.5.13) is not provided.<br>• The details regarding therapeutic indications provided in SmPC (1.5.14) are different from those approved by USFDA for the same product. Moreover the nature and contents of container is mentioned as 90ml in SmPC while 50ml in proposed pack size (1.5.4).<br>• Commitments of sub section 1.5.15, 1.5.16, 1.5.17, 1.5.18 and 1.5.21 are not provided.<br>• Protocols to implement Good Pharmacovigilance Practice by Pharmacovigilance department/section | |

| | | |
|---|---|---|
| | of the Manufacturer / Company (1.5.22) is not provided.<br>• Electronic review package (1.6.3) is not provided.<br>• Approval of manufacturing facility of API by regulatory body of country and validity and Vendor qualification / audit as per 1.6.5 is not provided.<br>• The real time stability data of API submitted in DMF has been conducted at 25ºC ±2ºC and 60% ± 5% RH, which is not as per the requirement of zone IV-A.<br>• Validation of analytical procedures (3.2.P.5.3) is not submitted.<br>• Stability study data (3.2.P.8.3) is not provided. Real-time and accelerated stability study data of 3 batches along with associated documents (documents confirming import of API, signed and stamped chromatograms and raw data sheets) as per the requirement of 278th meeting of Registration Board is required.<br>• Information required in module 4 for pharmacology (4.2.1), Pharmacokinetics (4.2.2) and Toxicology (4.2.3) including single dose toxicity (4.2.3.1) and repeat dose toxicity (4.2.3.2) is not provided.<br>• Page numbers are not mentioned on each page of the submitted dossier, similarly in Form 5-F "See attachment" is mentioned instead of specifying the exact page number. Since Form 5-F is a legal form therefore all details provided in this form or its annexures should be easily traceable in the dossier. | |
| | **Decision:Deferred for clarification of following points:**<br>• **Training evidence of technical staff with respect of manufacturing of applied drug (1.5.13) is not provided.**<br>• **The details regarding therapeutic indications provided in SmPC (1.5.14) are different from those approved by USFDA for the same product. Moreover the nature and contents of container is mentioned as 90ml in SmPC while 50ml in proposed pack size (1.5.4).**<br>• **Commitments of sub section 1.5.15, 1.5.16, 1.5.17, 1.5.18 and 1.5.21 are not provided.**<br>• **Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company (1.5.22) is not provided.**<br>• **Electronic review package (1.6.3) is not provided.**<br>• **Approval of manufacturing facility of API by regulatory body of country and validity and Vendor qualification / audit as per 1.6.5 is not provided.**<br>• **The real time stability data of API submitted in DMF has been conducted at 25ºC ±2ºC and 60% ± 5% RH, which is not as per the requirement of zone IV-A.**<br>• **Validation of analytical procedures (3.2.P.5.3) is not submitted.**<br>• **Stability study data (3.2.P.8.3) is not provided. Real-time and accelerated stability study data of 3 batches along with associated documents (documents confirming import of API, signed and stamped chromatograms and raw data sheets) as per the requirement of 278th meeting of Registration Board is required.**<br>• **Information required in module 4 for pharmacology (4.2.1), Pharmacokinetics (4.2.2) and Toxicology (4.2.3) including single dose toxicity (4.2.3.1) and repeat dose toxicity (4.2.3.2) is not provided.**<br>**Page numbers are not mentioned on each page of the submitted dossier, similarly in Form 5-F "See attachment" is mentioned instead of specifying the exact page number. Since Form 5-F is a legal form therefore all details provided in this form or its annexures should be easily traceable in the dossier.** | |
| 1195. | Name, address of Applicant / Marketing Authorization Holder | M/s Bosch Pharmaceuticals (Pvt) Ltd., Bosch House 221, Sector 23, Korangi Industrial Area, Karachi. |
| | Name, address of Manufacturing site. | M/s Bosch Pharmaceuticals (Pvt) Ltd., Bosch House 221, Sector 23, Korangi Industrial Area, Karachi. |
| | Status of the applicant | ✓ **Manufacturer**<br>□ Importer<br>□ Is involved in none of the above (contract giver) |
| | Dy No. and date of submission | Dy No. 21271: 13-06-2018 |
| | Details of fee submitted | PKR 20,000/-: 13-06-2018 |
| | Valid drug manufacturing license | DML issued on 16-02-2015 is submitted by the firm. |
| | Evidence of approval of manufacturing facility / approved section from licensing authority | Copy of approval letter dated 17-3-2015 of Tablet (General) section is submitted. |

| | | |
|---|---|---|
| | List of registered drugs in this section | Firm has submitted list of 07 products registered in this section. |
| | Manufacturer's site master file and credentials (for importers) | N.A |
| | Type of Application | □ New Drug Product (NDP)<br>✓ **Generic Drug Product (GDP)** |
| | Intended purpose of pharmaceutical product | □ Domestic sale<br>□ Export sale<br>✓ **Domestic and Export sales** |
| | For imported products, please specify one of following: | NA |
| | Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976 | NA |
| | The proposed proprietary name / brand name | **Prelox DS 200mg Tablet** |
| | Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit | Each film coated tablet contains:<br>Cefpodoxime (as proxetil)…….200mg |
| | Proposed Pack size | 10's (Alu/Alu blister Pack) |
| | Proposed unit price | As per SRO |
| | Pharmacotherapeutic Group of (API) | Cephalosporin |
| | Pharmacopoeial reference | USP |
| | Route of administration | Oral |
| | Dosage form of applied drug | **Tablet** |
| | For generic drugs (me-too status) | Oribro Tablets 200mg by Tabros Pharma (Reg#044350) |
| | The status in reference regulatory authorities | Cefpodoxime proxetil Tablet 200mg by Sandoz (**USFDA** Approved) |
| | Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens | Yes |
| | Description of Batch numbering system | Yes |
| | Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form). | Not provided |
| | Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). | **Yes** |
| | Commitments | Yes |
| | Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer. | Not |
| | Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company. | **Not provided** |
| | Information on Prior-related Applications | Not provided |
| | Electronic Review Package | Yes |
| | QIS (Quality Information Summary) | Yes |
| | **Drug Substance related Document including following:** | |
| | a. Name and address of API manufacturer. | Nectar Lifesciences Limited Vill Saidpura, The. Dera Bassi, Distt. Mohali, Punjab. India |
| | b. Approval of manufacturing facility of API by regulatory body of country and validity. | Not provided. |
| | c. Vendor qualification / audit is | □ **Document based** |

| | | |
|---|---|---|
| | | □ Site inspection based |
| | d. Reason for above point (c) | GMP status and DMF |
| | **MODULE 2: OVERVIEWS & SUMMARIES** | |
| | Drug Substance | Firm has submitted details of drug substance from DMF from the manufacturer of API |
| | Drug Product | Firm has submitted details of drug product |
| | **MODULE 3: QUALITY / CMC** | |
| | **3.2.S: Drug substance** | |
| | Manufacturer of API | Nectar Lifesciences Limited Vill Saidpura, The. Dera Bassi, Distt. Mohali, Punjab. India |
| | API Lot No. | |
| | Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin. | |
| | Documents confirming import of API | |
| | 3.2.S.1 General Information | Attached DMF provides details of nomenclature, structure and general properties. |
| | 3.2.S.2 Manufacture | Firm has submitted description of manufacturing process and process controls and control of materials |
| | 3.2.S.3 Characterization | Firm has provided details regarding elucidation of structure and other characteristics and impurities. |
| | 3.2.S.4 Control of drug substance | Firm has submitted details of specification, analytical procedures, validation, batch analysis and justification of specification. |
| | 3.2.S.5 Reference standards or materials | The DMF provided by firm has not submitted any details regarding reference standard or materials. |
| | 3.2.S.6 Container closure system | Firm has provided DMF which specify that material is packed in LDPE bag. |
| | 3.2.S.7 Stability | The real time stability data of API has been conducted at 25ºC ±2ºC and 60% ± 5% RH, which is not as per the requirement of zone IV-A. Accelerated stability data of API is submitted. |
| | **3.2.P: Drug Product** | |
| | 3.2.P.1 Description and composition of drug product | Firm has submitted description and composition of drug product. |
| | 3.2.P.2 Pharmaceutical development | Firm has submitted details of components of drug products, formulation, overages, and properties, manufacturing process development, container closure system, microbiological attributes and compatibility. |
| | 3.2.P.3 Manufacture | Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates.<br>Firm has not submitted process validation and or evaluation. |
| | 3.2.P.4 Control of excipients | Firm has provided details of specifications (excipients and finished product), analytical procedures, batch analysis and justification of specifications.<br>Firm has not submitted data for validation of analytical procedure and impurities characterization. |

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| | 3.2.P.5 Control of drug product | Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification. |
| | 3.2.P.6 Reference standard or materials | Firm has provided COA of working standard |
| | 3.2.P.7 Container closure system | Aluminium foil 10's |
| | 3.2.P.8 Stability | Firm has submitted stability commitment only.<br>**Firm has not submitted stability study data** |
| | Comparative dissolution profile | |
| | **MODULE 4: NON-CLINICAL / SAFETY** | |
| | 4.2.1 Pharmacology | Not provided |
| | 4.2.2 Pharmacokinetics | Not provided |
| | 4.2.3 Toxicology | Not provided |
| | **MODULE 5: CLINICAL / EFFICACY** | |
| | NA. | |
| | **REMARKS OF EVALUATOR** | |
| | • Training evidence of technical staff with respect of manufacturing of applied drug (1.5.13) is not provided.<br>• The clinical indication of Tonsillitis should not be mentioned in SmPC (1.5.14), since this indication is covered by 100mg cefpodoxime tablet only. Moreover Justify 3 years shelf life mentioned in SmPC and other sections.<br>• Justify the dosage "One tablet daily or as directed by physician" on inner label provided in 1.5.11, since once daily dose is not recommended in any indication as mentioned in SmPC.<br>• Commitments of sub section 1.5.15, 1.5.16, 1.5.17, 1.5.18, 1.5.19 and 1.5.21 are not provided.<br>• Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company (1.5.22) is not provided.<br>• Approval of manufacturing facility of API by regulatory body of country and validity and Vendor qualification / audit as per 1.6.5 is not provided.<br>• The real time stability data of API submitted in DMF has been conducted at 25ºC ±2ºC and 60% ± 5% RH, which is not as per the requirement of zone IV-A.<br>• Validation of analytical procedures (3.2.P.5.3) is not submitted.<br>• Stability study data (3.2.P.8.3) is not provided. Real-time and accelerated stability study data of 3 batches along with associated documents (documents confirming import of API, signed and stamped chromatograms and raw data sheets) as per the requirement of 278th meeting of Registration Board is required.<br>• Comparative dissolution Profile (CDP) along with reference product is not provided.<br>• Information required in module 4 for pharmacology (4.2.1), Pharmacokinetics (4.2.2) and Toxicology (4.2.3) including single dose toxicity (4.2.3.1) and repeat dose toxicity (4.2.3.2) is not provided.<br>• Page numbers are not mentioned on each page of the submitted dossier, similarly in Form 5-F "See attachment" is mentioned instead of specifying the exact page number. Since Form 5-F is a legal form therefore all details provided in this form or its annexures should be easily traceable in the dossier. | |
| | **Decision: Deferred for clarification of following points:**<br>• **Training evidence of technical staff with respect of manufacturing of applied drug (1.5.13) is not provided.**<br>• **The clinical indication of Tonsillitis should not be mentioned in SmPC (1.5.14), since this indication is covered by 100mg cefpodoxime tablet only. Moreover Justify 3 years shelf life mentioned in SmPC and other sections.**<br>• **Justify the dosage "One tablet daily or as directed by physician" on inner label provided in 1.5.11, since once daily dose is not recommended in any indication as mentioned in SmPC.**<br>• **Commitments of sub section 1.5.15, 1.5.16, 1.5.17, 1.5.18, 1.5.19 and 1.5.21 are not provided.**<br>• **Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company (1.5.22) is not provided.**<br>• **Approval of manufacturing facility of API by regulatory body of country and validity and** | |

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| | **Vendor qualification / audit as per 1.6.5 is not provided.**<br>• **The real time stability data of API submitted in DMF has been conducted at 25ºC ±2ºC and 60% ± 5% RH, which is not as per the requirement of zone IV-A.**<br>• **Validation of analytical procedures (3.2.P.5.3) is not submitted.**<br>• **Stability study data (3.2.P.8.3) is not provided. Real-time and accelerated stability study data of 3 batches along with associated documents (documents confirming import of API, signed and stamped chromatograms and raw data sheets) as per the requirement of 278th meeting of Registration Board is required.**<br>• **Comparative dissolution Profile (CDP) along with reference product is not provided.**<br>• **Information required in module 4 for pharmacology (4.2.1), Pharmacokinetics (4.2.2) and Toxicology (4.2.3) including single dose toxicity (4.2.3.1) and repeat dose toxicity (4.2.3.2) is not provided.**<br>• **Page numbers are not mentioned on each page of the submitted dossier, similarly in Form 5-F "See attachment" is mentioned instead of specifying the exact page number. Since Form 5-F is a legal form therefore all details provided in this form or its annexures should be easily traceable in the dossier.** |

**Evaluator-PEC-VI**

| | | |
|---|---|---|
| 1196. | Name, address of Applicant / Marketing Authorization Holder | M/s AGP limited, B-23-C, SITE, Karachi. |
| | Name, address of Manufacturing site. | M/s Mylan laboratories Ltd, Plot No. 11,12 & 13, Indore Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur-454775 Dist. Dhar, Madhya Pradesh, India |
| | Status of the applicant | □ Manufacturer<br>□ **Importer**<br>☐ Is involved in none of the above (contract giver) |
| | Dy No. and date of submission | Dy No. 31739, : 24-9-2018 |
| | Details of fee submitted | PKR 100,000/-: 24-9-2018 |
| | The proposed proprietary name / brand name | **HepBest 25mg tablets** |
| | Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit | Each film coated tablet contains:<br>Tenofovir Alafenamide Fumarate eq to tenofovir Alfenamide….25mg |
| | Dosage form of applied drug | Immediate release film coated tablet |
| | Route of administration | Oral |
| | Pharmacotherapeutic Group of (API) | Antiviral for Systemic use, Nucleoside and nucleotide reverse transcriptase inhibitor. ATC Code: J05AF13 |
| | Pharmacopoeial reference | In-House Formulation |
| | Proposed Pack size | 30's |
| | Proposed unit price | Rs.6151.98 for 30's |
| | The status in reference regulatory authorities | USFDA Approved |
| | For generic drugs (me-too status) | Not Applicable |
| | Valid drug manufacturing license/Drug Sale License | Copy of Drug sale License by way of Wholesale. Valid till 21-09-2019 is submitted |
| | Evidence of approval of manufacturing facility / approved section from licensing authority | Copy of certificate of Drug registration issued from office of controller Food and drug administration, Madhya Pradesh, India |
| | Type of Application | □ **New Drug Product (NDP)**<br>☐ Generic Drug Product (GDP) |
| | Intended use of pharmaceutical product | □ **Domestic sale**<br>□ Export sale |

| | | |
|---|---|---|
| | | ☐ Domestic and Export sales |
| | For imported products, please specify one of following: | ☐**Finished Pharmaceutical Product Import**<br>☐Bulk Import and local repacking (Specify status of bulk)<br>☐Bulk Import local repacking for Export purpose only |
| | Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976 | **NA** |
| | List of registered products | NA |
| | Manufacturer's site master file and credentials (for importers) | Yes |
| | Identification of signature of authorized persons , Incharge Production, Quality Control & Quality Assurance of manufacturer. | Yes |
| | Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens | Yes |
| | Description of Batch numbering system | Yes |
| | Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form). | N/A |
| | Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). | Yes |
| | Commitments | Yes |
| | Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer. | Yes |
| | Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company. | Yes |
| | Information on Prior-related Applications | N/A |
| | Electronic Review Package | Yes |
| | QIS (Quality Information Summary) | Yes |
| | **Drug Substance related Document including following:** | |
| | a. Name and address of API manufacturer. | M/s Mylan laboratories Limited, (Unit 10) Plot No. 86-Ramky Pharmacity, India |
| | b. Approval of manufacturing facility of API by regulatory body of country and validity. | Form no. 26 (Certificate of renewal of license to manufacture for sale of drugs, other than those specified in schedule X ) is submitted. Valid upto 21-8-2022 |
| | c. Vendor qualification / audit is | ☐ Document based<br>☐ **Site inspection based** |
| | d. Reason for above point (c) | GMP status and DMF |
| | **MODULE 2: OVERVIEWS & SUMMARIES** | |
| | Drug Substance | Firm has submitted overall summary of drug substance including general information, specification, and characterization, control of the API, reference standard, container closure system and stability. |
| | Drug Product | Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, manufacturing process development, container closure system, microbiological attributes and compatibility, controls of drug product, reference standards or materials and stability studies. |
| | **MODULE 3: QULITY / CMC** | |

| | | |
|---|---|---|
| | **3.2.S: Drug substance** | |
| | General Information | Attached DMF provides details of nomenclature, structure and general properties. |
| | Manufacture | M/s Mylan laboratories Limited, (Unit 10) Plot No. 86- Ramky Pharmacity, Andra Pradesh, India.<br>Firm has submitted detail of manufacturer, manufacturing process and process control, control of materials, control of critical steps and intermediates, process validation / evaluation and manufacturing process development. |
| | Characterization | Firm has provided details regarding elucidation of structure and other characteristics and impurities. |
| | Control of drug substance | Firm has submitted details of specification, analytical procedures, validation, batch analysis and justification of specification. |
| | Reference standards or materials | Firm has submitted details of In-house Working standard (Batch No. QCD-10/TAF/WS001/16) |
| | Container closure system | Firm has provided details on specifications for packaging material (HMLDPE bags) |
| | Stability | Stability study data of 3 batches of API has been provided .<br>Accelerated stability studies of API is conducted at 40+-2'C 75% +-5% humidity for 6 months. |
| | **3.2.P: Drug Product** | |
| | Description and composition of drug product | Firm has submitted description and composition of drug product |
| | Pharmaceutical development | Firm has provided details of drug substance, excipients, formulation development, overages, physicochemical and biological properties, manufacturing process development, container closure system, microbiological attributes and compatibility. |
| | Manufacture | Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and evaluation. |
| | Control of excipients | Firm has provided details of specifications, analytical procedures, validation of analytical procedures, justification of specifications, excipients of animal or human origin and novel excipients. |
| | Control of drug product | Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification. |
| | Reference standard or materials | Firm has submitted certificate of analysis of reference standards and impurity standards |
| | Container closure system | HDPE bottle with dessicant |
| | Stability | Firm has provided complete stability study data of 3 batches as per Zone IV-B |
| | Comparative dissolution profile | NA |
| | **MODULE 4: NON-CLINICAL / SAFETY** | |
| | Pharmacology | Firm has provided data of pharmacology of the said product |
| | Pharmacokinetics | Firm has provided data of pharmacokinetics of the said product |
| | Toxicology | Firm has provided data of single dose and repeat dose Toxicology of the said product |
| | **MODULE 5: CLINICAL / EFFICACY** | |

| | | | | |
|---|---|---|---|---|
| | Firm has submitted data regarding reports of Biopharmaceutic Studies, Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials, Reports of Human Pharmacokinetic (PK) Studies, Reports of Human Pharmacodynamic (PD) Studies, Reports of Efficacy and Safety Studies, Reports of Post-Marketing Experience and Case Report Forms and Individual Patient Listings. | | | |
| | **STABILITY STUDY DATA** | | | |
| | Manufacturer of API | M/s Mylan laboratories Limited, (Unit 10) Plot No. 86- Ramky Pharmacity, India | | |
| | API Lot No. | 50056945 | | |
| | Description of Pack (Container closure system) | 30, 90 film coated tablets packed in HDPE bottels | | |
| | Stability Storage Condition | Real time : 30˚C ± 2˚C / 75% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| | Time Period | Real time: 18 months<br>Accelerated: 6 months | | |
| | Frequency | Accelerated: 0, 1, 3, 5, 6 (Months)<br>Real Time: 0, 3, 6, 9, 12, 18, 24 (Months) | | |
| | Batch No. | 2012170 | 2012171 | 2012172 |
| | Batch Size | 2,30,000 Tablets | 2,30,000 Tablets | 2,30,000 Tablets |
| | Manufacturing Date | Aug-2016 | Aug-2016 | Aug-2016 |
| | Date of Initiation | 25-09-2016 | 26-09-2016 | 26-09-2016 |
| | No. of Batches | 03 | | |
| | **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | | |
| | **Documents To Be Provided** | | **Status** | |
| | COA of API | | Yes | |
| | Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin. | | Form no. 26 (Certificate of renewal of license to manufacture for sale of drugs, other than those specified in schedule X) is submitted. Valid upto 21-8-2022 | |
| | Protocols followed for conduction of stability study and details of tests. | | Yes | |
| | Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc. | | N.A | |
| | Documents confirming import of API etc. | | N.A | |
| | All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents. | | Yes | |
| | **Letter Communicated to Firm** | | **Firm's response/Remarks of the Evaluator** | |
| | Real time stability data of API is not as per the requirements of zone IV-A | | 12 months API stability study is provided. The Storage condition for Tenofovir Alafenamide Fumarte is "Store ar below 25'C in tight, light-resistant containers". Hence long term stability studies conducted at 25'C/ 60% RH. | |
| | Real time stability study data of Finish product till complete shelf-life (24 months) is required to be submitted. | | 24-months Long term stability studies conducted at 30'C / 75% are provided. | |
| | Product interchangeability (comparative dissolution profile) as per the requirements of sub section 3.2.R.3 is required to be submitted. | | The firm has submitted Comparative Dissolution profile with the Reference Product (Vemlidy 25mg tablet). | |

| | | |
|---|---|---|
| | | They have also provided summary of Bioavailability and Bioequivalence studies. |
| | **Decision: Approved with innovator's specification. Manufacturer will submit data of prospective validation on commercial batches before sale of the product.** | |

## d. Import applications of priority categories defined by Registration Board in its 257th meeting

**Evaluator PEC-III**

| | | |
|---|---|---|
| 1197 | Name and address of Applicant | M/s Origin Pharma (Pvt) Ltd., 41-Baber Block New Garden Town Lahore |
| | Detail of Drug Sale License | **Address:** 41-Baber Block, New Garden Town, Lahore<br>**Validity: 11/08/2019**<br>**Status:** License to sell drugs as distributor |
| | Name and address of manufacturer | World Medicine Ilac San Ve TiC A.S. Evren Mah. Cami Yolu Cad. No. 50, 34212 Gunesli, Bagcilar/Istanbul. |
| | Name and address of marketing authorization holder | World Medicine Ilac San Ve TiC A.S. Evren Mah. Cami Yolu Cad. No. 50, 34212 Gunesli, Bagcilar/Istanbul. |
| | Name of exporting country | Turkey |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 20400: 06-06-2018 |
| | Fee including differential fee | PKR 50,000/-: 6-6-2018 |
| | Brand Name +Dosage Form + Strength | Fluzamed (Fluconazole 0.3% Eye Drops) (ophthalmic solution) |
| | Composition | Each ml contains:<br>Fluconazole…..3mg |
| | Finished Product Specification | Firm has claimed inhouse specification |
| | Pharmacological Group | Antifungal |
| | Shelf life | 2 years (as per data of zone IV-A of 3 batches provided by the firm) |
| | Demanded Price | Rs. 800/- |
| | Pack size | 5ml HDPE eye drops bottle |
| | International availability | Could not be confirmed |
| | Me-too status | Could not be confirmed |
| | Detail of certificates attached | • Original, legalized CoPP (No. 2018/1187) along with translation in English issued by Turkish Medicine and Medical Devices Agency on 26-03-2018 confirming free sale status and GMP of the manufacturer.<br>• Sole agency letter between M/s World Medicine Ilac San and M/s Origin Pharma is provided on letter head of World medicine Ilac San. |
| | **Remarks of the Evaluator.**<br>• Evidence of approval of applied formulation in reference regulatory authorities approved in 275th meeting is required.<br>• Me-too status could not be confirmed. | |
| | **Decision: Deferred for following:**<br>**• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>**• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |

| | | |
|---|---|---|
| 1198 | Name and address of Applicant | M/S Bristol Mayer Biotech Pakistan, 73-B Guldasht Town Lahore Cantt Pakistan |
| | Detail of Drug Sale License | Address : 73-B Guldasht Town, Zarar Shaheed road Lahore<br>**Validity :** 07/04/2020<br>**Status:** to sell drugs in a whole sale distribution |
| | Name and address of manufacturer | Çerkezköy Organize Sanayi Bölgesi Karaağaç Mahallesi Faith Bulvari No: 38 Kapakli/ TEKIRDAĞ/TURKEY |
| | Name and address of marketing authorization holder | VEM ILAC San.ve Tic. A.s. Söğütözü Mahallesi 2177. Cad No:10 B/49 Cankaya/ANKARA/TURKEY |
| | Name of exporting country | Turkey |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No : 18446 Dated : 21/05/2018 |
| | Fee including differential fee | Rs : 50,000 Dated : 21/05/2018 |
| | Brand Name +Dosage Form + Strength | Blumet 100mg/10ml Injection |
| | Composition | Each ml Contains<br>Methylene blue ……10mg |
| | Finished Product Specification | USP |
| | Pharmacological Group | Antidote |
| | Shelf life | 36 months |
| | Demanded Price | As per SRO |
| | Pack size | 10ml Ampoule |
| | International availability | NA |
| | Me-too status | Not Available |
| | Detail of certificates attached | **Valid and Legalized CoPP**<br>**Certificate No**: 2018/1595<br>**Certified by:** Turkish Medicines and Medical devices Agency Söğütözü Mahallesi 2176. Sokak No:5 06520 Cankaya/Ankara/Turkey<br>Product license and date of issue : 2014/442 _26.05.2014<br>**Valid until :** 25-04-2022<br>**Free sale:** Free sale of the product in exporting country.:<br>Yes confirms from COPP<br>**GMP certificate**<br>GMP certificate No : 2018/1580<br>Date of Issue: 24-04-2018<br>Valid until : 24/04/2020<br>**Sole Contract Agreement**<br>07-06-2018 |
| | Remarks of the Evaluator. | • Long term Stability studies for only 06 months submitted.<br>• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.<br>• Refrence provided PROVAYBLUE 5mgml (50mg/10ml) USFDA is in different strength. And label provided of Akron, Inc. have disclaimer that this drug has not been found by FDA to be safe and effective, and this labelling has not been approved by FDA. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Long term Stability studies data for claimed shelf life.** | |

**Evaluator PEC-V**

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|---|---|---|
| 1199. | **Name and address of Applicant** | **M/s Mustafa Brothers,**<br>186-D, Peoples Colony No.1, Faisalabad. |
| | Detail of Drug Sale License | **Address:** Mustafa Brothers, P-186-D, Peoples Colony No.1 Faisalabad.<br>**Validity:** 21/06/2020<br>**Status:** License to sell drugs as a Distributor |
| | Name and address of manufacturer | M/s Asia Animal Pharmaceutical CO. LTD<br>No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam |
| | Name and address of marketing authorization holder | M/s Asia Animal Pharmaceutical CO. LTD<br>No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam |
| | Name of exporting country | Vietnam |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 14754 Dated 12/09/2017 |
| | Fee including differential fee | Rs. 100,000/- Dated 12/09/2017 |
| | Brand Name +Dosage Form + Strength | Marbofloxacin 25 Solution for Injection |
| | Composition | Each 1 ml contains:<br>Marbofloxacin…25mg |
| | Target species | Cattle, Poultry |
| | Finished Product Specification | In-house |
| | Pharmacological Group | Antibacterial for systemic use, Flouroquinolones |
| | Shelf life | 3 years |
| | Demanded Price | Decontrolled |
| | Pack size | 100 ml Glass bottle |
| | International availability | International availability could not be confirmed. |
| | Me-too status | N/A |
| | Detail of certificates attached | **Original Legalized Free sale Certificate**<br>**Certificate no.** 260/2017/QLT-CFS<br>**Certifying Authority:** Ministry of Agriculture and Rural Development, Department of Animal Health<br>**Validity:** 30-03-2019<br>**Original Legalized GMP certificate**<br>Certifying Authority: Ministry of Agriculture and Rural Development,<br>Validity: Aug 2022.<br>**Copy of Distribution Agreement**<br>M/s Mustafa Brothers<br>186-D, Peoples Colony No.1, Faisalabad.<br>&<br>M/s Asia Animal Pharmaceutical CO. LTD<br>No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam<br>**Validity:** 24, Aug, 2021 |
| | Stability Studies | • Zone IV A.<br>36 months data. |
| | Remarks of the Evaluator. | • Step of terminal sterilization has not been mentioned in manufacturing outline. Justify and clarify the same.<br>Firm has used filtration process through micro filter (1 mm-0.2mm) filter.<br>• Agreement does not mention the list of product to be imported. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting**<br>• **Clarification regarding step of terminal sterilization is needed** | |

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|---|---|---|
| 1200. | Name and address of Applicant | M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad. |
| | Detail of Drug Sale License | **Address:** Mustafa Brothers, P-186-D, Peoples Colony No.1 Faisalabad.<br>**Validity:** 21/06/2020<br>**Status:** License to sell drugs as a Distributor |
| | Name and address of manufacturer | M/s Asia Animal Pharmaceutical CO. LTD<br>No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam |
| | Name and address of marketing authorization holder | M/s Asia Animal Pharmaceutical CO. LTD<br>No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam |
| | Name of exporting country | Vietnam |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 14756 Dated 12/09/2017 |
| | Fee including differential fee | Rs. 100,000/- Dated 12/09/2017 |
| | Brand Name +Dosage Form+Strength | Thiamsone Injectable Solution |
| | Composition | Each 1 ml contains:<br>Thiamphenicol …100mg<br>Oxytetracycline…50mg<br>Dexamethasone…. 1mg |
| | Target species | Cattle, Poultry |
| | Finished Product Specification | In-house |
| | Pharmacological Group | Antibacterial for systemic use |
| | Shelf life | 3 years |
| | Demanded Price | Decontrolled |
| | Pack size | 100 ml Glass bottle |
| | International availability | International availability could not be confirmed. |
| | Me-too status | N/A |
| | Detail of certificates attached | **Original Legalized Free sale Certificate**<br>**Certificate no.** 262/2017/QLT-CFS<br>**Certifying Authority:** Ministry of Agriculture and Rural Development, Department of Animal Health<br>**Validity:** 30-03-2019<br>**Original Legalized GMP certificate**<br>Certifying Authority: Ministry of Agriculture and Rural Development,<br>Validity: Aug 2022.<br>**Agreement**<br>M/s Mustafa Brothers,<br>186-D, Peoples Colony No.1, Faisalabad.<br>&<br>M/s Asia Animal Pharmaceutical CO. LTD<br>No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam<br>**Validity:** 24, Aug, 2021 |
| | Stability Studies | • Zone IV A.<br>36 months data. |
| | Remarks of the Evaluator. | • Step of terminal sterilization has not been mentioned in manufacturing outline. Justify and clarify the same.<br>Firm has used filtration process through micro filter (1 mm-0.2mm) filter.<br>• Agreement does not mention the list of product to be imported. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting**<br>• **Clarification regarding step of terminal sterilization is needed.** | |

| | | |
|---|---|---|
| 1201. | Name and address of Applicant | M/s Helix Pharma (Pvt) Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road Karachi. |
| | Detail of Drug Sale License | **Address:** Helix pharma (pvt) Ltd., Hakim sons house A-56, S.I.T.E. Karachi.<br>**Validity:**<br>**Status:** Drug License by way of Wholesale |
| | Name and address of manufacturer | Reliance Life sciences Pvt Ltd., Plant 3,5,6, Dhirubhai life Sciences centre (DALC) r-282 Thane- Belapur Road, Rabale, Navi Mumbai- 400701, India. |
| | Name and address of marketing authorization holder | Reliance Life sciences Pvt Ltd., Plant 3,5,6, Dhirubhai life Sciences centre (DALC) r-282 Thane- Belapur Road, Rabale, Navi Mumbai- 400701, India. |
| | Name of exporting country | India |
| | Type of Form | Form 5A |
| | Diary No. & Date of R& I | Dy. No.3409 Dated 26/01/2018 |
| | Fee including differential fee | Rs. 100,000/- Dated 25/01/2018 |
| | Brand Name+Dosage Form+ Strength | Erlotirel 100 Tablets |
| | Composition | Each film coated tablet contains:<br>Erlotinib……. 100mg |
| | Finished Product Specification | In House |
| | Pharmacological Group | Anti-Cancer |
| | Shelf life | 24 months |
| | Demanded Price | As Per MRP |
| | Pack size | |
| | International availability | Approved in US-FDA |
| | Me-too status | Tarceva 100mg tablets of Roche Pakistan Limited, Karachi |
| | Detail of certificates attached | **Original legalized CoPP:**<br>Certificate No: COPP/CERT/KD/60727/2017/11/20552/103919<br>Certified by: Food & Drug administration, M.S. Bandra-Kurla Complex Bandra –Kurla Complex, Mumbai, Maharashtra State, India<br>Issued on: 23/08/2017<br>Valid up to: 17th May 2019<br>Free sale in exporting country: Confirms the free sale of the product in exporting country.<br>GMP**:**The facilities and operations conform to GMP as recommended by WHO as per CoPP.<br>**Original legalized Free sale Certificate:**<br>(This certificate is issued for export registration)<br>Certificate No: 6078190<br>Certified by: Food & Drugs Administration Konkan Division, Maharashtra State, India.<br>Issued date: 24/10/2017<br>Validity: Untill 23/10/2018 |
| | Remarks of the Evaluator. | • Reliance Life sciences has submitted two Original legalized Free sale Certificate as mentioned below:<br>One certificate is issued for export registration only.(In-House)<br>Second certificate is issued for product freely sold in India(IP)<br>• Submit complete stability study data both accelerated & real time of three batches of applied formulation as per zone IVa conditions as you have submitted only six month accelerated data for three batches & 3 months real time data for one batch and 6 month real time for two batches as per zone IVb conditions. |
| | **Decision: Deferred for submission of stability data at real time of three batches of applied formulation as per Zone IVa till claimed shelf life.** | |

| | | |
|---|---|---|
| 1202. | Name and address of Applicant | M/s Helix Pharma (Pvt)Ltd. Hakimsons House, A/56, S.I.T.E Manghopir Road Karachi. |
| | Detail of Drug Sale License | **Address:** Helix pharma (pvt) Ltd., Hakim sons house A-56, S.I.T.E. Karachi.<br>**Validity:**<br>**Status:** Drug License by way of Wholesale |
| | Name and address of manufacturer | Reliance Life sciences Pvt Ltd., Plant 3,5,6, Dhirubhai life Sciences centre (DALC) r-282 Thane- Belapur Road, Rabale, Navi Mumbai- 400701, India. |
| | Name and address of marketing authorization holder | Reliance Life sciences Pvt Ltd., Plant 3,5,6, Dhirubhai life Sciences centre (DALC) r-282 Thane- Belapur Road, Rabale, Navi Mumbai- 400701, India. |
| | Name of exporting country | India |
| | Type of Form | Form 5A |
| | Diary No. & Date of R& I | Dy. No.3410 Dated 26/01/2018 |
| | Fee including differential fee | Rs. 100,000/- Dated 25/01/2018 |
| | Brand Name +Dosage Form + Strength | Erlotirel 150 Tablets |
| | Composition | Each film coated tablet contains:<br>Erlotinib……. 150mg |
| | Finished Product Specification | In House |
| | Pharmacological Group | Anti-Cancer |
| | Shelf life | 24 months |
| | Demanded Price | As Per MRP |
| | Pack size | 3×10's tablets |
| | International availability | Approved in US-FDA |
| | Me-too status | Tarceva 150mg tablets of Roche Pakistan Limited, Karachi |
| | Detail of certificates attached | **Original legalized CoPP:**<br>Certificate No: COPP/CERT/KD/60572/2017/11/20441/103630<br>Certified by: Food & Drug administration, M.S. Bandra-Kurla Complex Bandra –Kurla Complex, Mumbai, Maharashtra State, India<br>Issued on: 11/08/2017<br>Valid up to: 17th May 2019<br>Free sale in exporting country: Confirms the free sale of the product in exporting country.<br>GMP**:**The facilities and operations conform to GMP as recommended by WHO as per CoPP.<br>**Original legalized Free sale Certificate:**<br>(This certificate is issued for export registration)<br>Certificate No: 6078191<br>Certified by: Food & Drugs Administration Konkan Division, Maharashtra State, India.<br>Issued date: 24/10/2017<br>Validity: Untill 23/10/2018 |
| | Remarks of the Evaluator. | • Reliance Life sciences has submitted two Original legalized Free sale Certificate described below:<br>One certificate is issued for export registration only.(In-House)<br>Second certificate is issued for product freely sold in India(IP)<br>• Data of 03 batches supported by attested respective documents like chromatograms, laboratory reports, data sheets etc. |
| | **Decision: Deferred for submission of stability data at real time of three batches of applied formulation as per Zone IVa till claimed shelf life.** | |

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|---|---|---|
| 1203. | Name and address of Applicant | M/s Punjab Medical Services, Office No. 4,5 Jalal Centre 2nd floor Opposite O.P.D gate Sir Ganga Ram Hospital Lahore |
| | Detail of Drug Sale License | **Adress:** Punjab Medical Services Pharmacy, Office No. 4,5 Jalal Centre 2nd floor Opposite O.P.D gate Sir Ganga Ram Hospital Lahore<br>**Validity:** 09/08/2019<br>**Status:** License to sell drugs in Pharmacy |
| | Name and address of manufacturer | M/s Actavis Italy S.P.A, Nerviano plant, Viale Pasteur 10 20014, Nerviano (milan), Italy. |
| | Name and address of marketing authorization holder | M/s Actavis Group PTC ehf.<br>Reykjavikurvegur 76-78, 220 Hafnarfjordur, Iceland. |
| | Name of exporting country | Iceland |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No.25077 : 19-07-2018 |
| | Fee including differential fee | PKR 100,000/-: 19-07-2018 |
| | Brand Name +Dosage Form+Strength | EPI PMS, 10mg/5ml Solution for Injection |
| | Composition | Each 5ml vial contains:<br>Epirubicin hydrochloride …10 mg |
| | Finished Product Specification | Manufacturer's specifications |
| | Pharmacological Group | Cytotoxic antibiotics and related substances (Anthracyclines and related substances) |
| | Shelf life | 36 months |
| | Demanded Price | As per SRO |
| | Pack size | Type I glass vials containing 5ml concentrated solution in pack size of 1's |
| | International availability | Epirubicin hydrochloride 2 mg/ml, solution for injection or infusion (5ml vial) by M/s Teva UK Limited (MHRA Approved) |
| | Me-too status | Ciazil Injection 10mg vial (5ml) by M/s Rotex (Reg#063978) |
| | Detail of certificates attached | **Original, Legalized CoPP**<br>Certificate No: 160032018/008<br>Certifying Authority: Icelandic Medicines Agency<br>Free Sale: Yes<br>Issue Date: 16-03-2018<br>**Copy of GMP certificate**<br>Certificate No: IT/130-1/H/2016<br>Certifying Authority: Agenzia Italiana del farmaco (AIFA)<br>Date of inspection: 05-10-2016<br>Validity : 3 years<br>**Letter of Authorization**<br>Firm has submitted letter of Authorization from M/s Actavis Group PTC ehf.Iceland for the applied product in the name of M/s Punjab Medical Services, Office No. 4,5 Jalal Centre 2nd floor Opposite O.P.D gate Sir Ganga Ram Hospital Lahore<br>Issue date: 25-09-2018 |

**Remarks of the Evaluator.**

- Manufacturer has cytotoxic section.
- Drug product is intended for storage in a refrigerator as per ICH guideline.

| Study | Storage condition | Minimum time period covered by data at submission |
|---|---|---|
| Long term | 5°C ± 3°C | 12 months |
| Accelerated | 25°C ± 2°C/60% RH ± 5% RH | 6 months |

- Firm has submitted stability study data of **3** batches. Details are as under:

  **Batch#31010**

  Long term (5°C ± 3°C) 36 months duration.

  Accelerated (25°C ± 2°C/60% RH ± 5% RH) **2 months** duration. (As per documents submitted by the firm significant changes: a 5%change in assay from its initial value. T3 and T6 months were

| | | |
|---|---|---|
| | not tested because the stability was interrupted after T2 months failure.<br>**Batch#31020**<br>Long term (5°C ± 3°C) 36 months duration.<br>Accelerated (25°C ± 2°C/60% RH ± 5% RH) **6 months** duration. (As per documents submitted by the firm significant changes: a 5%change in assay from its initial value at T3 and T6 months).<br>**Batch#31030**<br>Long term (5°C ± 3°C) 36 months duration.<br>Accelerated (25°C ± 2°C/60% RH ± 5% RH) **6 months** duration. (As per documents submitted by the firm significant changes: a 5%change in assay from its initial value. T3 and T6 months were not tested because the stability was interrupted after T2 months failure).<br>As per ICH HARMONISED TRIPARTITE GUIDELINE: STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1A(R2) for Drug products intended for storage in a refrigerator:<br>If significant change occurs between 3 and 6 months' testing at the accelerated storage condition, the proposed re-test period should be based on the real time data available at the long term storage condition.<br>If significant change occurs within the first 3 months' testing at the accelerated storage condition, a discussion should be provided to address the effect of short term excursions outside the label storage condition, e.g., during shipping or handling. This discussion can be supported, if appropriate, by further testing on a single batch of the drug product for a period shorter than 3 months but with more frequent testing than usual. It is considered unnecessary to continue to test a drug substance through 6 months when a significant change has occurred within the first 3 months.<br>• The finished product analytical procedure submitted by the firm refers to in-house method for the 'Assay' test, whereas USP and BP monograph available for applied formulation. | |
| | **Decision: Deferred for following reasons:**<br>• **Clarification for significant change in assay during accelerated stability studies.**<br>• **Scientific justification to address the effect of short term excursions outside the label storage condition, e.g., during shipping or handling.**<br>• **Scientific justification of applying in-house finished product analytical procedures whereas USP and BP monograph available for applied formulation.** | |
| 1204. | Name and address of Applicant | M/s Punjab Medical Services,<br>Office No. 4,5 Jalal Centre 2nd floor Opposite O.P.D gate Sir Ganga Ram Hospital Lahore |
| | Detail of Drug Sale License | **Adress:** Punjab Medical Services Pharmacy, Office No. 4,5 Jalal Centre 2nd floor Opposite O.P.D gate Sir Ganga Ram Hospital Lahore<br>**Validity:** 09/08/2019<br>**Status:** License to sell drugs in Pharmacy |
| | Name and address of manufacturer | M/s Actavis Italy S.P.A,<br>Nerviano plant, Viale Pasteur 10 20014, Nerviano (milan), Italy. |
| | Name and address of marketing authorization holder | M/s Actavis Group PTC ehf.<br>Reykjavikurvegur 76-78, 220 Hafnarfjordur, Iceland. |
| | Name of exporting country | Iceland |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No.25076 : 19-07-2018 |
| | Fee including differential fee | PKR 100,000/-: 19-07-2018 |
| | Brand Name +Dosage Form + Strength | **EPI PMS, 50mg/25ml Solution for Injection** |
| | Composition | Each 25ml vial contains:<br>Epirubicin hydrochloride …50 mg |
| | Finished Product Specification | Manufacturer's specifications |
| | Pharmacological Group | Cytotoxic antibiotics and related substances (Anthracyclines and related substances) |
| | Shelf life | 36 months |
| | Demanded Price | As per SRO |
| | Pack size | Type I glass vials containing 25ml concentrated solution in pack size of 1's. |

| | | |
|---|---|---|
| | International availability | Epirubicin hydrochloride 2 mg/ml, solution for injection or infusion (25ml vial) by M/s Teva UK Limited (MHRA Approved) |
| | Me-too status | Ciazil Injection 10mg vial (5ml) by M/s Rotex (Reg#063978) |
| | Detail of certificates attached | **Original, Legalized CoPP**<br>**Certificate No**: 160032018/008<br>**Certifying Authority:** Icelandic Medicines Agency<br>**Free Sale:** Yes<br>**GMP:** n/a<br>**Issue Date:** 16-03-2018<br>**Copy of GMP certificate**<br>**Certificate No**: IT/130-1/H/2016<br>Certifying Authority: Agenzia Italiana del farmaco (AIFA)<br>**Date of inspection:** 05-10-2016<br>**Validity** : 3 years<br>**Copy of Letter of Authorization**<br>Firm has submitted letter of Authorization from M/s Actavis Group PTC ehf.Iceland for the applied product in the name of M/s Punjab Medical Services, Office No. 4,5 Jalal Centre 2nd floor Opposite O.P.D gate Sir Ganga Ram Hospital Lahore<br>Issue date: 25-09-2018 |

**Remarks of the Evaluator.**

- Manufacturer has cytotoxic section.
- Drug product is intended for storage in a refrigerator as per ICH guideline.
-

| Study | Storage condition | Minimum time period covered by data at submission |
|---|---|---|
| Long term | 5°C ± 3°C | 12 months |
| Accelerated | 25°C ± 2°C/60% RH ± 5% RH | 6 months |

- Firm has submitted stability study data of **3** batches. Details are as under:

  **Batch#2CK001**

  Long term (5°C ± 3°C) 36 months duration.

  Accelerated (25°C ± 2°C/60% RH ± 5% RH) **2 months** duration. (As per documents submitted by the firm significant changes: a 5%change in assay from its initial value. T3 and T6 months were not tested because the stability was interrupted after T2 months failure.)

  **Batch#2CK002**

  Long term (5°C ± 3°C) 36 months duration.

  Accelerated (25°C ± 2°C/60% RH ± 5% RH) **2 months** duration. (As per documents submitted by the firm significant changes: a 5%change in assay from its initial value. T3 and T6 months were not tested because the stability was interrupted after T2 months failure).

  **Batch#3CK001**

  Long term (5°C ± 3°C) 24 months duration.

  Accelerated (25°C ± 2°C/60% RH ± 5% RH) **6 months** duration. (As per documents submitted by the firm significant changes: a 5%change in assay from its initial value at T6 months).

  As per ICH HARMONISED TRIPARTITE GUIDELINE: STABILITY TESTING OF NEW DRUG SUBSTANCES AND PRODUCTS Q1A(R2) for Drug products intended for storage in a refrigerator:

  If significant change occurs between 3 and 6 months' testing at the accelerated storage condition, the proposed re-test period should be based on the real time data available at the long term storage condition.

  If significant change occurs within the first 3 months' testing at the accelerated storage condition, a discussion should be provided to address the effect of short term excursions outside the label storage condition, e.g., during shipping or handling. This discussion can be supported, if appropriate, by further testing on a single batch of the drug products for a period shorter than 3 months but with more frequent testing than usual. It is considered unnecessary to continue to test a drug substance through 6 months when a significant change has occurred within the first 3 months.
- The finished product analytical procedure submitted by the firm refers to in-house method for the 'Assay' test, whereas USP and BP monograph available for applied formulation.

| | |
|---|---|
| | **Decision: Deferred for following reasons:**<br>• **Clarification for significant change in assay during accelerated stability studies.**<br>• **Scientific justification to address the effect of short term excursions outside the label storage condition, e.g., during shipping or handling.**<br>• **Scientific justification of applying in-house finished product analytical procedures whereas USP and BP monograph available for applied formulation.** |

**Evaluator PEC-XIV**

| | | |
|---|---|---|
| 1205. | Name and address of Applicant | M/s AA Pharma, 2nd floor, Shafi Court, Merewether Road, Civil Lines, Karachi |
| | Detail of Drug Sale License | **Address:** A-16 Block-13, Gulistan e Iqbal, Karachi<br>**Validity:** 22-05-2020<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | M/s Jiangsu Hengrui Medicine Co., Ltd. 38 Huanghe Road, Economic and technical development Zone, Lianyungang, Jiangsu 222047, China. |
| | Name and address of marketing authorization holder | M/s Jiangsu Hansoh pharmaceutical group Co., Ltd. No.9 Dongjin Roaf, Economic and technical development Zone, Lianyungang, Jiangsu 222069, China. |
| | Name of exporting country | China |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 26100, Dated 30-07-2018 |
| | Fee including differential fee | PKR 100,000/-, Dated 19-07-2018 |
| | Brand Name +Dosage Form + Strength | **ZEFEI** 200mg for injection |
| | Composition | Each vial contains:<br>Gemcitabine Hydrochloride eq. to Gemcitabine.....200mg |
| | Finished Product Specification | USP |
| | Pharmacological Group | Nucleoside metabolic inhibitor |
| | Shelf life | 24 months |
| | Demanded Price | ------ |
| | Pack size | 10 ml Type I glass vial, 1's |
| | International availability | Gemcitabine 200mg solution for infusion of Accord healthcare Ltd., **MHRA approved** |
| | Me-too status | Oncogem 200 Injection by AJ Mirza Pharma (Reg#045671) |
| | Detail of certificates attached | ●Original legalized CoPP issued by Jiangsu Provincial Food and Drug Administration, China confirms free sale of the product in the exporting country. Certificate No: LYG (copp) 20180019.<br>●Notarised GMP certificate of the manufacturer issued by China Food and Drug Administration is submitted which is valid until 22-05-2019. Certificate No: CN20140247.<br>●Legalized copy of letter of authorization dated 15-03-2018 has been submitted from M/s Jiangsu Hansoh Pharmaceutical Group Co., Ltd, China declaring M/s AA Pharma, 2nd floor, Shafi Court, Merewether Road, Civil Lines, Karachi do authorize for importation and distribution of the product in the territory of Pakistan. |
| | Remarks of the Evaluator. | • The firm has submitted 36 months real time stability study data for 3 batches<br>Batch # 16111512<br>Batch # 16111912<br>Batch # 16112312<br>• The firm has submitted 06 months accelerated stability study data and 12 months real time stability data for following 3 batches<br>Batch # 14100512<br>Batch # 14100712<br>Batch # 14101112 |
| | **Decision: Approved as per Import Policy for Finished Pharmaceutical products.** | |

| | | |
|---|---|---|
| 1206. | Name and address of Applicant | M/s AA pharma, 2nd floor, Shafi Court, Merewether Road, Civil Lines, Karachi |
| | Detail of Drug Sale License | **Address:** A-16 Block-13, Gulistan e Iqbal, Karachi<br>**Validity:** 22-05-2020<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | M/s Jiangsu Hengrui Medicine Co., Ltd. 38 Huanghe Road, Economic and technical development Zone, Lianyungang, Jiangsu 222047, China. |
| | Name and address of marketing authorization holder | M/s Jiangsu Hansoh pharmaceutical group Co., Ltd. No.9 Dongjin Roaf, Economic and technical development Zone, Lianyungang, Jiangsu 222069, China. |
| | Name of exporting country | China |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 26099, Dated 30-07-2018 |
| | Fee including differential fee | PKR 100,000/-, Dated 23-07-2018 |
| | Brand Name +Dosage Form + Strength | **ZEFEI** 1g for injection |
| | Composition | Each vial contains:<br>Gemcitabine Hydrochloride eq. to Gemcitabine.....1g |
| | Finished Product Specification | Nucleoside metabolic inhibitor |
| | Pharmacological Group | USP |
| | Shelf life | 24 months |
| | Demanded Price | ------ |
| | Pack size | 10 ml Type I glass vial, 1's |
| | International availability | Gemcitabine 1g solution for infusion of Accord healthcare Ltd., **MHRA approved** |
| | Me-too status | Oncogem 1g Injection by AJ Mirza Pharma (Reg#045672) |
| | Detail of certificates attached | ● Original legalized CoPP issued by Jiangsu Provincial Food and Drug Administration, China confirms free sale of the product in the exporting country. Certificate No: LYG (copp)20180019.<br>● Notarised GMP certificate of the manufacturer issued by China Food and Drug Administration is submitted which is valid until 22-05-2019. Certificate No: CN20140247.<br>● Legalized copy of letter of authorization dated 15-03-2018 has been submitted from *M/s Jiangsu Hansoh Pharmaceutical Group Co., Ltd, China declaring M/s AA Pharma, 2nd floor, Shafi Court, Merewether Road, Civil Lines, Karachi* do authorize for importation and distribution of the product in the territory of Pakistan. |
| | Remarks of the Evaluator. | • The firm has submitted 12 months real time stability study data for 3 batches<br>Batch # 15102812<br>Batch # 16060712<br>Batch # 16120212<br>• and 06 months accelerated stability study data for following 3 batches<br>Batch # 14111212<br>Batch # 14111612<br>Batch # 14112012 |
| | **Decision: Approved as per Import Policy for Finished Pharmaceutical products.** | |

**Case No. 07: Registration applications of import cases**

**a. New Cases (Veterinary)**

**Evaluator PEC-VI**

| | | |
|---|---|---|
| 1207. | Name and address of Applicant | M/s Mustafa Brothers 186-D Peoples Colony No.1 Faisalabad |
| | Detail of Drug Sale License | **Address:**P-1860-D, Peoples Colony No.1 Faisalabad<br>**Validity :** 12/2/2019<br>**Status:** License to sell drugs as a distributor |
| | Name and address of manufacturer | M/s Asia Animal Pharmaceutical Co. Ltd<br>Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho<br>City: Viet Nam. |
| | Name and address of marketing authorization holder | M/s Asia Animal Pharmaceutical Co. Ltd<br>Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho<br>City: Viet Nam. |
| | Name of exporting country | Viet Nam |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No : 14755 Dated : 12/09/2017 |
| | Fee including differential fee | Rs : 100,000 Dated : 25/08/2017 |
| | Brand Name +Dosage Form + Strength | Terramycin La<br>Solution For Injection |
| | Composition | Each ml contains :<br>Oxytetracycline HCL…..200mg |
| | Finished Product Specification | USP |
| | Pharmacological Group | Antibiotic |
| | Shelf life | 3 Years (As packaged for sale)<br>14 days (After first opening the immediate packaging) |
| | Demanded Price | Decontrolled |
| | Pack size | 100ml |
| | Me-too status | FLOXYTETRA L.A INJECTABLE SOLUTION Reg # 017137 |
| | Detail of certificates attached | **Free sale Certificate:** Issued by Ministry of Agriculture and Rural development and is valid until 29-3-2019<br>**GMP certificate**<br>Copy of GMP certificate issued from Ministry of Agriculture and Rural development/Socialist Republic of Viet Nam and is valid until 31 July 2022. |
| | Remarks of the Evaluator. | 3 batches tested at Accelerated stability (40'C+-2'C and 75% RH +-5%) for 6 months and Long term stability (30'C+-2'C and 65% RH +-5%) for 3years or 36months<br>a) 0112 Manufacturing date 24 March 2012<br>b) 0212 Manufacturing date 25 March 2012<br>c) 0312 Manufacturing date 26 March 2012 |
| | **Decision: Approved as per policy of inspection of manufacturers abroad** | |
| 1208. | Name and address of Applicant | M/s Mustafa Brothers 186-D Peoples Colony No.1 Faisalabad |
| | Detail of Drug Sale License | **Address:**P-1860-D, Peoples Colony No.1 Faisalabad<br>**Validity :** 12/2/2019<br>**Status:** License to sell drugs as a distributor |
| | Name and address of manufacturer | M/s Asia Animal Pharmaceutical Co. Ltd<br>Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho<br>City: Viet Nam. |
| | Name and address of marketing authorization holder | M/s Asia Animal Pharmaceutical Co. Ltd<br>Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho<br>City: Viet Nam. |
| | Name of exporting country | Viet Nam |

| | | |
|---|---|---|
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No : 14758 Dated : 12/09/2017 |
| | Fee including differential fee | Rs : 100,000 Dated : 12/09/2017 |
| | Brand Name +Dosage Form + Strength | Analgin C<br>Solution For Injection |
| | Composition | Each ml contains :<br>Analgin……250mg<br>Vitamin C……100mg |
| | Finished Product Specification | In-House |
| | Pharmacological Group | Antipyretic, Antiinflammatory |
| | Shelf life | 3 Years (As packaged for sale)<br>14 days (After first opening the immediate packaging) |
| | Demanded Price | Decontrolled |
| | Pack size | 100ml |
| | Me-too status | Could not be confirmed |
| | Detail of certificates attached | **Free sale Certificate:** Issued by Ministry of Agriculture and Rural development and is valid until 29-3-2019<br>**GMP certificate**<br>Copy of GMP certificate issued from Ministry of Agriculture and Rural development/Socialist Republic of Viet Nam and is valid until 31 July 2022. |
| | Remarks of the Evaluator. | 3 batches tested at Accelerated stability (40'C+-2'C and 75% RH +-5%) for 6 months and Long term stability (30'C+-2'C and 65% RH +-5%) for 3years or 36months<br>d) 0111 Manufacturing date March 2011<br>e) 0211 Manufacturing date March 2011<br>f) 0311 Manufacturing date March 2011<br>Analgin is a synonym of metamizole (a banned drug) |
| | **Decision: Registration Board referred the case to expert Working Group of veterinary drugs for review of formulation** | |
| 1209. | Name and address of Applicant | M/s Mustafa Brothers 186-D Peoples Colony No.1 Faisalabad |
| | Detail of Drug Sale License | **Address:**P-1860-D, Peoples Colony No.1 Faisalabad<br>**Validity :** 12/2/2019<br>**Status:** License to sell drugs as a distributor |
| | Name and address of manufacturer | M/s Asia Animal Pharmaceutical Co. Ltd<br>Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho<br>City: Viet Nam. |
| | Name and address of marketing authorization holder | M/s Asia Animal Pharmaceutical Co. Ltd<br>Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho<br>City: Viet Nam. |
| | Name of exporting country | Viet Nam |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No : 14757 Dated : 12/09/2017 |
| | Fee including differential fee | Rs : 100,000 Dated : 12/09/2017 |
| | Brand Name +Dosage Form + Strength | Ivermectin<br>Solution For Injection |
| | Composition | Each ml contains :<br>Ivermectin…..10mg |
| | Finished Product Specification | USP |
| | Pharmacological Group | Antiparasitic |
| | Shelf life | 3 Years (As packaged for sale)<br>28 days (After first opening the immediate packaging) |
| | Demanded Price | Decontrolled |
| | Pack size | 100ml. |
| | Me-too status | MECTIVER 1% INJECTION Reg # 014537 |

| | | |
|---|---|---|
| | Detail of certificates attached | **Free sale Certificate:** Issued by Ministry of Agriculture and Rural development and is valid until 29-3-2019<br>**GMP certificate**<br>Copy of GMP certificate issued from Ministry of Agriculture and Rural development/Socialist Republic of Viet Nam and is valid until 31 July 2022. |
| | Remarks of the Evaluator. | 3 batches tested at Accelerated stability (40'C+-2'C and 75% RH +-5%) for 6 months and Long term stability (30'C+-2'C and 65% RH +-5%) for 3years or 36months<br>g) 0110 Manufacturing date 16th March 2010<br>h) 0210 Manufacturing date 17th March 2010<br>i) 0310 Manufacturing date 18th March 2010 |
| | **Decision: Approved as per policy of inspection of manufacturers abroad** | |

**Evaluator PEC-VII**

| | | |
|---|---|---|
| 1210. | Name and address of Applicant | M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt |
| | Detail of Drug Sale License | **Address**: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan<br>**Validity:** 7-April- 2020<br>**Status:** License to sell drug as distributor |
| | Name and address of manufacturer | Vem ilac San. Ve Tic. A.S.<br>Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mahallesi. Fatih Bulvari. No 38 Kapakli/TEKIRDAG/Turkey |
| | Name and address of marketing authorization holder | Vem ilac San. Ve Tic. A.S.<br>Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mah. Fatih Blv. No 38 Kapakli/TEKIRDAG/Turkey |
| | Name of exporting country | Turkey |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.14613 Dated 19-01-2018 |
| | Fee including differential fee | Rs. 50,000/- Dated 19-04-2018 |
| | Brand Name+Dosage Form+Strength | Blumet I.V Solution for injection 50 mg/ 5ml |
| | Composition | Each 1 ml solution contain<br>Methylene Blue…. 10 mg |
| | Finished Product Specification | In-house |
| | Pharmacological Group | Antidotes; Other diagnostic agents |
| | Shelf life | 36 Months |
| | Demanded Price | NA |
| | Pack size | 5 ml glass ampoule of Type 1 |
| | International availability | NA |
| | Me-too status | NA |
| | Detail of certificates attached | **COPP (Original, Embassy Attested)**<br>**Certificate No**:2018/15g6<br>**Certifying Authority:** Ministry of health Turkish medicine and medical devise agency<br>**Valid Date:**25-4-2020<br>**Letter of Authorization (original)**<br>Date of Agreement:7-06-2018 (Valid for 5 year)<br>**Free sale (Original, Embassy Attested)**<br>**Certificate No**:2018/1581<br>**Certifying Authority:** Ministry of health Turkish medicine and medical devise agency<br>**Valid Date:**24-4-2020 |
| | Remarks of the Evaluator [VII] | • Stability is at 45°C ± 2°C / 75% ± 5% RH (6 months) and 30°C ± 2°C / 65% ± 5% RH (6 months) for 3 batches is provided. (Stability starting date: 11-7-2016)<br>• Evidence of approval of applied formulation in reference regulatory authorities not available. |

| | | |
|---|---|---|
| | | PROVAYBLUE 5 mg/ ml (50 mg/ 10 ml) (USFDA) is in different strength and provided label of 10 mg/ml itself claimed this drug is not found to be effective and safe by USFDA and this label is not approved by FDA. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Long term Stability study covering the shelf life of applied product under the conditions of zone IV-A.** | |
| 1211. | Name and address of Applicant | M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town, Zarrar Shaheed road, Lahore Cantt |
| | Detail of Drug Sale License | **Address**: M/S Bristal Mayer Biotech Pakistan, 73-B Guldasht town Zarrar Shaheed road, Lahore Cantt Pakistan<br>**Validity:** 7-April- 2020<br>**Status:** License to sell drug as distributor |
| | Name and address of manufacturer | Vem ilac San. Ve Tic. A.S.<br>Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mah. Fatih Blv. No 38 Kapakli/TEKIRDAG/Turkey |
| | Name and address of marketing authorization holder | Vem ilac San. Ve Tic. A.S.<br>Address: Cerkezkoy organize Sanayi Bolgsi, Karaagac Mahallesi. Fatih Bulvari. No 38 Kapakli/TEKIRDAG/Turkey |
| | Name of exporting country | Turkey |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.14610 Dated 19-01-2018 |
| | Fee including differential fee | Rs. 50,000/- Dated 19-04-2018 |
| | Brand Name +Dosage Form + Strength | Fuxesin 100 mg injection |
| | Composition | Each vial contain<br>Anidulafungin…. 100 mg<br>(Lyophilized powder for solution for infusion) |
| | Finished Product Specification | In-house |
| | Pharmacological Group | Antifungal |
| | Shelf life | 24 Months (2-8 ºC) |
| | Demanded Price | As per SRO |
| | Pack size | 20 ml, 50 ml, 100 ml Clear glass vial Type-I |
| | International availability | Ecalta 100 milligram(s) Powder and solvent for solution for infusion Pfizer Europe (MHRA) |
| | Me-too status | NA |
| | Detail of certificates attached | **COPP (Original, Embassy Attested)**<br>**Certificate No**:2018/1086<br>**Certifying Authority:** Ministry of health Turkish medicine and medical devise agency<br>**Valid Date:**20-3-2020<br>**Letter of Authorization (Original)**<br>Date of Agreement:1-01-2016 (Valid for 5 year)<br>**Free sale ( Original, Embassy Attested)**<br>**Certificate No**:2018/1568<br>**Certifying Authority:** Ministry of health Turkish medicine and medical devise agency<br>**Valid Date:**24-4-2020 |
| | Remarks of the Evaluator [VII] | • Stability is at 5°C ± 3°C (24 months) and 25°C ± 2°C / 60% ± 5% RH (for 3 batches)<br>• Innovator, ERAXIS (USFDA) for Injection unreconstituted vials and companion diluent vials should be stored at 2-8ºC; Excursions for 96 hours up to 25°C are permitted |

| | |
|---|---|
| | **Decision: Deferred for following:**<br>• **Clarification regarding diluent for reconstitution of product**<br>• **Clarification of applied dosage form whether lyophilized powder or lyophilized cake in comparison to Innovator product approved by Reference Regulatory Authorities.** |

## b. New Cases (Veterinary) Evaluator PEC-II

| | | |
|---|---|---|
| 1212. | Name and address of Applicant | M/s Saadat International, 117-Habitat Apartment, Shadman-II Jail Road, Lahore. |
| | Detail of Drug Sale License | Address: Saadat International, 117-Habitat Apartment, Shadman-II Jail Road, Lahore.<br>Validity: 12-06-2020<br>Status: License to sell drugs as a Distributor |
| | Name and address of manufacturer | M/s Merial 23 Rue Du Prieure, 44150 St Herblon, France. |
| | Name and address of marketing authorization holder | M/s Merial 29 Avenue Tony Garnier, 69007 Lyon<br>No. of product license: FR/V/8415906 9/1996 dated 13-09-1996 |
| | Name of exporting country | France |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.2919 Dated 30/01/2017 |
| | Fee including differential fee | Rs. 100,000/- Dated 30/01/2017 |
| | Brand Name+Dosage Form+Strength | Cofacoli solution |
| | Composition | Each ml contains:<br>Colistin (as sulphate)……. 2,000,000 IU |
| | Finished Product Specification | Manufacturer specifications. |
| | Pharmacological Group | Intestinal anti-infective agent |
| | Shelf life | 36 months |
| | Demanded Price | De-controlled |
| | Pack size | 1ltr. & 5ltr. |
| | International availability | Not applicable |
| | Me-too status | N/A |
| | Detail of certificates attached | • Original Legalized Certificate for a Veterinary Medicinal Product (Certificate No. 18-208889)<br>Certified by: Agence nationale du medicament veterinaire (anses) France<br>**Issued on:** 28-06-2018<br>**Free sale in exporting country:** Confirms the free sale of the product in exporting country.<br>**GMP:** The facilities and operations conform to GMP as recommended by WHO as per CoPP.<br>• **Legalized copy of GMP certificate issued by** Agence nationale du medicament veterinaire (anses) France in the name of s Merial 23 Rue Du Prieure, 44150 St Herblon, France, valid upto June, 2020.<br>• Notarized copy of "Letter of Appointment" has been submitted in which M/s Merial SAS has appointed M/s Saadat International, Lahore, Pakistan as official representative and sole agent in Pakistan for applied formulation, dated 22-06-2018. |
| | Remarks of the Evaluator. | • Firm has submitted 36 months long term stability data |
| | **Decision: Approved with innovator's specifications as per policy for inspections of manufacturer abroad.** | |

**Evaluator PEC-V**

| | | |
|---|---|---|
| 1213. | Name and address of Applicant | M/s Fair International Trading Co.<br>11 A-Syed Arcade, 2nd floor, Block 5, Gulshan e Iqbal, Karachi |
| | Detail of Drug Sale License | **Address:** D-94, Block 7, Gulshane Iqbal, Karachi<br>**Validity:** 04-07-2020<br>**Status:** Way of Wholesale |
| | Name and address of manufacturer | M/s Cenavisa, S.L. 43205-RUES/Spain Cami Pedra Estela, s/n |
| | Name and address of marketing authorization holder | M/s Cenavisa, S.L. 43205-RUES/Spain Cami Pedra Estela, s/n |
| | Name of exporting country | Spain |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 550 Dated 17/11/2016 |
| | Fee including differential fee | Rs. 100,000/- Dated 17/11/2016 |
| | Brand Name +Dosage Form + Strength | CENAMICINA FORTE 100mg<br>Solution for use in drinking water |
| | Composition | Each ml contains:<br>Enrofloxacin…….. 100mg |
| | Target species | Chicken (broilers) |
| | Finished Product Specification | In House |
| | Pharmacological Group | Anti-microbial |
| | Shelf life | 3 years |
| | Demanded Price | Decontrolled |
| | Pack size | 100ml bottle, 1 litre bottle, 5 litre barrel<br>HDPE bottles |
| | International availability | Baytril 10% Oral Solution by M/s Baeyer PLC UK Approved |
| | Me-too status | Enflox 10% solution by M/s Alina combine Pakistan (Reg # 035157) |
| | Detail of certificates attached | • **Original Legalized CoPP**<br>Certificate No. 752/2018<br>Certifying Authority: Agencia Espanola de medicaomentos Y productos sanitarios<br>Date of Issue: 30-10-2018<br>• GMP certificate (certificate No. ES/177HV/15) certified by Agencia Espanola de medicaomentos Y productos sanitarios issued on 31/05/2016.<br>• Distribution Agreement<br>Dated: 05-011-2018<br>Validity: 3 years |
| | Stability data | Batch no. 07201/13 (DOM:01-2013), 07202/13 (DOM:02-2013), 07205/13 (DOM:03-2013), |
| | Remarks of the Evaluator. | • The firm has claimed In House specifications and the product is not present in BP/USP.<br>• Clarification for change in address mentioned on drug sale license and Form 5 A.<br>Firm has submitted that address mentioned on DSL is their warehouse and on Form 5A is office address.<br>• Submit valid GMP certificate as provided one is not valid.<br>CENAVISA S.L. stablished in Cami Pedra Estela s/n in Reus/Spain, certifies that GPM certificate submitted with Application form for the registration procedure of CENAMICINA FORTE on the year 2016, was valid until 01/07/2018.<br>During this current year 2018, CENAVISA S,L. have been updating its facilities (Injectable line), for this reason, Spanish Authorities gave us an extension for this Certificate until 01/01/2019.<br>Next year, form that data, our authorities will conduct a new inspection to our factory and CENAVISA S.L. expect to be |

| | | |
|---|---|---|
| | | authorized and renew once again the GMP certification.<br>**Shortcomings**<br>• Long term stability studies conducted under the conditions of zone IV-A of 03 batches till shelf life along with the supporting document, chromatograms, raw data sheets etc as the provided data at condition IVA mentions the same batches as submitted initially at condition II. Clarification is also required in this regard.<br>Firm has submitted long term stability data as per Zone IVA but the supporting documents i.e. chromatograms does not support the datasheets.There are following observations in the submitted data.<br>o The sample injection of all time points seems to be run on same day,<br>o The firm has not submitted standard chromatograms, the peaks are not symmetrical, retention time vary at different time points.<br>o The submitted sample chromatograms are at following time points 0,12,24,36M.<br>o Firm has not submitted raw data sheets.<br>o Firm has not submitted clarification. |
| | **Decision: Deferred for the following:**<br>• **Submision of valid GMP certificate.**<br>• **Clarification regarding submitted Long term stability studies conducted under the conditions of zone IV-A of 03 batches till shelf life as the provided data at condition IVA mentions the same batches as submitted initially at condition II.** | |

**Evaluator PEC-III**

| | | |
|---|---|---|
| 1214 | Name and address of Applicant | M/s Chakwal Pharma International, OTI Plaza, 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore. |
| | Detail of Drug Sale License | **Address:** OTI Plaza, 2nd floor 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore.<br>**Validity:** 13-11-2019<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name and address of marketing authorization holder | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name of exporting country | Netherlands |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 21411: 17-11-2017 |
| | Fee including differential fee | PKR 100,000/-: 17-11-2017 |
| | Brand Name +Dosage Form + Strength | Alfamec1% solution for injection |
| | Composition | Each ml contains:<br>Ivermectin……..10mg |
| | Finished Product Specification | Firm has claimed inhouse specification while the finished product monograph is available in BP/USP |
| | Pharmacological Group | Antiparasitic |
| | Shelf life | 36 months |
| | Demanded Price | Decontrolled |
| | Pack size | 100ml |
| | International availability | Netherland approved |
| | Me-too status | Ivoron Injection by Breeze Pharma (Reg # 059152) |
| | Detail of certificates attached | • Original, legalized CoPP (No. 247607) issued by Medicines Evaluation Board Agency, Veterinary Medicinal Products Unit, and Ministry of Economic Affairs, Netherlands dated 13 June 2017 confirms free sale status and GMP of the manufacturer. |

| | | |
|---|---|---|
| | | • Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted.<br>• Copy of letter of exclusive sole distributor authorization dated 05-05-2017 between M/s Alfasan International B.V and M/s Chakwal Pharma International. |

**Remarks of the Evaluator.**

Firm was asked to clarify the following vide letter dated 4th September 2018, The firm has now provided following clarifications:

| Shortcomings | Reply of the firm |
|---|---|
| Clarification is required regarding the name of manufacturer since Form 5-A specify Alfasan International as manufacturer, while the manufacturer mentioned in CoPP is Alfasan Nederland, and the GMP certificate submitted is also of Alfasan International B.V. Furthermore the sole agency agreement is with M/s Alfasan International B.V, which is product license holder in country of origin, justification in this regard is also required. | Firm has submitted original, legalized letter from Alfasan International stating that as per agreement between Alfasan Nederland and Alfasan International BV it is agreed that Alfasan International is allowed to export the product for which Alfasan Nederland BV is the registration holder.<br>Firm has further stated that Alfasan is a multilayer group of companies all based in same physical address. Alfasan Nederland is the full holding company and registration holder of all products. Alfasan International's factory inspected by Dutch veterinary Authority is also based at the same address, therefore the GMP certificate has been issued in the name of Alfasan International. |
| Real time and accelerated stability study data of 3 batches as per the conditions of Zone IV-A, since the submitted stability studies are conducted at different conditions. | Firm has submitted data of 36 months of 3 batches conducted at 30°C and 65% RH. |

Firm has further submitted that their principle has performed stability studies as per **BP** monograph.

**Decision: Deferred for revision of Form5A for manufacturer revised agreement with Marketing authorization holder as per CoPP**

| | | |
|---|---|---|
| 1215 | Name and address of Applicant | M/s Chakwal Pharma International, OTI Plaza, 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore. |
| | Detail of Drug Sale License | **Address:** OTI Plaza, 2nd floor 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore.<br>**Validity:** 13-11-2019<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name and address of marketing authorization holder | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name of exporting country | Netherlands |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 21416: 17-11-2017 |
| | Fee including differential fee | PKR 100,000/-: 17-11-2017 |
| | Brand Name +Dosage Form + Strength | Lincomycin-Spectinomycin 5/10 solution for injection |
| | Composition | Each ml solution contains:<br>Lincomycin (as hydrochloride)……..50mg<br>Spectinomycin (as hydrochloride)…….100mg |
| | Finished Product Specification | Firm has claimed in house specification and the finished product monograph is not available in any pharmacopoeia. |
| | Pharmacological Group | Systemic antibiotics |
| | Shelf life | 36 months |
| | Demanded Price | Decontrolled |
| | Pack size | 250ml vial |
| | International availability | Netherland approved |

| | | |
|---|---|---|
| | Me-too status | Lincotin Injection by Star Labs (Reg # 025704) |
| | Detail of certificates attached | • Original, legalized CoPP (No. 247613) issued by Medicines Evaluation Board Agency, Veterinary Medicinal Products Unit, Ministry of Economic Affairs, Netherlands dated 15 June 2017 confirms free sale status and GMP of the manufacturer.<br>• Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted.<br>• Copy of letter of exclusive sole distributor authorization dated 05-05-2017 between M/s Alfasan International B.V and M/s Chakwal Pharma International. |

**Remarks of the Evaluator.**

Firm was asked to clarify the following vide letter dated 4th September 2018, The firm has now provided following clarifications:

| Shortcomings | Reply of the firm |
|---|---|
| Clarification is required regarding the name of manufacturer since Form 5-A specify Alfasan International as manufacturer, while the manufacturer mentioned in CoPP is Alfasan Nederland, and the GMP certificate submitted is also of Alfasan International B.V. Furthermore the sole agency agreement is with M/s Alfasan International B.V, which is product license holder in country of origin, justification in this regard is also required. | Firm has submitted original, legalized letter from Alfasan International stating that as per agreement between Alfasan Nederland and Alfasan International BV it is agreed that Alfasan International is allowed to export the product for which Alfasan Nederland BV is the registration holder.<br>Firm has further stated that Alfasan is a multilayer group of companies all based in same physical address. Alfasan Nederland is the full holding company and registration holder of all products. Alfasan International's factory inspected by Dutch veterinary Authority is also based at the same address, therefore the GMP certificate has been issued in the name of Alfasan International. |
| Real time and accelerated stability study data of 3 batches as per the conditions of Zone IV-A, since the submitted stability studies are conducted at different conditions. | Firm has submitted stability study data of 3 batches at 30ºC and 65% RH. The batches were manufactured in 2012. |

**Decision: Deferred for revision of Form5A for manufacturer revised agreement with Marketing authorization holder as per CoPP**

| | | |
|---|---|---|
| 1216 | Name and address of Applicant | M/s Chakwal Pharma International, OTI Plaza, 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore. |
| | Detail of Drug Sale License | **Address:** OTI Plaza, 2nd floor 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore.<br>**Validity:** 13-11-2019<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name and address of marketing authorization holder | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name of exporting country | Netherlands |
| | Type of Form | Form 5-A; |
| | Diary No. & Date of R& I | Dy No. 21415: 17-11-2017 |
| | Fee including differential fee | PKR 100,000/-: 17-11-2017 |
| | Brand Name+Dosage Form+Strength | Amoxycilline 20% LA suspension for injection |
| | Composition | Each ml suspension contains:<br>Amoxycillin trihydrate……..200mg |
| | Finished Product Specification | Firm has claimed in house specification and the finished product monograph is available in USP/BP |
| | Pharmacological Group | Antibacterial for systemic use |
| | Shelf life | 24 months |

| | | |
|---|---|---|
| | Demanded Price | Decontrolled |
| | Pack size | 100ml vial |
| | International availability | Netherland approved |
| | Me-too status | Novamox 20% LA Injection by Selmore |
| | Detail of certificates attached | • Original, legalized CoPP (No. 247609) issued by Medicines Evaluation Board Agency, Veterinary Medicinal Products Unit, Ministry of Economic affairs, Netherlands dated 13 June 2017 confirms free sale status and GMP of the manufacturer.<br>• Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted.<br>• Copy of letter of exclusive sole distributor authorization dated 05-05-2017 between M/s Alfasan International B.V and M/s Chakwal Pharma International. |

**Remarks of the Evaluator.**

| Shortcomings | Reply of the firm |
|---|---|
| Clarification is required regarding the name of manufacturer since Form 5-A specify Alfasan International as manufacturer, while the manufacturer mentioned in CoPP is Alfasan Nederland, and the GMP certificate submitted is also of Alfasan International B.V. Furthermore the sole agency agreement is with M/s Alfasan International B.V, which is product license holder in country of origin, justification in this regard is also required. | Firm has submitted original, legalized letter from Alfasan International stating that as per agreement between Alfasan Nederland and Alfasan International BV it is agreed that Alfasan International is allowed to export the product for which Alfasan Nederland BV is the registration holder.<br>Firm has further stated that Alfasan is a multilayer group of companies all based in same physical address. Alfasan Nederland is the full holding company and registration holder of all products. Alfasan International's factory inspected by Dutch veterinary Authority is also based at the same address, therefore the GMP certificate has been issued in the name of Alfasan International. |
| Real time and accelerated stability study data of 3 batches as per the conditions of Zone IV-A, since the submitted stability studies are conducted at different conditions. | Firm has submitted stability study data of 3 batches at 30ºC and 65% RH. |

Firm has submitted that the manufacturer has performed stability testing as per BP monograph

**Decision: Deferred for revision of Form5A for manufacturer revised agreement with Marketting authorization holder as per CoPP**

| | | |
|---|---|---|
| 1217 | Name and address of Applicant | M/s Chakwal Pharma International, OTI Plaza, 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore. |
| | Detail of Drug Sale License | **Address:** OTI Plaza, 2nd floor 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore.<br>**Validity:** 13-11-2019<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name and address of marketing authorization holder | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name of exporting country | Netherlands |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 21414: 17-11-2017 |
| | Fee including differential fee | PKR 100,000/-: 17-11-2017 |
| | Brand Name+Dosage Form+Strength | Xylazine 2% solution for injection |
| | Composition | Each ml solution contains:<br>Xylazine (as hydrochloride)……..20mg |
| | Finished Product Specification | Firm has claimed in house specification and the finished product monograph is available in USP. |
| | Pharmacological Group | Hypnotics and sedatives |

| | | |
|---|---|---|
| | Shelf life | 36 months |
| | Demanded Price | Decontrolled |
| | Pack size | 30ml vial |
| | International availability | Netherland approved |
| | Me-too status | Xylaz Injection by Prix Pharma (Reg # 013246) |
| | Detail of certificates attached | • Original, legalized CoPP (No. 247619) issued by Medicines Evaluation Board Agency, Veterinary Medicinal Products Unit, Ministry of Economic Affairs, Netherlands dated 16 June 2017 confirms free sale status and GMP of the manufacturer.<br>• Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted.<br>• Copy of letter of exclusive sole distributor authorization dated 05-05-2017 between M/s Alfasan International B.V and M/s Chakwal Pharma International. |

**Remarks of the Evaluator.**

| Shortcomings | Reply of the firm |
|---|---|
| Clarification is required regarding the name of manufacturer since Form 5-A specify Alfasan International as manufacturer, while the manufacturer mentioned in CoPP is Alfasan Nederland, and the GMP certificate submitted is also of Alfasan International B.V. Furthermore the sole agency agreement is with M/s Alfasan International B.V, which is product license holder in country of origin, justification in this regard is also required. | Firm has submitted original, legalized letter from Alfasan International stating that as per agreement between Alfasan Nederland and Alfasan International BV it is agreed that Alfasan International is allowed to export the product for which Alfasan Nederland BV is the registration holder.<br>Firm has further stated that Alfasan is a multilayer group of companies all based in same physical address. Alfasan Nederland is the full holding company and registration holder of all products. Alfasan International's factory inspected by Dutch veterinary Authority is also based at the same address, therefore the GMP certificate has been issued in the name of Alfasan International. |
| Real time and accelerated stability study data of 3 batches as per the conditions of Zone IV-A, since the submitted stability studies are conducted at different conditions. | Firm has submitted stability study data of 3 batches at 30ºC and 65% RH. |

Firm has performed stability testing as per in house specification while the product monograph is also available in USP. The difference in the specifications is provided in the table below:

| Test | Specification limit of the firm | Limits specified by USP |
|---|---|---|
| pH | 3.0 – 7.0 | 4.5 – 5.5 |

The stability data initially provided by the firm at zone II specified pH as 3.0 – 7.0, while the stability data provided by the firm afterwards contains the limit of pH 5.0 – 6.0.

**Decision: Deferred for revision of Form5A for manufacturer revised agreement with Marketting authorization holder as per CoPP**

| | | |
|---|---|---|
| 1218 | Name and address of Applicant | M/s Chakwal Pharma International, OTI Plaza, 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore. |
| | Detail of Drug Sale License | **Address:** OTI Plaza, 2nd floor 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore.<br>**Validity:** 13-11-2019<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name and address of marketing authorization holder | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name of exporting country | Netherlands |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 21413: 17-11-2017 |

| | |
|---|---|
| Fee including differential fee | PKR 100,000/-: 17-11-2017 |
| Brand Name+Dosage Form+Strength | Multivitamin solution for injection |
| Composition | Each ml solution contains:<br>Vitamin A…..15,000 IU<br>Cholecalciferol….1000 IU<br>Alfa-tocoferol acetate……20mg<br>Thiamine hydrochloride……10mg<br>Riboflavine sodium phosphate……6.85mg<br>Pyridoxine hydrochloride……..3mg<br>Cyanocobalamine……50 mcg<br>Nicotinamide……35mg<br>D-Panthenol……..25mg |
| Finished Product Specification | Firm has claimed in house specification and the finished product monograph is not available in any pharmacopoeia. |
| Pharmacological Group | Multivitamins |
| Shelf life | 36 months (Data not as per zone IV-A) |
| Demanded Price | Decontrolled |
| Pack size | 250ml vial |
| International availability | Netherland approved |
| Me-too status | Could not be confirmed |
| Detail of certificates attached | • Original, legalized CoPP (No. 247610) issued by Medicines Evaluation Board Agency, Veterinary Medicinal Products Unit, Ministry of Economic affairs, Netherlands dated 14 June 2017 confirms free sale status and GMP of the manufacturer.<br>• Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted.<br>• Copy of letter of exclusive sole distributor authorization dated 05-05-2017 between M/s Alfasan International B.V and M/s Chakwal Pharma International. |

**Remarks of the Evaluator.**

Firm was asked to clarify the following vide letter dated 4th September 2018, The firm has now provided following clarifications:

| Shortcomings | Reply of the firm |
|---|---|
| Clarification is required regarding the name of manufacturer since Form 5-A specify Alfasan International as manufacturer, while the manufacturer mentioned in CoPP is Alfasan Nederland, and the GMP certificate submitted is also of Alfasan International B.V. Furthermore the sole agency agreement is with M/s Alfasan International B.V, which is product license holder in country of origin, justification in this regard is also required. | Firm has submitted original, legalized letter from Alfasan International stating that as per agreement between Alfasan Nederland and Alfasan International BV it is agreed that Alfasan International is allowed to export the product for which Alfasan Nederland BV is the registration holder.<br>Firm has further stated that Alfasan is a multilayer group of companies all based in same physical address. Alfasan Nederland is the full holding company and registration holder of all products. Alfasan International's factory inspected by Dutch veterinary Authority is also based at the same address, therefore the GMP certificate has been issued in the name of Alfasan International. |
| Real time and accelerated stability study data of 3 batches as per the conditions of Zone IV-A, since the submitted stability studies are conducted at different conditions. | Firm has submitted stability study data of 3 batches at 30ºC and 65% RH. The batches were manufactured in 2012. |
| Me-too status | Firm has submitted following me-too<br>Multivor (Reg#048151) of ICI Pakistan<br>This me-too could **NOT** be confirmed since the claimed me-too contains different strength of riboflavin and cyanocobalamin |

| | | |
|---|---|---|
| | **Decision: Deferred for revision of Form5A for manufacturer revised agreement with Marketting authorization holder as per CoPP** | |
| 1219 | Name and address of Applicant | M/s Chakwal Pharma International, OTI Plaza, 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore. |
| | Detail of Drug Sale License | **Address:** OTI Plaza, 2nd floor 210-Lalazar commercial market, Thokar Niaz Baig, Raiwind Road Lahore.<br>**Validity:** 13-11-2019<br>**Status:** License to sell drugs by way of wholesale |
| | Name and address of manufacturer | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name and address of marketing authorization holder | Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands |
| | Name of exporting country | Netherlands |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 21412: 17-11-2017 |
| | Fee including differential fee | PKR 100,000/-: 17-11-2017 |
| | Brand Name +Dosage Form + Strength | Tylosin 20% solution for injection |
| | Composition | Each ml solution contains:<br>Tylosin (as tartrate)……..200mg |
| | Finished Product Specification | BP Specs |
| | Pharmacological Group | Macrolide |
| | Shelf life | 36 months |
| | Demanded Price | Decontrolled |
| | Pack size | 100ml |
| | International availability | Netherland approved |
| | Me-too status | Tylowan 20 Injection by Nawan Pharma (Reg # 025356) |
| | Detail of certificates attached | • Original, legalized CoPP (No. 247618) issued by Medicines Evaluation Board Agency, Veterinary Medicinal Products Unit, Ministry of Economic affairs, Netherlands dated 15 June 2017 confirms free sale status and GMP of the manufacturer.<br>• Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted.<br>• Copy of letter of exclusive sole distributor authorization dated 05-05-2017 between M/s Alfasan International B.V and M/s Chakwal Pharma International. |

**Remarks of the Evaluator.**

Firm was asked to clarify the following vide letter dated 4th September 2018, The firm has now provided following clarifications:

| Shortcomings | Reply of the firm |
|---|---|
| Clarification is required regarding the name of manufacturer since Form 5-A specify Alfasan International as manufacturer, while the manufacturer mentioned in CoPP is Alfasan Nederland, and the GMP certificate submitted is also of Alfasan International B.V. Furthermore the sole agency agreement is with M/s Alfasan International B.V, which is product license holder in country of origin, justification in this regard is also required. | Firm has submitted original, legalized letter from Alfasan International stating that as per agreement between Alfasan Nederland and Alfasan International BV it is agreed that Alfasan International is allowed to export the product for which Alfasan Nederland BV is the registration holder.<br>Firm has further stated that Alfasan is a multilayer group of companies all based in same physical address. Alfasan Nederland is the full holding company and registration holder of all products. Alfasan International's factory inspected by Dutch veterinary Authority is also based at the same address, therefore the GMP certificate has been issued in the name of Alfasan International. |
| Real time and accelerated stability study data of 3 batches as per the conditions of Zone IV-A, | Firm has submitted data of 36 months of **only 2** batches conducted at 35ºC and 65% RH |

| | | |
|---|---|---|
| | since the submitted stability studies are conducted at different conditions. | |
| | **Decision: Deferred for the Submision of Long term stability studies conducted under the conditions of zone IV-A of 1 batch till shelf life and revision of Form5A for manufacturer revised agreement with Marketting authorization holder as per CoPP** | |
| 1220 | Name and address of Applicant | M/s Unicare Enterprises Plot No. 587/1-B, street No. 3, Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad. |
| | Detail of Drug Sale License | **Address:** Plot No. 587/1-BStreet No. 3 Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad<br>**Validity:** 20-10-2018<br>**Status:** License to sell drugs as "distributor" |
| | Name and address of manufacturer | Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain |
| | Name and address of marketing authorization holder | Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain |
| | Name of exporting country | Spain |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 327: 23-01-2017 |
| | Fee including differential fee | PKR 100,000/-: 16-1-2017 |
| | Brand Name+Dosage Form+Strength | Flortek 100mg/ml (solution for oral administration) |
| | Composition | Each ml solution contains:<br>Florfenicol……100mg |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pharmacological Group | Antimicrobials for systemic use |
| | Shelf life | 36 months but not supported with data |
| | Demanded Price | Decontrolled |
| | Pack size | 500ml, 1L, 5L |
| | International availability | Approved and available in Spain |
| | Me-too status | Naflor 100mg/ml Oral solution by Nawan Pharma (049514) |
| | Detail of certificates attached | **GMP Certificate:**<br>Copy of GMP certificate (No. ES/189HV/16) is provided by the firm which states inspection conducted on 19-10-2016. The GMP certificate has been verified from Eudra GMP database as well.<br>**COPP:**<br>Original, legalized CoPP confirming free sale and GMP of the manufacturer issued by Departmento de medicamentos Veterinarios Parque Empresarial Madrid Spain dated 21 July 2016 is provided.<br>**Sole Agency Agreement:**<br>Copy of sole agency agreement between the MA holder in Spain and applicant in Pakistan is provided. |

**Remarks of the Evaluator.**

Following observations were forwarded to the applicant and the response received is as follows:

| Shortcomings | Reply of the firm |
|---|---|
| Justify the use of this product in poultry (as claimed in your label), since this drug is approved in country of origin and reference regulatory authority i.e. Spain for use in pigs for the treatment and prevention at the group level where clinical signs of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* sensitive to florfenicol are present. | Firm has submitted that this is a generic drug and following registered products are already being effectively used in poultry.<br>1. Naflore by Nawan Laboratories (049514)<br>2. Neflox by Selmore (049647)<br>3. Rivaflor 100 by Mylab (074100)<br>Firm has submitted copy of EMA report of committee for veterinary medicinal products for extension of florfenicol to chicken. This reports concludes the recommendation of inclusion of florfenicol for chicken with following condition:<br>*Not for use in animals from which eggs are produced for human consumption.* |

| | | |
|---|---|---|
| | Justify the claimed shelf life of 36 months, since the submitted stability data is not conducted as per the requirements of Zone IV-A, furthermore the submitted stability data concludes that the product is not within established limits when kept for accelerated stability testing and thus proposes a shelf life of 18 months with specific recommendation to not store product above 25°C. The shelf life approved by the country of origin for this product is also 18 months. | Firm has requested that the same shelf life as approved in country of origin may be granted. Firm has not submitted stability study data at the conditions of zone IV-A. |
| | **Decision: Deferred for the Submision of Long term stability studies conducted under the conditions of zone IV-A of 3 batches till shelf life.** | |
| 1221 | Name and address of Applicant | M/s Unicare Enterprises Plot No. 587/1-B, street No. 3, Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad. |
| | Detail of Drug Sale License | **Address:** Plot No. 587/1-BStreet No. 3 Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad<br>**Validity:** 20-10-2018<br>**Status:** License to sell drugs as "distributor" |
| | Name and address of manufacturer | Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain |
| | Name and address of marketing authorization holder | Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain |
| | Name of exporting country | Spain |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 328: 23-01-2017 |
| | Fee including differential fee | PKR 100,000/-: 16-1-2017 |
| | Brand Name +Dosage Form + Strength | Karidox 500mg/g water soluble powder |
| | Composition | Each gram powder contains:<br>Doxycycline (as hyclate)……..500mg |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pharmacological Group | Semi synthetic tetracycline |
| | Shelf life | 36 months |
| | Demanded Price | Decontrolled |
| | Pack size | 200g, 1Kg thermosealed bag |
| | International availability | Approved and available in Spain |
| | Me-too status | Could not be confirmed |
| | Detail of certificates attached | **GMP Certificate:**<br>Copy of GMP certificate (No. ES/189HV/16) is provided by the firm which states inspection conducted on 19-10-2016. The GMP certificate has been verified from Eudra GMP database as well.<br>**COPP:**<br>Original, legalized CoPP confirming free sale and GMP of the manufacturer issued by Departmento de medicamentos Veterinarios Parque Empresarial Madrid Spain dated 21 July 2016 is provided.<br>**Sole Agency Agreement:**<br>Copy of sole agency agreement between the MA holder in Spain and applicant in Pakistan is provided. |

**Remarks of the Evaluator.**

Following observations were forwarded to the applicant and the response received is as follows:

| Shortcomings | Reply of the firm |
|---|---|
| Justify the use of this product in calves and poultry for treatment of fowl cholera, coryza, infectious synovitis, avian spirochaetosis, colibacillosis, salmonellosis, necrotic enteritis, ornithosis, coli diarrhea and liver abscess. (as | Firm has submitted that this is a generic product and widely used in poultry and cattle in Pakistan and international reference countries. |

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| | claimed in your label), since this drug is approved in country of origin and reference regulatory authority i.e. Spain for use in Porcine for the treatment of clinical respiratory infections caused by strains of *Mycoplasma hyopneumoniae* and *Pasteurella multocida* sensitive to doxycycline and in Birds (Chickens and turkeys) for the treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* sensitive to doxycycline. | |
| | Justify the claimed shelf life of 36 months, since the submitted stability data proposed a shelf life of 24 months while the shelf life approved by the country of origin for this product is 18months. | Firm has requested that the same shelf life as approved in country of origin may be granted. Firm has not submitted stability study data at the conditions of zone IV-A. |
| | Evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) along with registration number, brand name and name of firm | Firm has submitted three references for me-too status, none of them could be verified from database. |
| | **Decision: Deferred for the Submision of Long term stability studies conducted under the conditions of zone IV-A of 3 batches till shelf life.** | |

**Evaluator PEC-VIII**

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| 1222. | Name and address of Applicant | M/s Vet line international Flat # 55/5, first floor, main shadman market, Lahore. |
| | Detail of Drug Sale License | **Address:** Vet line international Flat # 55/5, first floor, main shadman market, Lahore.<br>**Validity:** 11/02/2019<br>**Status:** Licence to sell as a "Distributer" |
| | Name and address of manufacturer | M/s Bela Pharm GmbH & Co.KG LohnerStrasse 19<br>49377 Vechta, Germany. |
| | Name and address of marketing authorization holder | M/s Bela Pharm GmbH & Co.KG LohnerStrasse 19<br>49377 Vechta, Germany. |
| | Name of exporting country | Germany |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.25452 Dated 21/12/2017 |
| | Fee including differential fee | Rs. 100,000/- Dated 20/12/2017 |
| | Brand Name +Dosage Form + Strength | Neomycinsulfat (Water Soluble Powder) |
| | Composition | Each 1gm of powder contains:<br>Neomycin Sulphate……. 1000mg |
| | Target Species | Cattle, Chicken |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pharmacological Group | Aminoglycoside antibiotic |
| | Shelf life | 2years months |
| | Demanded Price | De-Controlled |
| | Pack size | 500gm, 1kg |
| | International availability | Could not be confirmed |
| | Me-too status | Dufa-Neogut Water Soluble Powder Of M/S. N.B. Sons (Pvt) Ltd. |
| | Detail of certificates attached | **Copy of Original legalized CoPP**<br>**Certificate No. 41401-7/8-14/012**<br>**Certified by:** Staatl. Gewerbeaufsichtsamt Oldenburg, Theodor-Tantzen- Platz 8<br>D-26122 Oldenburg.<br>**Issued date:** 03/04/2014<br>**Free sale in exporting country:** Confirms the free sale of the product in exporting country. |

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| | | **GMP:** The facilities and operations conform to GMP as recommended by WHO as per CoPP. |
| | Remarks of the Evaluator. | • Submit stability study data of three batches of applied drug product both accelerated & real time according to zone IV-A conditions, as you have submitted stability study data of two batches of applied drug product.<br>• Submit Original legalized COPP as you have submitted Copy of COPP.<br>*Evaluation by PEC: The representative of firm has informed that they have submitted the Original legalized COPP in year 2014, at that time their application was rejected but after six month same formulation was approved by the Registration Board, now we have again submitted application for this formulation & documents are attached inside the dossier of previous application.* |
| | **Decision: Deferred for the Following:**<br>• **Submission of original, legalized and Valid CoPP.**<br>• **Submision of Long term stability studies conducted under the conditions of zone IV-A of remaining 1 batch till shelf life** | |

**c. Deferred Cases.**

**i. Human**

**Evaluator PEC-II**

Following cases previously presented in 284th meeting of Registration Board are reproduced here:

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| 1223 | Name and address of Applicant | M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan |
| | Detail of Drug Sale License | Copy of DSL of M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan (No. 05-352-0065-028601D) issued by Chief Drugs controller valid upto 27-02-2020 |
| | Name and address of manufacturer | M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany |
| | Name and address of marketing authorization holder | M/s Fresenius Medical Care Deutschland GmbH Else-Kroner-Straße 1 61352 Bad Homburg v.d.H./Germany.<br><br>MA. No: 50132.00.00 dated 19.02.2002 |
| | Name of exporting country | Germany |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 13004-B Dated 09-04-2018 |
| | Fee including differential fee | Rs. 50,000/- Dated 05-04-2018 |
| | Brand Name+Dosage Form+ Strength | multiBic 2 mmol/l potassium solution for haemodialysis/haemofiltration |
| | Composition | **BEFORE MIXING**<br>Each 1000ml solution contains:<br>**I.** Acidic electrolyte, glucose solution<br>(small compartment)<br>**Active substances:**<br>Potassium chloride=2.982 g<br>Calcium chloride dihydrate=4.410 g<br>Magnesium chloride hexahydrate=2.033 g<br>Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g<br>K+ = 40 mmol<br>Ca2+ = 30 mmol<br>Mg2+ = 10 mmol<br>Cl- = 122 mmol<br>Glucose = 111 mmol<br>**II.** Alkaline hydrogen carbonate solution<br>(large compartment) |

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| | | **Active substances:**<br>Sodium chloride=6.453 g<br>Sodium hydrogen carbonate=3.104 g<br><br>Na+ = 147 mmol<br>Cl- = 110 mmol<br>HCO3− = 37 mmol<br>**AFTER MIXING**<br>1000 ml of the ready-to-use solution contains:<br>Active substances:<br>Sodium chloride = 6.136 g<br>Potassium chloride = 0.1491 g<br>Sodium hydrogen carbonate = 2.940 g<br>Calcium Chloride Dihydrate = 0.2205 g<br>Magnesium Chloride Hexahydrate = 0.1017 g<br>Glucose Monohydrate (= anhydrous glucose 1.000 g) = 1.100 g<br>Sodium = 140 mmol<br>Potassium = 2.0 mmol<br>Calcium = 1.5 mmol<br>Magnesium = 0.50 mmol<br>Chloride = 111 mmol<br>Hydrogen Carbonate = 35 mmol<br>Glucose = 5.55 mmol |
| | Finished Product Specification | Manufacturer specifications |
| | Pharmacological Group | Haemofiltrates |
| | Shelf life | 2 years<br>Storage conditions after mixing of the two compartments (ready-to-use solution):<br>Chemical and physical in-use stability of the ready-to-use solution has been demonstrated for 48 hours at 30 °C. It is not recommended to store the ready-to-use solution longer than 48 h including duration of treatment or at a temperature higher than 30°C prior to the inlet of the pump unit.<br>From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately. |
| | Demanded Price | As per Drug Pricing Policy-2015 |
| | Pack size | 5000ml: Delivered in a double chamber bag (two-compartment).<br>Mixing of both solutions by opening the seam between the two chambers result in the<br>ready-to –use solution for heamofiltration. |
| | International availability | N/A |
| | Me-too status | Not verifiable |
| | Detail of certificates attached | • **<u>Original legalized CoPP</u>**<br>Certificate No: Ba4Q90<br>Certifying Authority: BFARM, Germany<br>Issue Date: 10-11-2017<br>Free sale in exporting country: Yes<br>• GMP: The facilities and operations of manufacturing site conform to GMP as recommended by WHO.<br>• <u>GMP Certificate</u><br>Certificate no. DE_SL_01_GMP _2017_1014 valid upto 05-07-2020<br>**Manufacturer Address:** M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany.<br>Legalized copy of GMP certificate issued by Ministerium for Soziales, Gesundheit, Frauen und Familie<br>**Sole Agency Agreement:** Original legalized Authorisation certificate issued by M/s Fresenius Medical Care Deutschland |

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| | | GmbH Else-Kroner- Straße 1 61352 Bad Homburg v.d.H./Germany declaring "M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan" as sole agent responsible for importation, distribution and all registration related matters for applied formulation. |
| | **Remarks of the Evaluator:**<br>Since the applied formulation is packed in a semi permeable plastic container hence firm has submitted 6 months accelerated (40°C / < 25 % RH) and 24 months long term (30°C / 35 % RH) stability studies of three batches | |
| | **Decision: Deferred for confirmation from Medical Devices and Medicated Cosmetics Division, whether applied formulation falls into classification of Medical devices or not as per prevailing rules.** | |
| 1224 | Name and address of Applicant | M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan |
| | Detail of Drug Sale License | Copy of DSL of M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan (No. 05-352-0065-028601D) issued by Chief Drugs controller valid upto 27-02-2020 |
| | Name and address of manufacturer | M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany |
| | Name and address of marketing authorization holder | M/s Fresenius Medical Care Deutschland GmbH Else-Kroner-Straße 1 61352 Bad Homburg v.d.H./Germany.<br>MA. No: 50736.00.00 dated 19.02.2002 |
| | Name of exporting country | Germany |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 13004-D Dated 09-04-2018 |
| | Fee including differential fee | Rs. 50,000/- Dated 05-04-2018 |
| | Brand Name+Dosage Form+ Strength | multiBic 4 mmol/l potassium solution for haemodialysis/haemofiltration |
| | Composition | **BEFORE MIXING**<br>BEFORE MIXING<br>Each 1000ml solution contains<br>**I.** Acidic electrolyte, glucose solution<br>(small compartment)<br>Active substances:<br>Potassium chloride=5.964 g<br>Calcium chloride dihydrate=4.410 g<br>Magnesium chloride hexahydrate=2.033 g<br>Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g<br>K+ = 80 mmol<br>Ca2+ = 30 mmol<br>Mg2+ = 10 mmol<br>Cl- = 162 mmol<br>Glucose = 111 mmol<br>**II.** Alkaline hydrogen carbonate solution<br>(large compartment)<br>Active substances:<br>Sodium chloride=6.453 g<br>Sodium hydrogen carbonate=3.104 g<br>Na+ = 147 mmol<br>Cl- = 110 mmol<br>HCO3− = 37 mmol<br>**AFTER MIXING**<br>1000 ml of the ready-to-use solution contains:<br>Active substances:<br>Sodium chloride=6.136 g<br>Potassium chloride=0.2982 g<br>Sodium hydrogen carbonate=2.940 g |

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| | | Calcium Chloride Dihydrate = 0.2205 g<br>Magnesium Chloride Hexahydrate = 0.1017 g<br>Glucose Monohydrate (= anhydrous glucose 1.000 g) = 1.100 g<br><br>Sodium = 140 mmol<br>Potassium = 4.0 mmol<br>Calcium = 1.5 mmol<br>Magnesium = 0.50 mmol<br>Chloride = 113 mmol<br>Hydrogen Carbonate = 35 mmol<br>Glucose = 5.55 mmol |
| | Finished Product Specification | Manufacturer specifications |
| | Pharmacological Group | Haemofiltrates |
| | Shelf life | 2 years<br>Storage conditions after mixing of the two compartments (ready-to-use solution):<br>Chemical and physical in-use stability of the ready-to-use solution has been demonstrated for 48 hours at 30 °C. It is not recommended to store the ready-to-use solution longer than 48 h including duration of treatment or at a temperature higher than 30°C prior to the inlet of the pump unit.<br>From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately. |
| | Demanded Price | As per Drug Pricing Policy-2015 |
| | Pack size | 5000ml: Delivered in a double chamber bag (two-compartment).<br>Mixing of both solutions by opening the seam between the two chambers result in the<br>ready-to –use solution for heamofiltration. |
| | International availability | |
| | Me-too status | Not verifiable |
| | Detail of certificates attached | • **<u>Original legalized CoPP</u>**<br>**Certificate No:** Ba4Q101<br>**Certifying Authority:** BFARM, Germany<br>**Issue Date: 10-11-2017**<br>**Free sale in exporting country: Yes**<br>• **GMP:** The facilities and operations of manufacturing site conform to GMP as recommended by WHO.<br>• **<u>GMP Certificate</u>**<br>**Certificate no.** DE_SL_01_GMP _2017_1014 valid upto 05-07-2020<br>**Manufacturer Address:** M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany.<br>**Legalized copy of GMP certificate issued by** Ministerium for Soziales, Gesundheit, Frauen und Familie<br><br>**Sole Agency Agreement:** Original legalized Authorisation certificate issued by M/s Fresenius Medical Care Deutschland GmbH Else-Kroner- Straße 1 61352 Bad Homburg v.d.H./Germany declaring "M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan" as sole agent responsible for importation, distribution and all registration related matters for applied formulation. |
| | **Remarks of the Evaluator:**<br>Since the applied formulation is packed in a semi permeable plastic container hence firm has submitted 6 months accelerated (40°C / < 25 % RH) and 24 months long term (30°C / 35 % RH) stability studies of three batches | |

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| | **Decision: Deferred for confirmation from Medical Devices and Medicated Cosmetics Division, whether applied formulation falls into classification of Medical devices or not as per prevailing rules.** | |
| 1225 | Name and address of Applicant | M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan |
| | Detail of Drug Sale License | Copy of DSL of M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan (No. 05-352-0065-028601D) issued by Chief Drugs controller valid upto 27-02-2020 |
| | Name and address of manufacturer | M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany |
| | Name and address of marketing authorization holder | M/s Fresenius Medical Care Deutschland GmbH Else-Kroner-Straße 1 61352 Bad Homburg v.d.H./Germany.<br><br>MA. No: 50735.00.00 dated 19.02.2002 |
| | Name of exporting country | Germany |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 13004-C Dated 09-04-2018 |
| | Fee including differential fee | Rs. 50,000/- Dated 05-04-2018 |
| | Brand Name +Dosage Form + Strength | multiBic 3 mmol/l potassium solution for haemodialysis/haemofiltration |
| | Composition | **BEFORE MIXING**<br>BEFORE MIXING<br>Each 1000ml solution contains<br>**I.** Acidic electrolyte, glucose solution<br>(small compartment)<br>Active substances:<br>Potassium chloride=4.473 g<br>Calcium chloride dihydrate=4.410 g<br>Magnesium chloride hexahydrate=2.033 g<br>Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g<br>K+ = 60 mmol<br>Ca2+ = 30 mmol<br>Mg2+ = 10 mmol<br>Cl- = 142 mmol<br>Glucose = 111 mmol<br>**II.** Alkaline hydrogen carbonate solution<br>(large compartment)<br>Sodium chloride=6.453 g<br>Sodium hydrogen carbonate=3.104 g<br>Na+ = 147 mmol<br>Cl- = 110 mmol<br>HCO3− = 37 mmol<br>AFTER MIXING<br>1000 ml of the ready-to-use solution contains:<br>Active substances:<br>Sodium chloride=6.136 g<br>Potassium chloride=0.2237 g<br>Sodium hydrogen carbonate=2.940 g<br>Calcium Chloride Dihydrate = 0.2205 g<br>Magnesium Chloride Hexahydrate = 0.1017 g<br>Glucose Monohydrate (= anhydrous glucose 1.000 g) = 1.100 g<br>Sodium = 140 mmol<br>Potassium = 3.0 mmol<br>Calcium = 1.5 mmol<br>Magnesium = 0.50 mmol<br>Chloride = 112 mmol<br>Hydrogen Carbonate = 35 mmol<br>Glucose = 5.55 mmol |

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| Finished Product Specification | Manufacturer specifications |
| Pharmacological Group | Haemofiltrates |
| Shelf life | 2 years<br>Storage conditions after mixing of the two compartments (ready-to-use solution):<br>Chemical and physical in-use stability of the ready-to-use solution has been demonstrated for 48 hours at 30 °C. It is not recommended to store the ready-to-use solution longer than 48 h including duration of treatment or at a temperature higher than 30°C prior to the inlet of the pump unit.<br>From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately. |
| Demanded Price | As per Drug Pricing Policy-2015 |
| Pack size | 5000ml: Delivered in a double chamber bag (two-compartment).<br>Mixing of both solutions by opening the seam between the two chambers result in the<br>ready-to –use solution for heamofiltration. |
| International availability | |
| Me-too status | Not verifiable |
| Detail of certificates attached | • **Original legalized CoPP**<br>Certificate No: Ba4Q96<br>Certifying Authority: BFARM, Germany<br>Issue Date: 10-11-2017<br>Free sale in exporting country: Yes<br>• GMP: The facilities and operations of manufacturing site conform to GMP as recommended by WHO.<br>• GMP Certificate<br>Certificate no. DE_SL_01_GMP _2017_1014 valid upto 05-07-2020<br>Manufacturer Address: M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany.<br>Legalized copy of GMP certificate issued by Ministerium for Soziales, Gesundheit, Frauen und Familie<br><br>Sole Agency Agreement: Original legalized Authorisation certificate issued by M/s Fresenius Medical Care Deutschland GmbH Else-Kroner- Straße 1 61352 Bad Homburg v.d.H./Germany declaring "M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan" as sole agent responsible for importation, distribution and all registration related matters for applied formulation. |

**Remarks of the Evaluator:**

For stability studies firm has referred as under:

"As all solutions of multiBic systems are closely related with only slight differences in their composition, they fulfil the requirements for applying a reduced stability testing plan with bracketing and matrixing.

According to ICH guidelines Q1A R2 "Stability Testing of New Drug Substances and Products" (CPMP/ICH/2736/99) and Q1D "Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products" (CPMP/ICH/4104/00), the stability study design has been set in such a way that only samples on the extremes regarding strength are tested.

Solutions chosen for stability testing represent the extremes regarding solution strength, as these are the ones which contain all ingredients in the highest (multiBic 4 mmol / l potassium) resp. the lowest (multiBic potassium-free) concentrations and multiBic 2 mmol /l potassium which represents the lowest strength including potassium chloride. Thus, the solutions are representative for the stability of the intermediate concentration, which is the solution multiBic 3 mmol/l, as well and further testing on this intermediate concentration is not necessary."

**Decision: Deferred for confirmation from Medical Devices and Medicated Cosmetics Division, whether applied formulation falls into classification of Medical devices or not as per prevailing rules.**

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| 1226 | Name and address of Applicant | M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan |
| | Detail of Drug Sale License | Copy of DSL of M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27-C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan (No. 05-352-0065-028601D) issued by Chief Drugs controller valid upto 27-02-2020 |
| | Name and address of manufacturer | M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany |
| | Name and address of marketing authorization holder | M/s Fresenius Medical Care Deutschland GmbH Else-Kroner-Straße 1 61352 Bad Homburg v.d.H./Germany.<br><br>MA. No: 50131.00.00 dated 19.02.2002 |
| | Name of exporting country | Germany |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 13004-A Dated 06-04-2018 |
| | Fee including differential fee | Rs. 50,000/- Dated 05-04-2018 |
| | Brand Name +Dosage Form + Strength | multiBic potassium free solution for haemodialysis/haemofiltration |
| | Composition | **BEFORE MIXING**<br>BEFORE MIXING<br>Each 1000ml solution contains<br>**I.** Acidic electrolyte, glucose solution<br>(small compartment)<br><br>Active substances:<br>Calcium chloride dihydrate=4.410 g<br>Magnesium chloride hexahydrate=2.033 g<br>Glucose monohydrate(=anhydrous glucose 20.00 g)=22.00 g<br><br>Ca2+ = 30mmol<br>Mg2+ = 10mmol<br>Cl- = 82mmol<br>Glucose = 111 mmol<br><br>**II.** Alkaline hydrogen carbonate solution<br>(large compartment)<br><br>Active substances:<br>Sodium chloride=6.453 g<br>Sodium hydrogen carbonate=3.104 g<br><br>Na+ = 147 mmol<br>Cl- = 110 mmol<br>HCO3− = 37 mmol<br>AFTER MIXING<br>1000 ml of the ready-to-use solution contains:<br>Active substances:<br>Sodium chloride=6.136 g<br>Sodium hydrogen carbonate=2.940 g<br>Calcium Chloride Dihydrate = 0.2205 g<br>Magnesium Chloride Hexahydrate = 0.1017 g<br>Glucose Monohydrate (= anhydrous glucose 1.000 g) = 1.100 g<br>Sodium = 140 mmol<br>Calcium = 1.5 mmol<br>Magnesium = 0.50 mmol<br>Chloride = 109 mmol<br>Hydrogen Carbonate = 35 mmol<br>Glucose = 5.55 mmol |

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| | Finished Product Specification | Manufacturer specifications |
| | Pharmacological Group | Haemofiltrates |
| | Shelf life | 2 years<br>Storage conditions after mixing of the two compartments (ready-to-use solution):<br>Chemical and physical in-use stability of the ready-to-use solution has been demonstrated for 48 hours at 30 °C. It is not recommended to store the ready-to-use solution longer than 48 h including duration of treatment or at a temperature higher than 30°C prior to the inlet of the pump unit.<br>From a microbiological point of view, once connected to the haemodialysis, haemofiltration or haemodiafiltration circuit, and as hydrogen carbonate is present, the product shall be used immediately. |
| | Demanded Price | As per Drug Pricing Policy-2015 |
| | Pack size | 5000ml: Delivered in a double chamber bag (two-compartment).<br>Mixing of both solutions by opening the seam between the two chambers result in the<br>ready-to –use solution for heamofiltration. |
| | International availability | |
| | Me-too status | Not verifiable |
| | Detail of certificates attached | • **Original legalized CoPP**<br>**Certificate No:** Ba4Q81<br>Certifying Authority: BFARM, Germany<br>Issue Date: 10-11-2017<br>Free sale in exporting country: Yes<br>• GMP: The facilities and operations of manufacturing site conform to GMP as recommended by WHO.<br>• **GMP Certificate**<br>**Certificate no.** DE_SL_01_GMP _2017_1014 valid upto 05-07-2020<br>Manufacturer Address: M/s Fresenius Medical Care Deutschland GmbH, 66606 St. Wendel / Germany.<br>Legalized copy of GMP certificate issued by Ministerium for Soziales, Gesundheit, Frauen und Familie<br><br>Sole Agency Agreement: Original legalized Authorisation certificate issued by M/s Fresenius Medical Care Deutschland GmbH Else-Kroner- Straße 1 61352 Bad Homburg v.d.H./Germany declaring "M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660,Pakistan" as sole agent responsible for importation, distribution and all registration related matters for applied formulation. |
| | **Remarks of the Evaluator:**<br>Since the applied formulation is packed in a semi permeable plastic container hence firm has submitted 6 months accelerated (40°C / < 25 % RH) and 24 months long term (30°C / 35 % RH) stability studies of three batches | |
| | **Decision:** Deferred for confirmation from Medical Devices and Medicated Cosmetics Division, whether applied formulation falls into classification of Medical devices or not as per prevailing rules. | |

**Evaluation by PEC:** With reference to above cited decision of Registration Board, confirmation was sought from Medical Devices and Medicated Cosmetics Division, to which Assistant Director-IV (MDMC) has responded as under vide letter No. F.No.16-4/2018-MD dated 08-01-2019:

In this regard, it is submitted that upon evaluation of the dossier, the above mentioned products shall be dealt as drugs due to following reasons.

I. The firm have provided Copp (Certificate of Pharmaceutical Products) of the above mentioned products from Sweden and Germany which is issued only for the Pharmaceutical products and not for medical devices.

II. The above mentioned products has been registered as drug in different countries live UK, Sweden, Netherlands, Germany, Belgium, Australia etc. and their Market Authorization numbers are available.

III. Above mentioned products are categorized as Pharmacotherapeutic group: Hemofiltrates, ATC code: B05ZB as mentioned in SPC (Summary of Product Characteristics). The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, Pharmacological and chemical properties.

IV. The formulation of the above mentioned products are also available in European Pharmacopoeia.

V. The products are administered directly into the bloodstream (Intravenously). GMDN code is available for Haemodialysis concentrate and dialysate solution but no GMDN code is found for solution to be administered intravenously to correct chemical imbalance of the blood caused by kidney failure.

**Decision:** **Registration Board after thorough deliberatioin and considering the aforementioned opinion from Medical Devices and Medicated Cosmetics Division, decided to approve the above presented products of M/s Fresenius Medical Care Pakistan (Private) Ltd. TAMC, First Floor, 27C III, M.M. Alam Road Gulberg III, Lahore 54660, Pakistan listed as follows:**

**i. multiBic potassium free solution for haemodialysis/haemofiltration,**
**ii. multiBic 3 mmol/l potassium solution for haemodialysis/haemofiltration,**
**iii. multiBic 4 mmol/l potassium solution for haemodialysis/haemofiltration,**
**iv. multiBic 2 mmol/l potassium solution for haemodialysis/haemofiltration**

**Evaluator PEC-V**

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| 1227. | Name and address of Applicant | M/s OBS Pakistan (Pvt.) Limited , C-14, Manghopir Road, S.I.T.E Karachi |
| | Detail of Drug Sale License | **Address**: C-14, Manghopir Road, S.I.T.E Karachi<br>**Validity:** 23 May 2018<br>**Status:** Drug License by Way of Retailsale |
| | Name and address of manufacturer | M/s Santen Pharmaceutical Co. Ltd Shiga Plant<br>348-3, Aza-suwa, Oaza- shide, Taga-cho, Inukami-gun, Shiga, Japan<br>M/s Santen Pharmaceutical Co. Ltd Shiga Plant will be responsible for<br>• Preparation of drug solution process.<br>• Filtration for sterilization and filling process.<br>• Release testing of product.<br>and M/s Santen Pharmaceutical Co. Ltd Noto Plant<br>2-14, Sikinami will be responsible for<br>• Packaging and labelling process.<br>• Release testing of product<br>• Batch release. |
| | Name and address of marketing authorization holder | M/s Santen Pharmaceutical Co. Ltd Shiga Plant<br>348-3, Aza-suwa, Oaza- shide, Taga-cho, Inukami-gun, Shiga, Japan |
| | Name of exporting country | Japan |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.3466 Dated 26-01-2018 |
| | Fee including differential fee | Rs. 100,000/- Dated 26-01-2018 |
| | Brand Name +Dosage Form + Strength | Taflotan Opthalmic Solution 0.0015%w/v |
| | Composition | Each ml contains:<br>Tafluprost….15ug |
| | Finished Product Specification | Inhouse |
| | Pharmacological Group | Glaucoma and Ocular Hypertension |
| | Shelf life | 3 years |
| | Demanded Price | MRP as per Originator pack |
| | Pack size | 1's 2.5ml polypropylene bottle with polypropylene dropper |

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| | International availability | Approved in USFDA<br>Zioptan By Merck Sharp, USA |
| | Me-too status | N/A |
| | Detail of certificates attached | **Original legalized CoPP**<br>Certificate No: 5141<br>Certifying Authority: Ministry of Health, Labour and Welfare, Government of Japan<br>Free Sale: Confirms the free sale of the product in exporting country.<br>GMP: The facilities and operations conform to WHO-GMP.<br>Issue Date: 6-02-2017<br>**GMP certificate**<br>Certificate No: 4874<br>Certifying Authority: Ministry of Health, Labour and Welfare<br>Issue date: 27-01-2017<br>**Free sale Certificate**<br>Certificate No: 4351<br>Certifying Authority: Ministry of Health, Labour and Welfare<br>Issue Date**:**22-11-2017<br>**Letter of Authorization**<br>Date of Agreement:05-10-2017<br>Validity :3 Years |
| | Remarks of the Evaluator. | **Firm provided the stability data at following conditions;**<br>● Long term test: 25C/40%RH & 30/75%RH (36 months)<br>● Accelerated Test: 40C/NMT 25%RH<br>The submitted stability data for accelerated condition is not as per Zone IV A requirement.<br>**Firm submitted the following reply;**<br>The stability testing was conducted in compliance with Stability testing of New Drug Substances and Products.<br>The accelerated test conditions has been performed under low humidity conditions 40C/25%RH instead of climate zone IVA high humidity condition which is not recommended and preferred for semi permeable container as stated in ICH.<br><br>*A Significant change has been observed in assay value of Tafluprost for all the three batches MTD1332, MTD1333 and MTD1334 at long term stability condition. Clarify.*<br>Upto 36 months storage at 30C/75% the decrease of tafluprost content is observed (6.5%-6.7%).<br>The increase of the related substances as degradation product of tafluprost are observed (1.6%-1.8%), but it is no problem for safety.<br>According to the above result , the amount of total degradation products is less then the decrease of tafluprost content, it is considered that the reason for the decrease of tafluprost are not only degradation but also adsorption to container.<br>The results of the other tests items are within the specifications, and there are no significant changes.<br>The stability is affected by temperature but it is stable for 36 months after distribution under light protected and below 30C.. |
| | **Previous Decision(M-282):**<br>Deferred for the following reasons:<br>● Submission of long term stability data according to Zone IVA condition. Submitted data for long term stability is at 25C/40%RH which is not according to Zone IVA for semi-permeable containers.<br>● Submission of test for determination of potential water loss in case of semipermeable membrane. | |
| | **Evaluation by PEC:**<br>Firm submitted the following reply: | |

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| | ● Submission of long term stability data according to Zone IVA condition. Submitted data for long term stability is at 25°C/40%RH which is not according to Zone IVA for semi-permeable containers.<br>Please note that the stability conducted on 25°C±2/40%±5 complies the criteria of WHO guidelines which clearly states the condition in which whether the long term studies are performed at on 25°C±2/40%±5 or 30°C±2/35%±5 is determined by the climatic condition under which the FPP is intended to be marketed. . Testing at 30 °C/35% RH can be an alternative to the storage condition at 25 °C/40% RH.<br>Also the region has claimed that incase of semi-permeable container, the low humidity condition 25°C±2/40%RH±5 is a more severe storage condition than high humidity condition 30 °C/35% RH.<br>**Evaluation**<br>However, the data is at 25 °C/40% RH and not at 30 °C/35% RH. Therefore, the stability is not as per guideline.<br>Moreover, the low humidity condition is 30 °C/35% RH and not 25°C/40%RH.<br>The firm has performed stability testing according to ASEAN requirement i.e. at 30°C/75%RH but test for water loss has not been conducted. Moreover, the stability data is of Shiga Plant whereas, M/s Santen Pharmaceutical Co. Ltd Noto Plant 2-14, Sikinami will be responsible for<br>i. Packaging and labelling process.<br>ii. Release testing of product<br>**iii.** Batch release. | |
| | **Decision:Deferred for the following reasons:**<br>● **Submission of long term stability data from M/s Santen Pharmaceutical Co. Ltd Noto Plant 2-14, Sikinami according to Zone IVA condition. Submitted data for long term stability is at 25C/40%RH which is not according to Zone IVA for semi-permeable containers.**<br>● **Submission of test for determination of potential water loss in case of semipermeable membrane.** | |
| 1228. | Name and address of Applicant | M/s Hakimsons (Impex) pvt. Limited, Hakimsons building, 19-west wharf road, Karachi. |
| | Detail of Drug Sale License | **Address:** Hakimsons building, 19-west wharf road, Karachi.<br>**Validity:** 15-Sep-2019<br>**Status:** Drug License by way of Wholesale |
| | Name and address of manufacturer | M/s Mylan Laboratories Limited<br>Plot No. 1606-1609, G.I.D.C<br>Sarigam, Dist. Val Sad, Gujrat, India |
| | Name and address of marketing authorization holder | M/s Mylan Laboratories Limited<br>Plot No. 1606-1609, G.I.D.C<br>Sarigam, Dist. Val Sad, Gujrat, India |
| | Name of exporting country | India |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.1114 Dated 29/09/2014 |
| | Fee including differential fee | Rs. 100,000/- Dated 26/09/2014 |
| | Brand Name +Dosage Form + Strength | ZINNIA F |
| | Composition | Each sugar coated white tablet contains:<br>Levonorgestrel……. 150mcg<br>Ethinylestradiol……..... 30mcg<br>Each sugar coated brown tablet contains:<br>Ferrous fumarate…….. 75mcg eq. to Ferrous iron 24.375mg |
| | Finished Product Specification | In House |
| | Pharmacological Group | contraceptive |
| | Shelf life | 5 years |
| | Demanded Price | Decontrolled for UNFP/USAID supplies only |
| | Pack size | Combo pack of 21 tablets of Levonorgestrel + Ethinylestradiol and 7 Tablets of Ferrous fumarate.<br>3 Blisters of 28 Tablet Each |
| | International availability | Ovranette® 150/30 micrograms sugar Coated Tablets.<br>MHRA Approved |

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| | Me-too status | |
| | Detail of certificates attached | **Original legalized CoPP**<br>**Certificate No.** 051459<br>**Issued by:** Food and Drugs Control Administration, Gujarat state, India<br>**Valid up to**: 09/04/2019<br>Confirms the free sale of the product in exporting country.<br>The facilities and operations conform to WHO-GMP. |
| | Remarks of the Evaluator. | The firm has claimed In House specifications while both tablets are **present in USP and BP.**<br>**Following are the short comings:**<br>• Evidence of approval of the product in reference regulatory authorities since the product is approved in USFDA in different strength and me too status of the product.<br>• No combo pack and sugar coated tablet could be confirmed. |
| | **Previous Decision(M-283):** | Deferred for the following reasons:<br>□ Confirmation whether applied formulation can be imported from India or otherwise as per prevailing Import Policy Order.<br>□ Evidence of approval of applied formulation as combo pack in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.<br>□ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) Along with registration number, brand name and name of firm as combo pack. |
| | **Fresh Evaluation:** Firm has submitted that:<br>• Confirmation whether applied formulation can be imported from India or otherwise as per prevailing Import Policy Order.<br>The applied formulation is estradiol and progesterone (sex hormone) and is not present in negative list.<br>• Evidence of approval of applied formulation as combo pack in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting.<br>Prequalified by WHO Ethinylestradiol/Levonorgestrel Tablet + Placebo (Ferrous Fumarate Tablet) | |
| | **Decision: Approved with Innovator's specifications as per policy of inspections for manufacturer abroad.** | |

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| 1229. | Name and address of Applicant | M/s Hoffmann Human Health Pakistan, ltd. 32-Babar Block, New Garden town,Lahore |
| | Detail of Drug Sale License | Address: 32-Babar Block, New garden town, Lahore.<br>Validity: 29, Nov, 2019<br>Status: License to sell drugs as a Distributor |
| | Name and address of manufacturer | Head Office: B-1,Extn./A-27, MCIE, Malthura Road, New Dehli 110044, India<br>Factory: M/s Panacea Biotec Ltd. Malpur, Baddi, Himachel Pradesh-173205, India<br>Form 5-A + Sole |
| | Name and address of marketing authorization holder | M/s Panacea Biotec Ltd. Malpur, Baddi, Himachel Pradesh-173 205, India |
| | Name of exporting country | India |
| | Type of Form | Form 5-A |
| | & Date of R& I | Dy. No.17792 Dated 11/10/2017 |
| | Fee including differential fee | Rs. 100,000/- Dated 11/10/2017 |
| | Brand Name +Dosage Form + Strength | MYCEPT 250mg Capsule |
| | Composition | Each capsule contains:<br>Mycophenolate mofetil…..250mg |
| | Finished Product Specification | BP |
| | Pharmacological Group | Immunosuppressant |
| | Shelf life | 24 months |

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| | Demanded Price | Rs. 4000/- per box of 30 capsule |
| | Pack size | 3x10's Blister strip. |
| | International availability | Cellcept 250mg Capsules |
| | Me-too status | N/A |
| | Detail of certificates attached | • **Original legalized CoPP** (certificate No.MB/05/203/WHO/GMP/18-116) certified by State Drugs Controller, Licensing Authority cum Controlling Authority, Himachel Pradesh, India valid till 11/02/2020 confirms the free sale of the product in exporting country. The facilities and operation conform to WHO-GMP. (does not contains the name of Pakistan)<br>• Free sale certificate (Legalized) confirming free sale of the applied product is attached.<br>• Letter of Authorization valid up to 30, April 2020. |
| | Remarks of the Evaluator. | Product is present in USP not in BP. |
| | Previous Decision(M-286): | Deferred for confirmation whether applied formulation can be imported from India or otherwise as per prevailing Import Policy Order. |
| | Fresh Evaluation: | Immunosuppressants are not present in negative list as per prevailing Import Policy Order. |
| | **Decision: Approved with Innovator's specifications as per policy of inspections for manufacturer abroad.** | |
| 1230. | Name and address of Applicant | M/s Hoffmann Human Health Pakistan, ltd. 32-Babar Block, New Garden town,Lahore |
| | Detail of Drug Sale License | Address: 32-Babar Block, New garden town, Lahore. Validity: 29, Nov, 2019 Status: License to sell drugs as a Distributor |
| | Name and address of manufacturer | Head Office: B-1,Extn./A-27, MCIE, Malthura Road, New Dehli 110044, India Factory: M/s Panacea Biotec Ltd. Malpur, Baddi, Himachel Pradesh-173205, India Form 5-A + Sole |
| | Name and address of marketing authorization holder | M/s Panacea Biotec Ltd. Malpur, Baddi, Himachel Pradesh-173 205, India |
| | Name of exporting country | India |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.17793 Dated 11/10/2017 |
| | Fee including differential fee | Rs. 100,000/- Dated 11/10/2017 |
| | Brand Name +Dosage Form + Strength | MYCEPT 500 tablet (film coated tablet) |
| | Composition | Each film coated tablet contains: Mycophenolate mofetil…..500mg |
| | Finished Product Specification | In House |
| | Pharmacological Group | Immunosuppressant |
| | Shelf life | 24 months |
| | Demanded Price | Rs. 8000/- per box of 30 capsule |
| | Pack size | 3x10's Blister strip. |
| | International availability | Cellcept 500mg Film-Coated Tablets |
| | Me-too status | N/A |
| | of certificates attached | • **Original legalized CoPP** (certificate No. MB/05/203/WHO/GMP/18/117) certified by State Drugs Controller, Licensing Authority cum Controlling Authority, Himachel Pradesh, India valid till 11/02/2020 confirms the free sale of the product in exporting country. The facilities and operation conform to WHO-GMP. (does not contains the name of Pakistan)<br>• Free sale certificate (Legalized) confirming free sale of the applied product is attached. |

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| | | ● Letter of Authorization valid upto 30, April 2020. |
| | Remarks of the Evaluator. | Product is present in USP. |
| | Previous Decision(M-286): | Deferred for confirmation whether applied formulation can be imported from India or otherwise as per prevailing Import Policy Order. |
| | Fresh Evaluation: | Immunosuppressants are not present in negative list as per prevailing Import Policy Order. |
| | **Decision: Approved with Innovator's specifications as per policy of inspections for manufacturer abroad.** | |
| 1231. | Name and address of Applicant | M/s Pharmatech Pakistan (PVT) Limited, D-86/A, Mangophir Road, SITE, Karachi. |
| | Detail of Drug Sale License | Address: Pharmatech Pakistan (Pvt.) Ltd. Pharmatech Pakistan (Pvt.) Ltd.<br>Validity: 22/06/2019<br>Status: Drug sale license by the way of wholesale |
| | Name and address of manufacturer | M/s Laboratorios Menarini, S.A. C/ Alfonso XII, n0 587 08918 Badalona (Barcelona), Spain |
| | Name and address of marketing authorization holder | M/s Menarini International Operations Luxembourg, S.A. 1, Avenue de la Gare Lxembourg L-1611 Luxembourg |
| | Name of exporting country | Spain |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No.17272 Dated 06/10/2017 |
| | Fee including differential fee | Rs. 300,000/- Dated 05/10/2017 |
| | Brand Name +Dosage Form + Strength | KETESSE 25mg Granules for oral solution |
| | Composition | Each sachet contains:<br>Dexketoprofen trometamol…….. 36.9mg<br>(Eq. to Dexketoprofen…….. 25mg) |
| | Finished Product Specification | In House |
| | Pharmacological Group | NSAIDS |
| | Shelf life | 36 months |
| | Demanded Price | For 4's pack Rs. 640/-<br>For 10's pack Rs. 1600/-<br>For 20's pack Rs. 3200/- |
| | Pack size | 4's, 10's, 20's |
| | International availability | Spain Approved |
| | Me-too status | --- |
| | Detail of certificates attached | ● Original legalized CoPP (certificate No. 2018/00153) certified by Spanish Agency of Medicines and Medical Devices, Spain issued on 22/1/2018 confirms the free sale of the product in exporting country. The facilities and operations conform to WHO-GMP.<br>● Agreement/Authorization Issued by M/s Menarini Asia Pacific Holdings 30 PasirPangjang Road 8-32, Maple Tree Business City Singapore<br>Validity: 29-03-2019 |
| | Remarks of the Evaluator:<br>● The firm has claimed In House specifications and the product is not present in USP/BP.<br>● Sole agency agreement/letter of authorization.<br>● Clarification is required since significant changes (more than 5%) have been observed in assay value of stability studies between initial and final time points.<br>Clarification of significant changes in assay, value of stability studies from principal A. Menarini is as under:<br>a. The observed decrease in the assay values between initial and final time points of the provided stability data cannot be considered a critical issue since this trend doesn't affect the requested quality profile of the drug.<br>b. More in detail, as reported in the submitted section 3.2.P.8 (Dossier Vol- 2, Annexure XXI", the stability of the drug product has been verified for the entire shelf life at 30°C/ 75% RH, 30°C/65% RH & 30°C/60% RH long term conditions, and the obtained results are fully accompanied with the | |

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| | shelf life specifications proving that the observed decrease in the assay value does not significantly affect the quality profile of the finished medicinal product. Taking into account all the above mentioned considerations, the applicant deems that the observed decrease in the assay value during storage does not represent a critical aspect, thus excluding any risk of the quality and the efficacy of the finished medicinal product as well as for the safety of the patients. |
| | **Description of the product:**<br>The drug is indicated for symtomatic treatment of pain of mild to moderate intensity, such as musculo-skeletal pain, dysmonerrhoea, dental pain. |
| | **Decision(M-282):**<br>Deferred for following reasons:<br>● Justification of clarification regarding significant changes in assay values at long term stability condition.<br>● Evidence of relationship between product license holder "M/s Menarini International Operations Luxembourg, S.A. 1, Avenue de la Gare Lxembourg L-1611 Luxembourg and "M/s Menarini Asia Pacific Holdings,30 Pasir Pangjang Road,8-32, Maple Tree Business City Singapore".Provide agreement /Authority Letter from product license holder. |
| | **Fresh Evaluation:**<br>Firm has submitted the following reply:<br>• Justification of clarification regarding significant changes in assay values at long term stability condition.<br>We, Laboratorios Menarini, S.A., located in Alfonso XII, 587, 08918 Badalona, Spain, proposed finished product manufacturer of dexketoprofen trometamol 25mg granules for oral solution, hereby ***DECLARE*** that the observed decrease in the assay values between initial and final time points of the provided stability data have not be considered as a critical issue since this trend doesn't negatively affect the requested quality profile of the drug product as defined by the shelf-life specifications reported in the submitted section 3.2.P.5.1, for the entire proposed shelf life.<br>More in detail, as reported in the submitted section 3.2.P.8, the stability profile of the drug product has been verified for the entire shelf life at 30 °C/75% RH, 30 °C/65% RH and 25 °C/60% RH long term conditions. In addition, notwithstanding the observed decrease in the assay value, we would like to point out that the lower specification limit of assay at the end of shelf life has been settled to 92%, according of the results of the first ICH stability studies performed on the product, thus allowing a loss in the assay more than 5% which may occur during storage if the whole shelf-life span is considered. Thus it should be noted that, seeing the significant change observed in the assay value during the studies under accelerated conditions, also intermediate and long term conditions, both for climatic zone II and IV, have been investigated, confirming that the decrease of the assay happens gradually throughout the shelf-life and corresponds to an increase of the impurities content, proving that the phenomenon is properly controlled and falls into the natural degradation of the active ingredient. Furthermore, the concerned stability studies demonstrate that the quality profile of the medicinal product is maintained, being all the results in compliance with the shelf-life specifications thus confirming that the observed decrease in the assay value does not affect the quality profile of the finished medicinal product.<br>Taking all the above mentioned consideration into account, we deem that the observed decrease in the assay value during storage does not represent a critical aspect, thus excluding any risk for the quality and efficacy of the finished medicinal product, as well as for the safety of the patients.<br>• Evidence of relationship between product license holder "M/s Menarini International Operations Luxembourg, S.A. 1, Avenue de la Gare Luxembourg L-1611 Luxembourg and "M/s Menarini Asia Pacific Holdings,30 Pasir Pangjang Road,8-32, Maple Tree Business City Singapore".Provide agreement /Authority Letter from product license holder.<br>Firm has submitted letter of declaration concerning the transfer of ownership of the rights on the product Ketesse Granules for Oral Solution.<br>We, MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A., a company existing under the law of Luxembourg, with registered officers at 1, Avenue de la Gare, L-1611 Luxembourg, and LABORATORIOS MENARINI SA, a company existing under the law of Spain, with registered offices at ownership of all rights relating to the product Ketesse Granules for oral solution 25mg/ Sachet with respect to the country of Pakistan, to A. MENARIINI ASIA-PACIFIC HOLDINGS PTE. LTD., a company incorporated in Singapore and with registered offices located at 30 pasir Panjang Road, #08-32 Mapletree Business City, Singapore 117110. |
| | **Decision: Approved with Innovator's specifications as per policy of inspections for manufacturer abroad.** |

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| 1232. | M/s. Revive Health Care,<br>Office No.503, 5th Floor, 6 Main Gulberg, Jail Road, Lahore.<br><br>M/s. GENFARMA LABORATORIO,<br>S.L. Site address Avda. De la Constitucion, 198-199, Poligono Industrial Monte Boyal, Casarrubios del Monte 45950 (Toledo) Espana, Spain. | Colicraft 1,000,000 IU Lypholized powder for solution for Injection<br><br>Each vial contains:-<br>Colistimethate Sodium …1,000,000 I.U<br><br>(Antibiotic)/Polymyxin<br><br>USP Specifications<br>03 years | Form 5A<br>Dy No.619 R&I dated 31-12-2015<br>Rs.50,000/-<br>As per PRC. | Colomycin Injection 1 Million International Units. powder for soln for inj infusion by M/s Forest Laboratories, UK MHRA approved | COPP was issued by Spain on dated 04-05-2016.<br><br>GMP compliant as per COPP dated 04-05-2016. | 260th Meeting Registration Board held on 28-29th June, 2016<br>Deferred for confirmation whether formulation is me too or otherwise |
| | **Evaluation by PEC**<br>• The applied product is approved/registered by the board for sale in Pakistan. i.e. Colistat Injection 1MIU (vial) by M/s Medisure Laboratories, Karachi (Reg#076160)<br>• Firm has also submitted differential fee of Rs. 50,000/- (Challan#0824422) Dated 16-01-2019 | | | | | |
| | **Decision: Approved as per policy of inspections for manufacturer abroad.** | | | | | |

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| 1233. | Name and address of Applicant | M/s Himmel Pharmaceuticals (Pvt) Ltd,<br>House#793-D, Block-C, Faisal Town, Lahore. |
| | Detail of Drug Sale License | **Address:** House#793-D, Block-C, Faisal Town, Lahore.<br>**License no.:** 05-352-0065-016174D<br>**Validity:** 06/02/2020<br>**Status:** License to sell drugs as a Distributor. |
| | Name and address of manufacturer | **Product license holder:** M/s Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5 Planta, 08038, Barcelona, Espana/ Spain.<br>**Manufacturing site:** M/s PRASFARMA, S.L,<br>C/Sant Joan, 11-15, 08560, Manlleu (Barcelona), Espana/ Spain. |
| | Name and address of marketing authorization holder | M/s Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5 Planta, 08038, Barcelona, Espana/ Spain |
| | Name of exporting country | Spain |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 25078: 19-07-2018 |
| | Fee including differential fee | PKR 100,000/-: 19-07-2018 |
| | Brand Name +Dosage Form + Strength | **HimTam 20mg Tablets** |
| | Composition | Each tablet contains:<br>Tamoxifen (as citrate) …20mg |
| | Finished Product Specification | In-house specifications |
| | Pharmacological Group | Hormone antagonists and related agents (Anti-estrogens) |
| | Shelf life | 2 Years |
| | Demanded Price | As per SRO |
| | Pack size | Type I glass vials containing 15ml concentrated solution in pack size of 1's |
| | International availability | TAMOXIFENO FUNK 20 mg Comprimidos by M/s Spain (CIMA Spain Approved) |
| | Me-too status | Bilem Tablets 20mg by M/s Getz Pharma (Reg#036690) |
| | Detail of certificates attached | ● Original legalized CoPP issued on 05-10-2017 by Agencia Espanola Del Medicamento Y Productos Sanitarios confirms free sale of the product.<br>● Original legalized GMP certificate of the manufacturer is submitted which is valid until 16th June 2020. Certificate # NCF/1739/001/CAT. The certificate is issued by Ministry of |

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| | | Health of Government of Catalonia- Spain.<br>• Original, legalized and valid Sole agency agreement by M/s PRASFARMA, S.L, C/Sant Joan, 11-15, 08560, Manlleu (Barcelona), Espana/ Spain., issued on 16-11-2017 and valid for 3 years is submitted by the firm. |

**Remarks of the Evaluator.**

- The product is registered in Spain by M/s Mylan under name: TAMOXIFENO FUNK 20 mg Comprimidos (Marketing authorisation number: 58110)
- The Sole agency agreement/ contract is issued in the name of manufacturer i.e. M/s PRASFARMA, S.L, who is not product license holder of the product.
- Firm has claimed in-house specifications whereas the product monograph is available in BP.
- The difference in BP and in-house specifications is as follows:

| Tests | BP specifications | In-house specifications |
|---|---|---|
| Assay limits | 90-110% | 95-105% |

- Firm has submitted 6 months accelerated stability study data and 36 months real-time stability study data of 3 batches of batch A-20, A-21 and H-7 manufactured in January 2016,(as per Zone IV-A)
  Initiation dates:
  Batch # A-20 (October 2007)
  Batch # A-21(October 2007)
  Batch # H-7(October 2014)

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| Decision of previous meeting of RB | Deferred for submission of legalized and valid sole agency agreement between the applicant and product licence holder i.e M/s Mylan Pharmaceuticals, S.L. Plot 2-4, 5 Planta, 08038, Barcelona, Espana/ Spain. **(M-286)** |

**Evaluation by PEC:**

Firm has submitted Explanation letter issued by M/s Mylan Pharmaceuticals, S.L. Plom 2-4, 5 Planta, 08038, Barcelona, Espana/ Spain **(Product licence holder)** stating that:

**"**M/s Mylan Pharmaceuticals, S.L as holder of registered product in Spain TAMOXIFENO FUNK 20 mg Comprimidos , has authorized PRASFARMA, S.L, to apply for COPP, in order to register this product in Pkistan by by Himmel Pharmaceuticals (Pvt) Ltd. PRASFARMA, S.L is manufacturer of product.

Both companies PRASFARMA, S.L, and Mylan Pharmaceuticals, S.L. have a business relation regarding registration of products outside Europe and we have no objection on this registration of Tamoxifen (HimTam) by Himmel Pharmaceuticals (Pvt) Ltd**."**

**Decision: Approved with BP specifications as per policy of inspections for manufacturer abroad.**

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| | Name and address of Applicant | M/s AGP (Private) Limited, B-23, S.I.T.E, Karachi |
| | Name and address of manufacturer | M/s Mylan Laboratories Limited, Plot No. 11, 12 & 13 Indore Special Economic Zone, Pharma Zone, Phase-II, Sector_III, Pithampur-454775, Dist,-Dhar (Madhya.Pradesh.) India |
| | Name and address of marketing authorization holder | M/s Mylan Laboratories Limited, Plot No. 11, 12 & 13 Indore Special Economic Zone, Pharma Zone, Phase-II, Sector_III, Pithampur-454775, Dist,-Dhar (Madhya.Pradesh.) India<br>*Corporate Office:* House No8-2-293/82/J-III, Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad-500 033, India |
| | Name of exporting country | India |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. 3169 Dated 02/03/2017 |
| | Fee including differential fee | Rs. 50,000/- Dated 13/02/2017 |
| | Brand Name +Dosage Form + Strength | **TREZAV**<br>(Immediate Release, Film Coated Tablet) |
| | Composition | Each Film Coated Tablet Contains:<br>Lamivudine……. 150mg<br>Nevirapine……200mg<br>Zidovudine……...300mg |
| | Finished Product Specification | Manufacturer's specifications |
| | Pharmacological Group | Anti-Retroviral |

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| | Shelf life | 60 months |
| | Demanded Price | 2634.05/- per bottle of 60 tablets |
| | Pack size | 60 Tablets in HDPE bottle |
| | International availability | LAMIVUDINE; ZIDOVUDINE; NEVIRAPINE by Cipla Limited, Tentative Approval by USFDA<br>**Tentative Approval:**<br>If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does |
| | Me-too status | Zidolam-N tablets. by A"raf Pharmaceuticals (Imported) (Reg#041106) |
| | Detail of certificates attached | Legalized and Valid CoPP (certificate No. 7/2014) issued by Food and Drug Administration, Bhopal, Madhya Pradesh, India valid till 26/09/2018 confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO as per CoPP. |
| | Remarks of the Evaluator. | • The firm has claimed In House manufacturing specifications and the product is not present in pharmacopoeia (USP & BP).<br>• Firm has stated that initially the product was manufactured at Mylan Laboratories, Nashik site due to commercial reasons the product has been transferred to Mylan Laboratories Indore. Provided stability data from Nashik site is of 5 years but stability data from new site that is Indore, is of only 2 years which does not support the shelf life. |
| | Decision of previous meeting of RB | Registration Board deferred the case for the following reasons:<br>• Submission of long-term stability data till shelf life of the product.<br>• Clarification whether anti-viral drugs can be imported from India or otherwise.<br>• Evidence of approval in reference regulatory authorities.<br>**(M-271).** |

**Evaluation by PEC**

- The applied product is approved/registered by the board for sale in Pakistan. i.e. Zidolam-N tablets. by A"raf Pharmaceuticals (Imported) (Reg#041106)
  Firm has submitted differential fee of Rs. 50,000/- (Challan#0789324) Dated 21-01-2019
- This formulation is also **WHO prequalified**.
  Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg by Mylan Laboratories Ltd, Plot No.564/A/22, Road No. 92, Jubilee Hills, Hyderabad, Telangana, 500096, India (WHO Reference Number: HA426 *)
- Firm has submitted that the product is not included in the **SRO No. 280 (I) /2012** 'List of items not imported from India' therefore the product can be imported.
- Firm has submitted **6 months** accelerated stability study data and **48 months** real-time stability study data of 3 batches of batch 3027703, 3028149 and 3028150 conducted by the manufacturer i.e: Mylan Laboratories Limited, Plot No. 11, 12 & 13 Indore Special Economic Zone, Pharma Zone, Phase-II, Sector_III, Pithampur-454775, Dist,-Dhar (Madhya.Pradesh.) India.

  Accelerated stability conditions: 40℃ ±2 ℃, 75%RH±5%RH
  Long-term stability conditions: 30℃ ±2 ℃, 75%RH±5%RH

| Batch# | Mfg date | Initiation date |
|---|---|---|
| 3027703 | June 2014 | 12-09-2014 |
| 3028149 | June 2014 | 12-09-2014 |
| 3028150 | July 2014 | 12-09-2014 |

**Decision: Approved with Innovator's specifications as per policy of inspections for manufacturer abroad.**

| | | |
|---|---|---|
| 1235 | Name and address of Applicant | M/s Himmel Pharmaceuticals Pvt Ltd.<br>793-D, Block "C" Faisal Town Lahore, Pakistan |
| | Detail of Drug Sale License | **Adress:** M/s Himmel Pharmaceuticals, 793D, Block C, Faisal Town, District Lahore.<br>**Validity:** 06-02-2020<br>**Status:** License to sell drugs as a Distributor. |
| | Name and address of the manufacturer | M/s BEACON Pharmaceuticals Limited, kathali, Bhaluka, Mymensingh, Bangladesh<br>Head office:<br>BEACON Business Centre, 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh |
| | Name and address of marketing authorization holder | M/s BEACON Pharmaceuticals Limited, kathali, Bhaluka, Mymensingh, Bangladesh<br>Office Address: 9/A, Toyenbee Circular Road, Motijheel Dhaka, Bangladesh |
| | Name of exporting country | Bangladesh |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | 27959, 16-08-2018 |
| | Fee including differential fee | 50,000/-, 11-08-2018 |
| | Brand Name +Dosage Form + Strength | **Regonix 40 Tablet** |
| | Composition | Each film coated tablet contains:<br>Regorafenib Monohydrate…..41.491mg eq. to 40mg Regorafenib |
| | Finished Product Specification | In-house specifications |
| | Pharmacological Group | Anti-Cancer; Protein Kinase inhibitor |
| | Shelf life | 24 months |
| | Demanded Price | Not mentioned |
| | Pack size | 1 × 28's in HDPE bottle |
| | International availability | STIVARGA 40mg Tablet of Bayer Hlthcare **(USFDA approved)** |
| | Me-too status | N/A |
| | Detail of certificates attached | ● Original legalized CoPP issued on 28-02-2018 by **Directorate General of Drug Administration**, Aushad Bhaban, Mohakhali, Dhaka-1212, Bangladesh confirms free sale of the product in the exporting country. Certificate No: DA/ 6-110/2016/4366.<br>● Original legalized GMP certificate of the manufacturer is submitted which is issued on 20-07-2017. Certificate No: DA/ 6-110/06/10002.<br>● Original , legalized letter dated 03-03-2018 from M/s Beacon Pharmaceuticals Limited., Kathali, Bhaluka, Mymensingh, Bangladesh declaring M/s Himmel Pharmaceuticals Pvt Ltd. 793-D Block 'C', Faisal Town, Lahore, Pakistan as authorized agent to register and sell the applied product in the territory of Pakistan. |
| | Remarks of the Evaluator. | • Firm has submitted 6 months accelerated (40 $^{o}$C ±2 $^{o}$C, 75%RH±5%RH) stability study data and 24 months real-time (30 $^{o}$C ±2 $^{o}$C, 65%RH±5%RH) stability study data of 3 batches.<br>• Manufacturing dates:<br>Batch #3100007 (05-2016)<br>Batch #3100008 (05-2016)<br>Batch #3100009 (05-2016)<br>*Dissolution method mentioned in Finished product specifications is not as per recommendation of FDA. Clarification is required.* |

<table>
<tr><td></td><td>Previous Decision</td><td>Deferred for following: (M-286)<br>Clarification/ revision of label claim on Form-5A as per CoPP.<br>Clarification since the submitted dissolution test method is not in accordance with USFDA recommendation.<br>Deferred for further deliberation upon justification of using dissolution method other than that recommended by USFDA for innovator’s product (M-287).</td></tr>
<tr><td></td><td>Evaluation by PEC</td><td>The firm has submitted revised Form-5A with correct label claim and fee challan of Rs. 5000/- (deposit slip # 0762366) dated 14-12-2018.<br>Dissolution method<table><tr><td>In-house dissolution conditions</td><td>USFDA Recommended</td></tr><tr><td>Apparatus: USP Type II (paddle)<br>Dissolution medium: 0.1M HCl with 2% SLS<br>Revolution: 100 RPM<br>Dissolution time: 45 min</td><td>Apparatus: USP Type II (paddle)<br>Dissolution medium:<br>Acetate Buffer pH 4.5 with 0.1% Sodium Dodecyl Sulfate (SDS)<br>Revolution: 75 RPM<br>Dissolution time: 45 min</td></tr></table>The firm has submitted justifcation regarding dissolution method that Regorafenib tablet is a non-pharmacopoeial product and we use in-house developed method based on BRITISH Pharmacopeia: Recommendations on Dissolution Testing.<br>The pH of the dissolution medium is usually set between pH 1 and pH 8. In justified case higher pH may be needed. For the lower pH values in the acidic range, 0.1M hydrochloric acid is normally used.<br>Using the paddle or basket apparatus, the volume of dissolution medium is normally 500-1000ml. A stirring speed of 50 rpm and 100 rpm is normally chosen; it must not exceed 150 rpm.<br>The firm has submitted that Regorafenib is non-pharmacopeial product and we will adopt FDA recommended dissolution method in future.</td></tr>
<tr><td></td><td colspan="2">Decision: Deferred for submission of stability data applying USFDA recommedne ddissolution method for applied formulation.</td></tr>
</table>

### iii. Veterinary

**Evaluator PEC-XIV**

| | | |
|---|---|---|
| 1236 | Name and address of Applicant | M/s. Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha, Pakistan |
| | Detail of Drug Sale License | Valid upto 2019. |
| | Name and address of the manufacturer | M/s. Kombipharm International Co. Ltd., 17, Gyeongje-Ro, Siheung-SI, Gyeonggi-DO, South Korea, The Republic of Korea |
| | Name and address of marketing authorization holder | M/s. Kombipharm International Co. Ltd., 17, Gyeongje-Ro, Siheung-SI, Gyeonggi-DO, South Korea, The Republic of Korea |
| | Name of exporting country | Korea |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy No. 722, 25-09-2014 |
| | Fee including differential fee | Rs.100,000/- 25-09-2014 |
| | Brand Name +Dosage Form + Strength | Komi Pink Spray |
| | Composition | Each Liter contains:-<br>Florfenicol……20g<br>Cetrimide……..10g<br>Dimethyl Phthalate……...10g<br>Crystal violet……..q.s.<br>N-Methylpyrrolidone…….q.s.<br>PVP (Povidone)…….q.s.<br>Isopropanol……q.s. |
| | Finished Product Specification | In-house |
| | Pharmacological Group | Antibiotic-Peptidyl transferase inhibitor |
| | Shelf life | 36 months (supported by realtime and accelerated stability study data) |
| | Demanded Price | As per SRO |
| | Pack size | 50ml, 100ml, 250ml, 500ml |
| | International availability | Available in in korea as per CoPP |
| | Me-too status | Could not be confirmed |
| | Detail of certificates attached | 1. Original legalized free sale certificate issued by Animal and Plant Quarantine Agency Korea on 09-06-2014 confirms free sale availability in Korea<br>2. Original legalized GMP certificate issued by Animal and Plant Quarantine Agency Korea on 09-06-2014 confirms GMP status of manufacturing site |
| | Remarks of the Evaluator. | 1. Firm has claimed in house spec's and the product is not present in BP and USP<br>Letter of shortcoming was issued to the firm on 14th April 2015 and the reply received is still deficient for<br>"The drug sale license is to sell drugs in pharmacy and not for distribution" |
| | Previous Decisions | **Decision of 270th meeting:**<br>In 270th meeting Registration Board deferred the case as the concerned member of Board (veterinary expert) was not available.<br>Deferred for evidence of approval in reference regulatory authorities **(M-272).** |
| | **Evaluation by PEC** | The firm has submitted two references as evidence of international approval of the product.<br>1. TOPAZONE NF SRAY, Mexico<br>The reference cannot be verified; Moreover, Mexico is not our reference country.<br>2. FLOXY-SPRAY, Ukraine<br>The reference has been verified while the firm is unable to provide evidence of approval in 02 more countries of E.U. |

| | | |
|---|---|---|
| | | Moreover the product which is registered in Ukraine has a strength of 2.5gm/100ml while the applied product has strength of 2gm/100ml.<br>The firm has submitted reference of formulation approved in USFDA the composition of which as follows:<br>Claro Solution<br>Florfenicol……16.6mg/ml<br>Terbinafine as hydrochloride……14.8mg/ml<br>Mometasone furoate……2.2mg/ml<br>Our product Komipink Spray is a similar topical formulation with Florfenicol as an active ingredient and used for treatment of bacterial infection, scabies and wounds.<br>The samples of Komipink spray have been **utilized and appreciated by Pakistan Army** and they have demanded this product availability as soon as possible, since the Pakistan Army accommodates a great number of Horses, Dogs and Mules for different defense purposes. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |

**Case No. 08: Registration applications of drugs for which stability study data is submitted**

**a. New cases**

**b. Deferred cases**

**Evaluator PEC-XIV**

| 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<br><br>GMP Inspection Report Date & Remarks | Previous DRB Decision / Remarks (if any) |
|---|---|---|---|---|---|
| 1237. | M/s Seraph Pharmaceutical, plot # 210, Industrial Triangle, Kahuta Road, Islamabad | Neovel Tablets 800mg<br><br>Each film coated tablet contains:<br>Sevelamer Carbonate……800mg<br><br>Phosphate binder<br><br>Innovator's specifications | Form-5D<br>Diary No. 1647 dated 11-01-2018,<br>Rs. 50,000/- dated 10-01-2018,<br>30's;<br>As recommended by PRC | Renvela 800mg Tablet of Sanofi Aventis, (USFDA approved)<br><br>The panel inspection dated 11-06-2018 unanimously recommended issuance of GMP Certificate. | |

| STABILITY STUDY DATA | |
|---|---|
| Drug | Neovel Tablets 800mg |
| Name of Manufacturer | M/s Seraph Pharmaceutical, plot # 210, Industrial Triangle, Kahuta Road, Islamabad |
| Manufacturer of API | M/s Suleshvari Pharma, Ankleshwar-393002, Gujarat, india |
| API Lot No. | 17/SVMC/029 |
| Description of Pack (Container closure system) | Alu/Alu Blister in unit carton |
| Stability Storage Condition | Accelerated: 40°C ± 2°C & 75±5%RH<br>Real Time: 30°C ± 2°C & 65±5%RH |
| Time Period | Accelerated: 26 (Weeks)<br>Real Time: 26 (Weeks |

| | | | |
|---|---|---|---|
| Frequency | Accelerated: 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (Weeks)<br>Real Time: 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (Weeks) | | |
| Batch No. | T001 | T002 | T003 |
| Batch Size | 800 Tablets | 800 Tablets | 800 Tablets |
| Manufacturing Date | 03-18 | 03-18 | 03-18 |
| Date of Initiation | 23-03-2018 | 27-03-2018 | 29-03-2018 |
| No. of Batches | 3 | | |
| Date of Submission | 31-10-2018 (Dy. No. 36103) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s Suleshvari Pharma, India has been 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. | The firm has submitted copy of GMP certificate of M/s Suleshvari Pharma, India (Certificate No. S-GMP/17021394) issued by Food & Drug Control Administration, Ghandhinagar, Gujarat State, India. |
| 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 (Invoice#SP/EXP-55/2017-18) for the import of Sevelamer Carbonate (3.00Kg) attested by ADC DRAP, Islamabad dated 08-03-2018. |
| 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 provided 26 Weeks Accelerated and 26 Weeks Real Time Stability Data for 03 Batches.

Report on investigation of genuineness / authenticity of data submitted for registration of NEOVEL Tablet 800mg (Sevelamer Carbonate 800mg) by M/s Seraph Pharmaceutical, Islamabad.

**Reference No:** F.13-11/2017-PEC (Pt) dated 14th December, 2018.
**Investigation Date:** 27th December, 2018.
**Investigation Site:** M/s Seraph Pharmaceutical Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad.

**Background:**

The Chairman Registration Board approved the following panel for on-site investigation to confirm genuineness / authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc.

**Composition of Panel:**

1. Dr. Hafsa Karam Elahi, Additional Director, QA&LT-I, DRAP Islamabad
2. Mr. Muhammad Tahir Waqas, Assistant Director (QA&LT), DRAP Islamabad
3. Mst. Haleema Sharif, Assistant Director (PEC), DRAP Islamabad

**Scope of investigation:**

Investigation to confirm genuineness / authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases

were also audited. The details of investigation may be summarized as under:

**Detail of Investigation:**

<table>
<tr><th>Q.#</th><th>Question</th><th>Observation by Panel</th></tr>
<tr><td>1.</td><td>Do you have documents confirming the import API including approval from DRAP?</td><td>Firm have copy of AD (I&E, Islamabad) attested commercial invoice for import of 3kg Sevelamer Carbonate, Batch No. 17/SVMC/029.</td></tr>
<tr><td>2.</td><td>What was the rationale behind selecting the particular manufacturer of API?</td><td>Firm informed that they have selected API’s supplier on the basis of GMP Certification, Vendor Prequalification (Desktop) and keeping in view the price advantage.</td></tr>
<tr><td>3.</td><td>Do you have documents confirming the import of API reference standard and impurity standards?</td><td>Phosphate binding capacity is evaluated using Potassium Phosphate which is purchased locally.<br>No impurities / degradation products have been found.</td></tr>
<tr><td>4.</td><td>Do you have certificate of Analysis of the API, reference standards and impurity standards?</td><td>Firm have Certificate of Analysis of the API (Batch No. 17/SVMC/029).</td></tr>
<tr><td>5.</td><td>Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?</td><td>Firm have copy of GMP certificate No. S-GMP 17021394 of M/s Suleshvari Pharma, India issued by Food and Drug Control Administration, Gujrat, India.</td></tr>
<tr><td>6.</td><td>Do you use API manufacturer method of testing for testing API?</td><td>Firm have used API manufacturer method of testing for testing API (Sevelamer Carbonate).</td></tr>
<tr><td>7.</td><td>Do you have stability studies reports on API?</td><td>Firm have shown copy of 12 Months (Accelerated) and 48 Months (Real Time) Stability Study Reports on 03 Batches of API (Sevelamer Carbonate) conducted by the API Manufacturer (M/s Suleshvari Pharma, India).</td></tr>
<tr><td>8.</td><td>If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?</td><td>Firm claims that no impurities / degradation products are present hence impurity profiling was not performed.</td></tr>
<tr><td>9.</td><td>Do you have method for quantifying the impurities in the API?</td><td>Firm claims that no impurities / degradation products are present hence impurity profiling was not performed.</td></tr>
<tr><td>10.</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>Firm have 0.953 gm of the API (Sevelamer Carbonate) remaining.</td></tr>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>Firm have used pharmaceutical grade excipients:<ul><li>Hydrogenated Vegetable Oil</li><li>Microcrystalline Cellulose</li></ul></td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>Firm have shown documents confirming the import of the used excipients.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>Firm have test reports and other records on the excipients used.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of applied product?</td><td>Firm have shown a generalized protocol for the development of new products.<br>Firm was advised to adopt SOP for Product Specific New Product Development Protocol.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>Various combinations of Drug–excipient mixture were prepared and analyzed by keeping at accelerated conditions by the firm. The results were found satisfactory.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>Firm have performed comparative studies (Disintegration and Swelling Test) of their product with SELCARB Tablet 800mg of M.s Genome Pharma. Details are as follows:
<table>
<tr><th>Details</th><th>Test Product</th><th>Reference Product</th></tr>
<tr><td>Brand</td><td>NEOVEL</td><td>SELCARB</td></tr>
<tr><td>Batch No.</td><td>T001</td><td>001</td></tr>
<tr><td>Mfg. Date</td><td>3/2018</td><td>5/2018</td></tr>
</table>
Test product showed comparable results with the reference product.</td></tr>
</table>

| | | |
|---|---|---|
| 17. | Do you have product development (R&D) section? | Firm have product development (R&D) section. |
| 18. | Do you have necessary equipment available in product development section for development of applied product? | Firm have necessary equipment available in product development section for development of applied product. However compression was done in Production area using ZP-17 compression machine. |
| 19. | Are the equipment in product development section qualified? | The equipment in product development section were qualified. |
| 20. | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | Firm have proper maintenance / calibration / re-qualification program for the equipment used in PD section. |
| 21. | Do you have qualified staff in product development section with proper knowledge and training in product development? | RND Manager (Pharmacist, 08 years exp.) is involved in Product Development (RND). |
| 22. | Have you manufactured three stability batches for the stability studies of applied product as required? | Three (03) stability batches have been manufactured in 03-2018 for the stability studies of applied product having batch size of 800 tablets each. |
| 23. | Do you have any criteria for fixing the batch size of stability batches? | Keeping in view the DRAP's criteria, guidelines and no. of units required for test / analysis the firm had developed a criteria for fixing batch size of stability batches. |
| 24. | Do you have complete record of production of stability batches? | Firm have shown record of production of stability batches. |
| 25. | Do you have protocols for stability testing of stability batches? | Firm have detailed protocols for stability testing of stability batches. |
| 26. | Do you have developed and validated the method for testing of stability batches? | Firm have developed and validated the method for testing of stability batches. |
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | Not applicable. |
| 28. | Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug? | Firm have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug. |
| 29. | Is your method of analysis stability indicating? | No impurities / degradation products have been found. |
| 30. | Is your HPLC software 21CFR Compliant? | No. The analysis was performed using UV-1601 Spectrophotometer (Schimadzu, BIOSPEC). |
| 31. | Can you show Audit trail reports on stability study testing? | The log book of UV-1601 Spectrophotometer (Schimadzu, BIOSPEC) was checked and submitted documents were cross verified. |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | No degradation products.<br>Stability batches are kept on Real Time Stability Testing. |
| 33. | Do you have stability batches kept on stability testing? | Firm have stability batches kept on Real Time Stability Testing. |
| 34. | Do you have valid calibration status for the equipment used in production and analysis? | Firm have valid calibration status for the equipment used in production and analysis. |
| 35. | Do proper and continuous monitoring and control are available for stability chamber? | Adequate monitoring and control are available for stability chambers (China Chong Qing Chuang, CSH-2225D-C) with built-in Digital Data Loggers.<br>Power backup has been ensured with UPS & 150kV Generator. |
| 36. | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | Related manufacturing area, equipment, personnel and utilities are as per cGMP compliance. |

| |
|---|
| **CONCLUSION:**<br>On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of NEOVEL Tablet 800mg (Sevelamer Carbonate 800mg) is verifiable to satisfactory level. |
| **Decision: Deferred for following: (M-287)**<br>Justification of applying UV Spectrophotometric method for Assay analysis of applied formulation instead of HPLC method.<br>In vitro bio equivalence equilibrium binding studies and Equilibrium kinetic studies for the applied product.<br>**Evaluation by PEC:** The firm has submitted that<br>"As the vendor of raw material of sevelamer carbonate "Suleshvari, India" is using the UV method for the analysis of sevelamer carbonate, so we also used the vendor's UV method for analysis of raw material and product. Moreover, we validated the testing method, which showed that the UV method is suitable for analysis of product.<br>In-vitro kinetic binding study and equilibrium binding study of the drug product was performed as per FDA guidelines and results were compared with the competitor's brand "Selcarb 800mg Tablet".<br>The firm has submitted details of validation of analytical method. |
| **Decision: Registration Board decided to approve registration of "Neovel 800 mg Tablets" by M/s Seraph Pharmaceuticals (Pvt) Ltd., Plot #210, Industrial triangle kahuta road Islamabad. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.** |

## c. Onsite Verification of stability study data

**Evaluator PEC-II**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1238 | M/s PharmEvo Pvt Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi. | Teragis 100mg tablet<br>Each film coated tablet contains:-<br>Trelagliptin……100mg<br>(Anti-diabetic) | Form 5-D<br>Diary No. 438 dated 28-03-2016<br>Rs. 50,000/-<br>14's,<br>As per PRC | Zafatek Tablets approved by PMDA of Japan |
| | **Evaluation by PEC:**<br>The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board. Moreover firm has stated that they are submitting following actual technical data of the product along with the stability data, as the previously submitted data in the dossier was tentative data:<br>Details of submitted data are as under:<br>(Dy.# 2700 (PEC) dated 17-09-2018) | | | |

| **STABILITY STUDY DATA** | |
|---|---|
| Drug | Teragis 100mg tablet |
| Name of Manufacturer | M/s PharmEvo Pvt Ltd, A-29, North West Industrial Zone, Light Industrial Zone, Port Qasim, Karachi. |
| Manufacturer of API | Trelagliptin: M/s Ruyuan HEC Pharm, Guangdong province, China |
| API Lot No. | TGLT-201704002 |
| Description of Pack (Container closure system) | Alu –Alu foil in unit carton |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 75% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH |
| Time Period | Real time: 6 months<br>Accelerated: 6 months |
| Frequency | Accelerated: 0,3,6 month<br>Real Time: 0,3,6 month |

| | | | |
|---|---|---|---|
| Batch No. | 18PD-2202-02-T | 18PD-2203-03-T | 18PD-2204-04-T |
| Batch Size | 2500 tablets | 1000 tablets | 1000 tablets |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | 19-02-2018 | 19-02-2018 | 19-02-2018 |
| No. of Batches | 03 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COAS of API | Yes. |
| 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. | Copy of GMP certificate issued by issued by State office for Health and Social Affairs Berlin, valid upto 19-05-2019, in the name of M/s Ruyuan HEC Pharm Co., Ltd., Xiaba Development Zone, 512721 Shaoguan City, Ruyuan County, Guangdong Province, China.<br>The said certificate has been verified form following web-link of Eudra GMP as accessed on 21-12-2018:<br>http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=35719<br>Moreover Firm has submitted a declaration from M/s Ruyuan HEC Pharm Co., Ltd stating as under:<br>"We have submitted the application to Guangdong Province FDA for GMP inspection. Once the inspection is approved, we will provide the revised provincial GMP immediately." |
| 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. | Copy of ADC attested invoice has been submitted. |
| 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 |

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Teragis (Trelagliptin) 100mg Tablets by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.**

**Reference No:** F.13-11/2017-PEC (Pt) dated 26th December, 2018.
**Investigation Date and Time:** 7th February, 2019. (Afternoon)
**Investigation Site:** Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.
**Background:**
Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi for registration of Teragis (Trelagliptin) 100mg & 5mg Tablets and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

**Composition of Panel:**

1. Dr. Rafeeq Alam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi. (Member Registration Board)
2. Dr. Asfandyar Ajab Khan, Assistant Director, CDL, DRAP, Karachi.
3. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

**Details of Investigation:**

**Teragis (Trelagliptin) Tablets 100mg**

| Q. No. | Question | Observation by panel |
|---|---|---|
| 1. | Do you have documents confirming the of Trelagliptin API including approval from DRAP? | The firm has imported Trelagliptin 1.5Kg vide Invoice No. WIS170027 dated 19/04/2017 from M/S WIS Pharmtech Co. Ltd. Manufactured by M/s Ruyuan HEC Pharm Co. Ltd. for the manufacturing of lab scale batches of TERAGIS 100mg Tablets. The firm has proper approval for the import of the API from DRAP, Karachi. |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Vendor Evaluation procedure which include the GMP status of the firm, DMF source and capability to provide API reference standard and impurity standard. |
| 3. | Do you have documents confirming the import of Trelagliptin, reference standard and impurity standards? | Firm has documents confirming the import of Trelagliptin, The APIs working standard was imported at the time of import of the APIs whereas the manufacturer has provided the both impurity standards later free of cost. |
| 4. | Do you have certificate of Analysis of the API, reference standards and impurity standards? | The firm has certificates of analysis for API, Working standards of the API and impurities standards. |
| 5. | Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin? | Firm has GMP certificate issued by the Shaoguan Food and Drug Administration, China |
| 6. | Do you use API manufacturer method of testing for testing API? | The firm has used API manufacturer method for testing the API. |
| 7. | Do you have stability studies reports on API? | The firm has stability studies reports on API. |
| 8. | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | The stability testing has been performed as per SIM method and however no degradation products are reported by the manufacturer. However process related impurities have been quantified during stability studies. |
| 9. | Do you have method for quantifying the impurities in the API? | The firm has API manufacturer method for quantifying the impurities in the API. |
| 10. | Do you have some remaining quantities of the API, its reference standard and impurities standards? | Firm has some quantities of the API and working standard, however they have consumed all the impurity standards. |

| | | |
|---|---|---|
| 11. | Have you used pharmaceutical grade excipients? | The firm has used pharmaceutical grade excipients and include microcrystalline cellulose PH.101, Mannitol, Hydroxypropyl Cellulose, Cross Carmellose Sodium, Sodium Stearyl Fumerate and Opadry white and iron oxide red has been used for coating. |
| 12. | Do you have documents confirming the import of the used excipients? | The firm has necessary documents confirming the import of the used excipients. |
| 13. | Do you have test reports and other records on the excipients used? | The firm has test reports and other records on the excipients used. |
| 14. | Do you have written and authorized protocols for the development of TERAGIS 100mg Tablets? | The firm has written and authorized protocols for the development of TERAGIS 100mg Tablets. |
| 15. | Have you performed Drug-excipient compatibility studies? | The firm has not performed Drug-excipient compatibility studies as the composition of their tablets is similar to that of the innovator product (Zafatek Tablets). |
| 16. | Have you performed comparative dissolution studies? | The firm has not performed comparative dissolution profile because they are unable to get pack from Japan without Japanese prescription which is only available in Japan, however the data available with the firm shows that the product is highly soluble and dissolves more than 85% within 15minutes in all three media. Therefore, f2 calculation are not required. |
| 17. | Do you have product development (R&D) section? | The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities. |
| 18. | Do you have necessary equipment available in product development section for development of Teragis 100mg & 5mg Tablets? | The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Teragis 100mg Tablets. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose. |
| 19. | Are the equipment in product development section qualified? | All the equipment used in product development are qualified. |
| 20. | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | The firm has proper maintenance / calibration programme. Re-qualification program for the equipment used in PD section. |
| 21. | Do you have qualified staff in product development section with proper knowledge and training in product development? | The firm has 06 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product. 03 QC Analysts are dedicated for New |
| 22. | Have you manufactured three stability batches for the stability studies of Teragis 5 mg Tablets as required? | The firm has manufactured three stability batches for the stability studies of:<br>Teragis 100mg Tablets with Batch Numbers:<br>18PD-2202-02-T, 18PD-2203-03-T & 18PD-2204-04- |
| 23. | Do you have any criteria for fixing the batch size of stability batches? | The criteria for fixing batch size is number of tablets required per testing and number of testing frequencies. |
| 24. | Do you have complete record of production of stability batches? | The firm has complete record of production of stability batches. |
| 25. | Do you have protocols for stability testing of stability batches? | The firm has detailed protocols for stability testing of stability batches |
| 26. | Do you have developed and validated the method for testing of stability batches? | The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation. |

| | | |
|---|---|---|
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other | Method transfer studies have not been done, however, validation of the method has been performed. |
| 28. | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Trelagliptin and the finished drug? | The firm has documents confirming the installation and operational qualification of the equipment / instruments being used in the test and analysis of Trelagliptin and the finished drug. |
| 29. | Do your method of analysis stability indicating? | The firm's method of testing is stability indicating as supported by forced degradation. |
| 30. | Do your HPLC software 21CFR Compliant? | The HPLC software is 21CFR Compliant as per record available with the firm. |
| 31. | Can you show Audit trail reports on Trelagliptin testing? | Audit trail on the testing reports are available. |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of the stability batches. |
| 33. | Do you have stability batches kept on stability testing? | The firm has kept all the three batches on real time and accelerated stability testing. Currently, 9 months studies have been completed with satisfactory |
| 34. | Do you have valid calibration status for the Equipment used in Teragis100mg & 5mg tablets production and analysis? | The firm has valid calibration status for the equipment used in Teragis tablets production and analysis. |
| 35. | Do proper and continuous monitoring and control are available for stability chamber? | The firm has 14 stability chambers, 02 for accelerated and 12 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring. The data of data loggers is reviewed every 15th day. |
| 36. | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant. |

**Conclusions:**

On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Teragis (Trelagliptin) 100mg Tablets is verifiable to satisfactory level.

1. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Teragis 100mg Tablets.

Recommendations:

**1.** The firm may kindly be granted necessary registration of Teragis 100mg tablets.

**Decision: Registration Board decided to approve registration of "Teragis 100mg tablets" by M/s Pharm evo Pharmaceuticals (Pvt) Ltd., Karachi. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1239. | M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28 km | Ledinil Tablet<br>Each film coated tablet contains:- | Form 5<br>Diary No. 1928<br>dated 20-04-2014 | Approved by USFDA |

| | | | | |
|---|---|---|---|---|
| | Ferozepur Road, Lahore. | Sofosbuvir…400mg<br>Ledipasvir……90mg<br>(Anti-viral) | Rs. 50,000/-<br>14's,<br>Rs.630,000/-<br>28's Rs.11,97,000/- | |
| | **Previous Decision:**<br>The case was presented in 260th meeting of Registration Board wherein Board deferred for rectification of mentioned deficiencies and submission of stability data. | | | |
| | **Evaluation by PEC:**<br>Now the firm has submitted stability data along with documents as per checklist approved in 276th meeting of Registration Board for exemption from "On site investigation of submitted stability data". Detailsof submitted data are as under:<br>(Dy.# 31647 dated 19-09-2018) | | | |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Ledinil Tablet | | |
| Name of Manufacturer | M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28 km Ferozepur Road, Lahore. | | |
| Manufacturer of API | Sofosbuvir: M/s Nantong Chanyoo Pharmatech Co., Ltd. Jiangsu Province, China.<br>Ledipasvir Co povidone: M/s Changzhou Pharmaceutical Factory, Jiangsu province China. | | |
| API Lot No. | Sofosbuvir: RD-RD-SFB-201706021<br>Ledipasvir Copovidone: 201705001 | | |
| Description of Pack (Container closure system) | Plastic jar | | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 65% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| Time Period | Real time: 6 months | Accelerated: 6 months | |
| Frequency | Accelerated: 0,1,3,6 month<br>Real Time: 0,3,6 month | | |
| Batch No. | TP/078-T1/S1 | TP/078-T1/S3 | TP/078-T1/S4 |
| Batch Size | 1000 tablets | 1000 tablets | 1000 tablets |
| Manufacturing Date | 02-10-2017 | 03-10-2017 | 04-10-2017 |
| Date of Initiation | 03-10-2017 | 04-10-2017 | 05-10-2017 |
| No. of Batches | 03 | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr. No.** | **Documents To Be Provided** | **Status** |
| 1. | COAS of API | Yes. |
| 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. | Copy of License for Drug Production (License # S.20160512) issued to M/s Nantong Chanyoo Pharmatech Co., Ltd. Jiangsu Province, China. |
| 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. | Copies of ADC attested invoices have been submitted. |
| 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 |
| **Details of data submitted for exemption form On-site investigation** | | |
| **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 "Sofonil 400mg (Sofosbuvir) Tablets", which was conducted on 06th March, 2017 and was presented in 268th meeting of Registration board held on 20-21st March, 2017. Registration Board decided to approve registration of Sofonil Tablets (Sofosbuvir 400mg) by M/s. NovaMed Pharmaceutical (Pvt.) Ltd., Lahore.<br>Following observation regarding HPLC system was recorded in report:<br>• The HPLC software is 21CFR compliant as per record available with the firm<br>• Audit trail on the testing reports were shown to the panel during inspection. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | Firm has submitted following:<br>• Copy of commercial invoice (No. CYI17214) for Sofosbuvir (Batch #RD-SFB-201705281 & RD-SFB-201706021), attested by AD (I&E), DRAP Lahore on 29-06-2017.<br>• Copy of commercial invoice (No. CYI17160) for Ledipasvir copovidone (Batch #201705001), attested by AD (I&E), DRAP Lahore on 31-07-2017. |
| 3. | Documents for the procurement of reference standard and impurity standards. | Firm has submitted DHL receipts of date 10-07-2017, with contents mentioned as "Ledipasvir/Velpatasvir sample for lab testing purpose & weight of shipment as 1Kg. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Firm has submitted following:<br>i. Copy of License for Drug Production (License # S.20160512) issued to M/s Nantong Chanyoo Pharmatech Co., Ltd. Jiangsu Province, China.<br>ii. Copy of GMP certificate (certificate# JS20180818) valid upto 09/07/2023 issued by Jiangsu Food & Drug Drug Administration, has been submitted. |
| 5. | Mechanism for Vendor pre-qualification | Firm has submitted following:<br>i. SOP for Vendor Evaluation (Document#. QC/Gen/080/073) |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | Firm has submitted following:<br>i. COA of Sofosbuvir (Batch. # RD-RD-SFB-201706021) from M/s Nantong Chanyoo Pharmatech.<br>ii. COA of working standard for Sofosbuvir (Batch. # WSFB39-170401) from M/s Nantong Chanyoo Pharmatech.<br>iii. COAs of Impurity standards mentioned in COA of Sofosbuvir.<br>iv. COA of Ledipasvir Copovidone (Batch #. 201705001) from M/s Changzhou Pharmaceutical Factory, Jiangsu province China.<br>v. COA of Ledipasvir working standard (batch #. WRS201601001) from M/s Changzhou Pharmaceutical Factory, Jiangsu province China.<br>vi. COAs of Impurity standards mentioned in COA of Ledipasvir Co povidone |
| 7. | Documents for the procurement of excipients used in product development? | Firm has submitted commercial invoices for all the excipients used in the applied formulation, details of which are as under: |

<table>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted R&D staff list comprising of 7 members.</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>Firm has submitted following:<br>i. Copy of SOP for Ledinil tablet Development (Document#. R&D/Doc/06/TP-78 effective date 18-10-2017<br>ii. Stability study protocol for Ledinil tablet (R7D/Doc/18/TP/078) approved on 25-09-2017.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has Batch Manufacturing Record, including Pre-, Dispensing sheets, Master formulation & Standard Manufacturing procedure, for all the three batches of Ledinil tablet i.e.
<table>
<tr><th>Sr.#</th><th>Batch No.</th><th>Mfg. Date</th></tr>
<tr><td>1</td><td>TP/078-T1/S1</td><td>02-10-2017</td></tr>
<tr><td>2</td><td>TP/078-T1/S2</td><td>03-10-2017</td></tr>
<tr><td>3</td><td>TP/078-T1/S3</td><td>04-10-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted reconciliation sheet for use of Ledinil tablets for all the three stability batches.</td></tr>
<tr><td colspan="3">QA/QC DATA</td></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 following:<br>i. Manually filled sheets for temperature & humidity record of Accelerated & Real time conditions for the time period of 25-09-2017 to 28-09-2018.<br>ii. Moreover Firm has referred to Inspection report dated 22-01-208, by the Area FID, for the “Verification of data logging system of Stability Chamber” with following declaration:<br>• The scope/ ranges of the Stability Chambers was as under:<br>i. 25°C & 60% RH<br>ii. 30°C & 65% RH<br>iii. 40°C & 75% RH<br>• Temperature & Humidity record of the chambers was available at the time of inspection and was being recorded twice a day.<br>• The firm also had provided automatic electric supply by the Generator & USP system as back-up arrangement, along with continuous alarm system for monitoring.<br>• Both stability chambers were calibrated, their performance qualification was also being performed.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>• Firm has submitted Method of analysis & COA for Sofosbuvir & Ledipasvir copovidone from M/s Nantong Chanyoo Pharmatech Co., Ltd. & M/s Changzhou Pharmaceutical Factory, Jiangsu province China respectively.</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>Firm has submitted following for both accelerated & real time stability studies of all three stability batches:<br>i. Method of analysis. (Document #. QC/FP/006/N-108) with effective date of 08-10-2017.<br>ii. Lab reports<br>iii. Raw data sheets<br>iv. HPLC Chromatograms (for Assay analysis & Dissolution analysis)</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>• Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (25°C ± 2°C & 60±5%RH) stability studies reports of three batches of Sofosbuvir of 6 months from M/s Nantong Chanyoo Pharmatech Co., Ltd.<br>• Firm has submitted both accelerated 6 months (40°C ± 2°C & 75±5%RH) stability studies & long term 12 months (25°C ± 2°C & 60±5%RH) stability studies reports of three batches of</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Ledipasvir copovidone from M/s Changzhou Pharmaceutical Factory, Jiangsu province China.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>Firm has submitted analysis reports for all the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>Firm has stated that since formulation of Dasvir tablet is same as per Innovator Harvoni tablet so no need for drug excipient compatibility.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative dissolution study protocol & results. The details of reference product & Sample product are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of Novamed</th></tr>
<tr><td>Brand name</td><td>Synget-LS 400/90mg of M/s Getz Pharma</td><td>Ledinil tablets</td></tr>
<tr><td>Batch No.</td><td>010F90</td><td>TP/78-T1/S1</td></tr>
<tr><td>Mfg. date</td><td>09-2017</td><td>10-2017</td></tr>
<tr><td>Expiry date</td><td>09-2019</td><td>--</td></tr>
</table>
• Comparative study dissolution study has been performed in following mediums:<br>i. pH 1.2 HCl buffer with similarity factor of 86<br>ii. pH 4.5 Acetate buffer with similarity factor of 52<br>iii. pH 6.8 Phosphate buffer with similarity factor of 51</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for HPLC analysis of both stability studies.</td></tr>
<tr><td colspan="3">Previous Decision: Registration Board in its 285th meeting decided to defer the case for confirmation of data logging of stability chambers for applied product i.e. Ledinil Tablets, by Area FID.</td></tr>
<tr><td colspan="3">Evaluation by PEC: Now the Inspection report has been received from Mr. Shoaib Ahmed (FID lahore) vide letter No. 1456/2019-DRAP (L-V) dated 25-01-2019. The inspection was conducted on 22-01-2019 for the Verification of data of Stability Chamber. The observations & conclusion of inspection are as under:<br>Observations:<br>• The scope/ ranges of the Stability Chambers was as under:<br>i. 30°C & 65% RH<br>ii. 40°C & 75% RH<br>• Temperature & Humidity record of the chambers was available at the time of inspection and was being recorded twice a day.<br>• The firm also had provided automatic electric supply by the Generator & USP system as back-up arrangement, along with continuous alarm system for monitoring.<br>• Both stability chambers were calibrated, their performance qualification was also being performed.<br>Conclusion:<br>Keeping in view of above, the genuineness / authenticity of stability data submitted by the firm for registration of Ledinil tablets has been verified.<br>The case is submitted for consideration of Registration Board</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “Ledinil tablets” by M/s Novamed Pharmaceuticals., Lahore. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
</table>

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1240. | M/s Global Pharmaceuticals (Pvt.) Ltd.<br><br>Plot # 204-205, Industrial Triangle Kahuta Road.<br><br>Islamabad. | CORDIN Gel 4%<br><br>Each gram contains:-<br><br>Chlorhexidine Gluconate 7.1% eq. to Chlorhexidine…4%w/w<br><br>(Bisbiguanide Disinfectant)<br>BP Specs. | Form 5<br><br>Dairy No. 17440 dated 09-10-2017<br><br>Rs.50,000/-<br><br>As per DRAP Policy. | Not available in reference SRAs, However available in WHO Model List of Essential Medicines for Children and Nepal, Nigeria.<br><br>GMP compliant dated 12-07-2017. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | CORDIN Gel 4% (Chlorhexidine Gluconate) | | |
| Name of Manufacturer | M/s Global Pharmaceuticals (Pvt.) Ltd. Islamabad. | | |
| Manufacturer of API | M/s Unilab Chemicals & Pharmaceuticals (Pvt.) Ltd. India | | |
| API Lot No. | F/006/16 | | |
| Description of Pack (Container closure system) | Aluminum Tubes | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 26 Weeks<br>Real Time: 26 Weeks | | |
| Frequency | Accelerated: 0,6,8,12,16,20,24,26 (Weeks)<br>Real Time: 0,6,8,12,16,20,24,26 (Weeks) | | |
| Batch No. | T-006(Q) | T-007(Q) | T-008(Q) |
| Batch Size | 100 Tubes | 100 Tubes | 100 Tubes |
| Manufacturing Date | 02-2017 | 02-2017 | 02-2017 |
| Date of Initiation | 23-03-2017 | 23-03-2017 | 23-03-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 09-10-2017 (Dy. No. 17440) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | Copy of Certificate of a Pharmaceutical Product **(Chlorhexidine Gluconate Solution BP)** marked YES at 3.3, issued by Food and Drug Administration (Maharashtra) India is submitted. Importing Country is mentioned 'As per Annexure'; **however the annexure is not enclosed.** |

| | | |
|---|---|---|
| 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. | Copy of ADC (Islamabad) attested Commercial Invoice is submitted. |
| 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[1]**

- The firm has provided 26 Weeks Accelerated and 26 Weeks Real Time Stability Data for 03 Lab Scale Batches.
- Copy of Certificate of a Pharmaceutical Product **(Chlorhexidine Gluconate Solution BP)** marked YES at 3.3, issued by Food and Drug Administration (Maharashtra) India is submitted. Importing Country is mentioned 'As per Annexure'; **however the annexure is not enclosed.**

The Registration Board was apprised that the firm has submitted copy of GMP certificate No. 6077690 issued by FDA, Maharashtra, India for M/s Unilab Chemicals & Pharmaceuticals (Pvt.) Ltd. India.

Decision: Registration Board deliberated that it has been decided that onsite inspection for verification of data will be exempted as decided in instant meeting. Thus the Board decided as follows:
Onsite inspectionby following panel to confirm genuineness/ authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc.
- Additional Director (E&M), DRAP Islamabad
- Director DTL Rawalpindi
- Area FID, DRAP, Islamanbad

OR
Firm can submit requisite documents as decided in instant meeting in Case No. 02 (On site investigation of submitted data).

**Report on Inspection of Authenticity / Genuineness of data submitted for registration of Cordin gel (Chlorhexidine) 4 % by M/s. Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad.**

**Inspection Date and Time:** 09th & 10th January, 2019 (Afternoon)
**Inspection Site: M/s. Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad.**

**Background:**
**M/s. Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad** applied for registration of **Cordin gel (Chlorhxidine) 4 % with following composition:**

**CORDIN Gel 4%**
**Each gram contains:-**
**Chlorhexidine Gluconate 7.1% eq. to Chlorhexidine…4%w/w**
Chairman Registration Board constituted a three member panel for on-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents, import of API, quality, specification, test analysis, facilities etc. Panel was requested to conduct inspection of the firm to verify the submitted data by the firm and to submit a report on approved format for further consideration of case by the Registration Board.

**Composition of Panel:**
1. Additional Director, QA & LT, DRAP, Islamabad.
2. Area FID, Islamabad.
3. Mr. Arsalan Tariq, Assistant Director, QA & LT, DRAP, Islamabad.

**Scope of Inspection:**
On-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents, import of API, quality, specification, test analysis, facilities

**Tools for Inspection:**
The Inspection was conducted by using a structured questionnaire approved by DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of inspection is summarized as under:

**Detail of Inspection:**

| Q. No. | Question | Observation by panel |
|---|---|---|
| 1. | Do you have documents confirming the import of API including approval from DRAP? | **Chlorhexidine Gluconate Solution BP**<br>Invoice Number: **E-008/2016-17**<br>ADC attestation date: **11.05.2016**<br>Exporter: M/s Unilab Chemicals and Pharmaceuticals Pvt Ltd W-32, M.I.D.C. Phase-II Dombivli (East) District: Thane<br>Manufacturer: as above<br>Batch No. F-006/16<br>Mfg. Date: Jan, 2016<br>Exp. Date: Dec,2018<br>Quantity: 5kg |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | The firm has submitted that manufacturer of API was selected on the basis of Valid GMP, Client List of API manufacture contains International and Local clientele, Stability Data (Accelerated and Real Time).<br>The selection of vendor was discussed in detail in the light of GMP guidelines and firm was advised to devise an S.O.P for the purpose. There should be a detailed report/study for such prequalification studies. |
| 3. | Do you have documents confirming the import of Chlorhexidine Gluconate Solution BP reference standard and impurity standards? | The firm imported following reference and impurity standards:<br>✓ Chlorhexidine Gluconate Solution Working Standard from the Source/Manufacturer (Batch No. WS/006/16; WS/001/17; WS/003/18).<br>✓ Firm has also imported *CRS* containing impurities A, B, F, G, H, I, J, K, L, N and O for identification/quantification of specified impurities from Cavax Entrprises vide purchase order no. NIL and Delivery Challan No. GP/611 dated 28-08-2017.<br>✓ For specified impurity P the firm imported reagent grade Chloroaniline R from Sigma-Adrich vide invoice no. Inv. 3240 dated 28.01.2016.<br>Remarks:<br>✓ Firm did not imported BP reference standard of API.<br>✓ The CRS is imported after date of manufacturing of Trial Batches i.e. 14-02-2017 as per BMR submitted. |
| 4. | Do you have certificate of Analysis of the API, reference standards and impurity standards? | The firm has submitted COAs of following drugs (APIs)/materials of source as mentioned below:<br>**Chlorhexidine Gluconate Solution BP**<br>✓ Chlorhexidine Gluconate Solution BP Working Standard<br>✓ Reagent Grade for Impurity P (Ph. Eur.)<br>✓ *CRS* containing impurities A, B, F, G, H, I, J, K, L, N and O |

| | | |
|---|---|---|
| 5. | Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin? | **Chlorhexidine Gluconate Solution BP**<br>The firm has submitted copy of GMP certificate in the name of Manufacturer that is "M/s Unilab Chemicals and Pharmaceuticals Pvt Ltd (705082) W-32, M.I.D.C. Phase-II Dombivali Manpada - 421204 District: Thane (Zone6)" of **Chlorhexidine Gluconate Solution BP** by the Certifying Authority of "Food & Drugs Administration (Maharashta State), India."<br>Validity: 24-08-2015 to 23-08-2016<br>**Remarks:**<br>✓ The GMP certificate mentions that this certificate is issued for purpose of RAJASTHAN MEDICAL SERVICES CORPORATION LTD., JAIPUR, RAJASTHAN (GOVERNMENT TENDER PURPOSE). |
| 6. | Do you use API manufacturer method of testing for testing API? | The firm stated that they have used pharmacopoeial (B.P.) method for testing of API. |
| 7. | Do you have stability studies reports on API? | Firm has submitted data of long term stability studies of three batches F/010/09 (Mfg: Jan, 2009), F/014/09 (Mfg: Jan, 2009) & F/015/09 (Mfg: Jan, 2009) up to 48 months and accelerated data up to 7 months conducted by the API manufacturer M/s Unilab Chemicals and Pharmaceuticals Pvt Ltd (705082) W-32, M.I.D.C. Phase-II Dombivali Manpada - 421204 District: Thane (Zone6) under conditions of Zone-IV A that is 30 $C^o$ $\pm$ 2 $C^o$ & 65 % RH $\pm$ 5 % and 40 $C^o$ $\pm$ 2 $C^o$ & 75 % RH $\pm$ 5 % for API namely Chlorhexidine Gluconate Solution BP. The data submitted by the API manufacturers lies within the limits for the Assay & pH.<br>**Remarks:**<br>✓ The firm acquired old stability data from the API manufacturer instead of latest. |
| 8. | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | The firm has submitted the stability testing studies showing no capability of calculating API quantitatively in a precise manner free from impurities, excipients and degradation products (as per definition of SIM). No degradation products have been quantified. The applicant relies on data of manufacturer.<br>However, upon enquiring said observation, the firm submitted an open part of Drug Master File (DMF) received from the source i.e. M/s Unilab Chemicals and Pharmaceuticals Pvt Ltd (705082) W-32, M.I.D.C. Phase-II Dombivali Manpada – 421204 verifying stability conducted on SIM method. |
| 9. | Do you have method for quantifying the impurities in the API? | The firm stated that they have used Pharmacopoeial (B.P.) method for quantifying the impurities in the API. |
| 10. | Do you have some remaining quantities of the API, its reference standard and impurities standards? | The firm has submitted remaining quantities of the API, reference standard and impurities standards as per details below: |

| | | |
|---|---|---|
| | | **Consumption Summary**<br>**Raw Materials & Working Standards**<br>(see table below) |

| S# | Entity Name | Batch No. | Received amount | Consumption Details | Consumed amount | Remaining amount (approx.) |
|---|---|---|---|---|---|---|
| 1 | Chlorhexidine Gluconate solution | F/006/16 | 5 kg | Raw material Testing | 100 ml Or 106 g | 4894 gm |
| | | | | Pre formulation Trial T-040 | 171.3 ml Or 181.6 g | 4712.4 gm |
| | | | | Pre formulation Trial T-041 | 171.3 ml Or 181.6 g | 4530.8 gm |
| | | | | Pre formulation Trial T-004 | 17.13ml Or 18.16 g | 4512.64 |
| | | | | Three Stability Batches T-006, T-007, T -008 | 514ml Or 544.73 g | 3967.9 gm |
| 2 | Chlorhexidine acetate (Working. Standard ) | WS/006/16 | 10 g | • Raw material Testing | 0.120 grams | 9.88 gram |
| 3 | Chlorhexidine acetate (Working. Standard ) | WS/001/17 | 5 g | • Stability Batches | 1.2 grams | 3.80 gram |
| 4 | Chlorhexidine acetate (Working. Standard ) | WS/003/18 | 5 g | • Stability Batches | 0.072 grams (approx.) | 4.928 gram |
| 5 | Chlorhexidine Impurities ABFGHIJKLN & O | Y0001545 | 10 mg | Related substances | 10 mg | Nill |

| | | |
|---|---|---|
| 11. | Have you used pharmaceutical grade excipients? | The firm has used pharmaceutical grade excipients as indicated from the COAs submitted by firm. |
| 12. | Do you have documents confirming the import of the used excipients? | The firm purchased the excipients used in the applied formulation from local suppliers as per details below: |

| S# | Item name | B# | Local Supplier | Import from | Release Date from QC |
|---|---|---|---|---|---|
| 1 | Guar Gum | A01/2016100 | Scientific Trader | GUANGRAO LIUHE CHEMICAL CO., LTD. | 22/07/2016 |
| 2 | Sodium Acetate | EADK31 | Chief scientific Agency | DUKSAN PURE CHEMICALS CO., LTD | 19/02/17 |

| | | |
|---|---|---|
| 13. | Do you have test reports and other records on the excipients used? | The firm has performed tests on above mentioned excipients and hence has test reports and other records on the excipients used. |
| 14. | Do you have written and authorized protocols for the development of Cordin Gel 4% (**Chlorhexidine Gluconate Solution BP**)? | The firm has written and authorized protocols for the development of Cordin Gel 4% (**Chlorhexidine Gluconate Solution BP**). But submitted documented was not in accordance with ICH Q-8 which pertains to Pharmaceutical Development. The firm was advised to improve the submitted protocol in the light of said document. |
| 15. | Have you performed Drug-excipients compatibility studies? | The firm has not performed Drug-Excipients compatibility studies as their formulation (API & Excipients) is similar/comparable to that of the Umbipro Gel by GSK approved by EMA. |
| 16. | Have you performed comparative dissolution studies? | The product is Pharamcopoeial (B.P.) wherein dissolution is not a parameter to be measured as product quality specifications. The firm submitted an evidence of WHO multisource (generic) development guidelines justifying not performance of the comparative dissolution as the dosage form of applied drug is aqueous Gel. However, they have performed quality comparison with already approved similar formulation namely Sepidyl Gel of M/s Aspin Pharma (pvt) Ltd. Karachi by DRAP for physical identification and pH and assay testing. |
| 17. | Do you have product development (R&D) | The firm possesses an approved Research & Development (R&D) and Validation Department for product development studies. |

| | | |
|---|---|---|
| | section | |
| 18. | Do you have necessary equipment available in product development section for development of Cordin Gel? | The firm has following necessary equipment in R & D section though for the development of Cordin Gel. |

**Research & Development**

| Machine /Equipment Name | Machine ID # | Model/Make | Capacity | Location | Qualification No. | Calibration Date | Calibration Due Date |
|---|---|---|---|---|---|---|---|
| Multifunctional Experimental Machine | GL/R&D/698 | SD-1/STC-China | 1.00kg | R&D | IQ-234/08-10 OQ-235/08-10 PQ-236/08-10 | N/A | N/A |
| Manual Capsule Filling Machine | GL/R&D/668 | Manual/Pakistan | 600cap/Hr. | R&D | IQ-237/03-13 OQ-238/03-13 PQ-239/03-13 | N/A | N/A |
| Magnetic Stirrer | GL/R&D/738 | 78HW1/China | -- | R&D | IQ-317/09-15 OQ-318/09-15 | N/A | N/A |
| Disintegration Apparatus | GL/R&D/755 | BJ-2/Guoming-china | Double Basket | R&D | IQ-338/02-16 OQ-339/02-16 | 20-08-2017 | 20-08-2018 |
| Precision Balance | GL/R&D/878 | TX-360/Akura-Japan | 360gm | R&D | IQ-249/03-13 OQ-250/03-13 | 20-08-2017 | 20-08-2018 |
| Weighing Balance | GL/R&D/001 | SBZ/Pakistan | 10.0 Kg | R&D | IQ-523/03-17 OQ-524/03-17 | 20-08-2017 | 20-08-2018 |
| Stability Chamber (Accelerated) | GL/R&D/655 | I-01/Instrumed/Pakistan | 100 Packs | R&D | IQ-244/03-13 OQ-245/03-13 PQ-246/03-13 | 18-08-2017 | 18-08-2018 |
| Stability Chamber(Real Time) | GL/R&D/654 | R1-201/Rasell-Pakistan | 200 Packs | R&D | IQ-110/05-08 OQ-111/05-08 PQ-112/05-18 | 19-08-2017 | 19-08-2018 |
| Dissolution Apparatus | GL/R&D/777 | RC-8/Guoming-China | 8 Vessels | R&D | IQ-594/08-17 OQ-595/08-17 | 20-08-2017 | 20-08-2018 |
| HPLC | GL/R&D/753 | Hitachi | -- | R&D | External | 28-07-2017 | 28-07-2018 |
| HPLC | GL/R&D/819 | Hitachi | -- | R&D | External | 13-08-2018 | 13-08-2019 |
| Stability Chamber(Real Time) | GL/R&D/035 | Thermolab / India | - | R&D | IQ-110/05-08 OQ-111/05-08 PQ-356/04-16 | 17-08-2017 | 17-08-2018 |
| Stability Chamber(Real Time) | GL/R&D/768 | SC750L / Instruments | - | R&D | - | 05-09-2018 | 05-09-2019 |

| | | |
|---|---|---|
| 19. | Are the equipment in product development section qualified? | The equipment used in production and analysis of trial batches are qualified as per details mentioned in reply of above question # 18. |
| 20. | Do you have proper maintenance/calibration/re-qualification program for the equipment used in PD section? | The firm has calibration program for the equipment used in production and QC as per details mentioned in reply of question 18. |
| 21. | Do you have qualified staff in product development section with proper knowledge and training in product development? | The firm has appointed a team of following technical personnel: |

| Sr. #. | Employee Name | Designation | Qualification | Experience |
|---|---|---|---|---|
| 1. | Mr. Muhammad Jamil | Manager R&D | M. Sc. Analytical Chemistry | 17 years |
| 2. | Dr. Tanseer Abbas | Executive | Pharm -D | 06 Years |
| 3. | Atif Ali | Executive | M. Sc. Chemistry | 5 years |
| 4. | Dr. Anas Ullah | Senior analyst | Pharm D | 4.5 years |
| 5. | Muhammad Zubair | Analyst | M. Sc. Chemistry | 1.5 Years |
| 6. | Miss Kainat Zahra | Pharmacist | Pharm D | 06 month |

| | | |
|---|---|---|
| 22. | Have you manufactured three stability batches for the stability studies of Cordin Gel as required? | The firm has manufactured following three stability batches for the stability studies of Cordin Gel: |

| S. No. | Stability Batchs | Batch Sizes |
|---|---|---|
| a. | T006(Q) | 100 x 5 gm Tubes |
| b. | T007(Q) | 100 x 5 gm Tubes |
| c. | T008(Q) | 100 x 5 gm Tubes |

| | | |
|---|---|---|
| 23. | Do you have any criteria for fixing the batch size of stability batches? | The firm has set the criteria for fixing the batch size of stability batches as/& derived the quantity sufficient for the studies both in accelerated and real time studies to cover all testing time points as per details below: |

| | | |
|---|---|---|
| | | <table><tr><th>S. No.</th><th>Tubes /Packs for real time studies</th><th>Tubes for accelerated studies</th><th>Total packs per batch required</th></tr><tr><td>a.</td><td>48 tubes</td><td>24 tubes</td><td>48 + 24= 72 tubes</td></tr></table><br>Batch size = 100 x 5 gm tubes= 500 gm = 0.5 kg |
| 24. | Do you have complete record of production of stability batches? | The firm has complete record of production of stability batches. Starting from Raw Material manufacturing order sheet assuring the traceability of manufacturing and analysis of all the three stability batches. |
| 25. | Do you have protocols for stability testing of stability batches? | The firm has controlled protocol of testing of stability batches of applied formulation at 30 $C^o$ $\pm$ 2 $C^o$ & 65 % RH $\pm$ 5 % with them for real time studies and at 40 $C^o$ $\pm$ 2 $C^o$ & 75 % RH $\pm$ 5 % for accelerated studies. |
| 26. | Do you have developed and validated the method for testing of stability batches? | The firm has used Pharmacopoeial (B.P) method for testing of finished drug in their stability studies. The firm has also submitted a report verifying the validation studies of the analytical method covering following parameters of validation:<br>i. Specificity<br>ii. Precision<br>a. Repeatability<br>iii. Accuracy<br>**Remarks:**<br>The firm has started initial testing of samples placed on stability on 20.03.2017 while the validation of testing method performed on 26.03.2017. |
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | The firm has not conducted method transfer studies. According to the firm since their analytical method is Pharmacopoeial hence no method transfer studies are required. |
| 28. | Do you have documents confirming the qualification of equipments/ instruments being used in the test and analysis of APIs and the finished drug | The firm showed documents confirming the qualification of equipment / instruments being used in the test and analysis of APIs and the finished drug. |
| 29. | Do your method of analysis stability indicating? | The firm's method of testing is stability indicating for stability testing of their finished product being pharmacopoeial (B.P). However, the data sheet submitted by firm does not verify the testing of impurity on samples kept on stability studies though, firm submitted an impurity testing report for *p-Chloroaniline* on samples of all three batches conducted on six month time interval dated 27.09.2017 but document shows no temperature/humidity conditions and the manufacturing date written as 07/2017. The firm has conducted impurity testing one time at 6 month time point it was discussed to conduct the impurity testing at initial and end time point (i.e., 0 and 6) to get an exact verification of impurity profiling/level. |
| 30. | Do your HPLC software is 21CFR compliant? | Firm has 1 HPLC dedicated for R&D testing at the time of studies conducted (now they have 2) and is 21 CFR II compliant. This HPLC system is used for stability studies of **Cordin Gel**. The HPLC used for the stability studies is 21-CFR compliant. However, the record from logbooks, analytical test reports was randomly found verifiable onsite. A complete trail of such testing was available and verifiable. |
| 31. | Can you show Audit Trail reports on Cordin Gel testing? | A complete trail of such testing was found available and verifiable from log books, analytical test reports and software of HPLC as well. |
| 32. | Do you have some | The firm has remaining quantities of stability batches as per following details: |

| | | |
|---|---|---|
| | remaining quantities of degradation products and stability batches? | **Reconciliation sheet**<br>S# \| Product Name \| Batch No. \| Total packs \| Sample for Accelerated study \| Sample for Real Time Study \| Initial testing \| Remaining Packs<br>1 \| Cordin Gel \| T-006 \| 96 \| 24 \| 48 \| 5 \| 19<br>T-007 \| 95 \| 24 \| 48 \| 5 \| 18<br>T-008 \| 94 \| 24 \| 48 \| 5 \| 17 |
| 33. | Do you have stability batches kept on stability testing? | The firm has completed the accelerated stability testing on the three stability batches of Cordin Gel. Also the firm has completed the real time stability testing up to 18 months on all three batches with satisfactory results. |
| 34. | Do you have valid calibration status for the equipments used in production in analysis? | The firm has valid calibration status for the equipment used in Cordin Gel production and analysis as per record available during onsite visit. |
| 35. | Do proper and continuous monitoring and control are available for stability chamber? | Continuous power supply and monitoring with back up from generator and UPS are available for stability chamber to address the problem of interrupted power supply or load shedding. Portable digital data loggers are available for continuous monitoring of temperature and humidity conditions of stability chamber. The firm submitted data of temperature and humidity conditions of stability chambers used for accelerated and real time studies date-wise for every next hour. |
| 36. | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The related manufacturing area, equipment, personnel and utilities are rated as GMP compliant. |

**Conclusions & Recommendations:**

1. On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Cordin
Gel is **verifiable** to a satisfactory level.

2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suitable for the manufacturing of Cordin
Gel, therefore, the panel recommends the registration of Cordin
Gel in the name of the manufacturer.

**Decision: Registration Board decided to approve registration of "Cordin Gel" by M/s Global Pharmaceuticals (Pvt) Ltd., Plot #204-205, industrial triangle Kahuta road. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months**

| | | |
|---|---|---|
| 1241. | **Name and address of manufacturer / Applicant** | M/s Sami Pharmaceuticals Pvt. Ltd |
| | Brand Name +Dosage Form + Strength | Iburo Injection 800mg/8ml |
| | Composition | Each vial contains:<br>Ibuprofen…800mg |
| | Diary No. Date of R& I & fee | Dy. No. 31027; 14-09-2018; Rs. 50,000/-, 14-09-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5D |
| | Finished product Specifications | Innovator specifications |
| | Pack size & Demanded Price | Rs. 13,500/vial<br>Rs. 13,5000/10's vial |
| | Approval status of product in Reference Regulatory Authorities | Approved in USFDA<br>Caldolor by Cumberlands Pharmaceuticals |
| | Me-too status (with strength and dosage form) | N/A |
| | GMP status | Last GMP Inspection dated 3-10-2017 with conclusive remarks of good level of GMP compliance. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Iburo Injection 800mg/8ml | | |
| Name of Manufacturer | M/s Sami Pharmaceuticals Pvt. Ltd | | |
| Manufacturer of API | SI Group ,Orangeburg, SC, USA | | |
| API Lot No. | 4050-3159 | | |
| Description of Pack<br>(Container closure system) | Glass Vial | | |
| Stability Storage Condition | Real Time: 30$^{o}$C ± 2$^{o}$C / 65% ± 5%RH<br>Accelerated:40$^{o}$C ±2$^{o}$C / 75% ± 5%RH | | |
| Time Period | Real Time: 06 Months<br>Accelerated: 06 Months | | |
| Frequency | Real Time: 0,3,6 Months(on going)<br>Accelerated: 0,1,2,3,4,6 Months | | |
| Batch No. | Lab-01 | Lab-02 | Lab-03 |
| Batch Size | 10.5 liter (1333 vials) | 10.5 liter (1333 vials) | 10.5 liter (1333 vials) |
| Manufacturing Date | Dec 2017 | Dec 2017 | Dec 2017 |
| Date of Initiation | Jan 2018 | Jan 2018 | Jan 2018 |
| No. of Batches | 03 | | |
| Date of Submission | Dy. No. 31027; 14-09-2018 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes<br>Lot number: 4050-3159 |
| 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. | SI Group, Inc. ,725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA) 12/31/2019 |
| 3. | Protocols followed for conduction of stability study and details of tests. | Yes |
| 4. | Data of 03 batches will be supported by attested | Yes |

| | | |
|---|---|---|
| | respective documents like chromatograms, laboratory reports, data sheets etc. | |
| 5. | Documents confirming import of API etc. | Yes<br>Invoice No:442831<br>Ibuprofen 40 Microns<br>ADC Attested Invoice dated: 09-10-2017<br>Quantity: 5 Kg |
| 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 claimed In House specifications and the product is not present in USP/BP.

| Sr. No. | Deficiencies/Shortcomings | Reply by Firm |
|---|---|---|
| **1.** | Justify the quantity of API i.e. 805.713/vial used in the formulation as the label claim is 800mg/vial. | Quantity of API has been calculated on the basis of its potency and considering the assay value, moisture content etc., |
| **2.** | Batch No of API not mentioned on ADC invoice and Form 6. | We attached herewith FORM 7 marked as Annexure 02, which in essence is batch declaration obtained from the Manufacturer on its letter head as per Drug Act, 1976.<br>FORM 6 and endorsement from ADC was applied against FORMs 3 and 7. |
| **3.** | Approval of API by regulatory authority of country of origin or valid GMP certificate of API manufacturer issued by regulatory authority of country of origin. | SI Group, Inc., 725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA)<br>Registration of Establishment No. 3011012288<br>Validity: 12/31/2019 |
| **4.** | Clarify how 10.5 L batch size is equivalent to 1333 vials? | Batch size of the lab scale batches are 10.5 liters, vials produced from 10.5 liters are 1312 vials approx.<br>903 vials sent for stability, remaining vials utilized in initial test analysis<br>Due to typographical error in analytical reports; no. of vials 1333 was mistakenly written instead of 903 vials-Sorry |
| **5.** | The batch no Lab-01 the standard 3 was ran on 7 July 2018 at 6:09 pm and sample on 8 July 2018 at 2:34 am. Justify the time gap between standard and sample. (Accelerated Condition). | • Method of analysis of assay has gradient program of 75 minutes<br>• Complete analysis at single frequency of stability at 3rd and 6th month consist of at least 15 runs<br>• At 6th month time point, in analysis of Ibuprofen sequence of injections started on Saturday, July 07, 2018 at 3:38:01 PM<br>• Ended on Sunday, July 08, 2018 at 10:34:28 AM that is also verified by our attached audit trail marked as Annexure 06 |
| **6.** | The batch no Lab-01 the standard 3 was ran on 3 April 2018 at 6:09 pm and sample on 4 April 2018 at 3:00 am. Justify the time gap between standard and sample. (Real time Condition). | • Method of analysis of assay has gradient program of 75 minutes<br>• Complete analysis at single frequency of stability at 3rd and 6th<br>month consist of at least 15 runs<br>• Similarly, at 3rd month time point, sequence of injections started on Tuesday, April 03, 2018 at 3:37:22 PM and<br>• Ended on Wednesday, April 04, 2018 at 09:20:01 |

| | | |
|---|---|---|
| | | AM that is also verified by our attached audit trail marked as Annexure 07 |
| **7.** | The batch no Lab-2 an intense peak has been observed in both standards and samples at RT between 50 min and 60minutes, especially in standard .Justify. (Accelerated Condition). | Due to system behavior, extra peak appears on both standard and samples that means this peak is due to system response, not due to degradation |

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Iburo (Ibuprofen) 800mg/8ml Injection by M/s Sami Pharmaceuticals Pvt. Limited, Karachi.**

**Reference No:** F.13-11/2017-PEC (Pt) dated 23rd January, 2019.
**Investigation Date and Time:** 28th January, 2019. (Forenoon)
**Investigation Site:** Factory premises of M/s Sami Pharmaceuticals Pvt. Ltd. Karachi.

**Background:**

Chairman Registration Board considered the applications of M/s. Sami Pharmaceuticals (Pvt.) Ltd., Karachi for registration of Iburo (Ibuprofen) 800mg/8ml Injection and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

1. An intense peak was observed for batch no. Lab-02 in both standard and sample at Retention time between 50min and 60mins. The firm provided the following justification that "Due to system behaviour extra peak appears on both standard and samples shall mean this peak is due to system response, not due to degradation".

**Composition of Panel:**

4. Dr. Rafeeq Alam, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board.
5. Mr. Aslam Shah, Member Registration Board.
6. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

**Details of Investigation:**

| S.No. | Description | Observation by panel |
|---|---|---|
| 1 | Do you have documents confirming the import of API including approval from DRAP? | The firm has imported 5.0kg Ibuprofen raw material from M/s SI Group Inc, United States, vide invoice no. 442831 dated 05-09-2017 and has obtained approval from DRAP Karachi.<br>Batch No. \| Quantity Imported<br>4050-3159 \| 5.0kg |
| 2 | Do you have any rationale behind selecting the particular manufacturer | There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through:<br>• Postal Audit checklist<br>• GMP approval by competent authority |
| 3 | Do you have documents confirming the Import of Reference standard and Impurities standards? | The firm has imported EP grade 250mg of reference standard and impurity standard from EDQM |

| | | |
|---|---|---|
| 4 | Do you have certificate of analysis of the API reference standard and impurities standards? | The firm has Certificate of Analysis for API, working standards and impurity standard. |
| 5 | Do you have any approval of API or GMP certificate of manufacturer issued by regulatory authority of country of origin? | The API manufacturer is registered establishment by USFDA the USFDA identifier is 3011012288 which is valid till 31-Dec-2019. The firm has also provided copy of GMP certificate issued by TGA Australia. |
| 6 | Do you use API manufacturer method of Testing for testing of API? | The firm has used pharmacopoeial method of testing. |
| 7 | Do you have stability Studies Report on API? | The firm has stability studies report of API Ibuprofen conducted by API manufacturer. |
| 8 | If Yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified.? | The manufacturer of API has performed the stability studies of API as per SIM Method. |
| 9 | Do you have method for quantifying the impurities in the API? | The firm has methods for quantifying the impurities in API. |
| 10 | Do you have some remaining quantities of the API, Its reference standard and impurities standard? | The firm has 3.20Kg API Ibuprofen but have consumed all reference standard and impurity standard. |
| 11 | Have you used pharmaceutical grade excipients? | The firm has used pharmaceutical grade excipient L-arginine. |
| 12 | Do you have documents confirming the import of the used excipients | The firm has documents confirming the import of the used excipients. |
| 13 | Do you have test reports and other records on the excipients? | The firm has test reports and other records on the excipients. |
| 14 | Do you have written and authorized protocols for the development of Iburo 800mg/8ml Injection? | The firm has written and authorized protocol for the development of Iburo 800mg/8ml Injection. |
| 15 | Have you performed Drug-Excipient compatibility studies? | Since firm has used same excipients as used by the innovator. Therefore, compatibility studies were not performed. |
| 16 | Have you performed comparative studies? | The firm has performed comparative studies on the basis of physical, chemical and microbiological analysis. |
| 17 | Do you have Product Development / R&D Section? | The firm has product development (R&D) Section with the facility of manufacturing oral and topical preparation only. The product under consideration has been manufactured in routine sterile area of the firm. The firm has dedicated analytical section for development of analytical methods and testing of new products. |
| 18 | Do you have necessary equipment's available in product development section for development of Iburo 800mg/8ml Injection? | The firm has necessary equipment available in routine sterile area for development of Iburo Injection 800mg/8ml. |
| 19 | Are the equipment's in product development qualified? | The available equipment in Product Development and sterile area are qualified. |
| 20 | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD? | There is proper maintenance / calibration program for the equipment used in PD. |
| 21 | Do you have qualified staff in product development section with proper knowledge and training in product development? | The firm has 08 Pharmacists and 02 Chemists for Product Development Formulation and 6 Pharmacist and 4 Chemists in Analytical side. |

<table>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Iburo 800mg/8ml Injection as required?</td><td>The firm has manufactured three stability batches of each 10.5L.<table><tr><th colspan="3">Iburo 800mg/8ml Injection</th></tr><tr><td>Batch No</td><td>Date of Mfg.</td><td>Expiry Date</td></tr><tr><td>Lab-01</td><td>12-17</td><td>11-19</td></tr><tr><td>Lab-02</td><td>12-17</td><td>11-19</td></tr><tr><td>Lab-03</td><td>12-17</td><td>11-19</td></tr></table></td></tr>
<tr><td>23</td><td>Do you have any criteria for fixing the batch size of stability of batches?</td><td>The criteria for fixing the batch size of stability batches is the number of Injection per testing frequencies.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record for the stability batches of Iburo 800mg/8ml Injection.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches</td><td>The firm has protocols for testing of stability batches.</td></tr>
<tr><td>26</td><td>Do you have developed and validated the method for testing of stability batches</td><td>The firm has developed and validated method of testing of finish product Iburo 800mg/8ml Injection, based on method of testing of API.</td></tr>
<tr><td>27</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is by any other lab.</td><td>Method transfer studies is not applicable as the firm developed and validated their own method.</td></tr>
<tr><td>28</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of the product’s API and product Iburo 800mg/8ml Injection?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the Iburo 800mg/8ml Injection.</td></tr>
<tr><td>29</td><td>Do your method of analysis Stability indicating?</td><td>The firm’s Method of analysis is Stability indicating.</td></tr>
<tr><td>30</td><td>Do your HPLC software 21CFR compliant?</td><td>The HPLC software is 21CFR compliant.</td></tr>
<tr><td>31</td><td>Can you show audit trail reports on Iburo 800mg/8ml Injection testing?</td><td>The firm has audit trail Reports on testing.</td></tr>
<tr><td>32</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm has some remaining quantities of stability batches only.</td></tr>
<tr><td>33</td><td>Do you have batches kept on stability testing?</td><td>The firm has three stability batches kept on stability for Real time stability testing. 9 Months Real Time and 6 months Accelerated stability studies has been completed.</td></tr>
<tr><td>34</td><td>Do you have valid calibration status for the equipment’s used in Iburo 800mg/8ml Injection production and analysis?</td><td>The firm has valid calibration status for the equipment used in Iburo 800mg/8ml Injection production and analysis.</td></tr>
<tr><td>35</td><td>Do Proper and Continuous monitoring and control are available for stability chamber?</td><td>Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software 21CFR compliance.</td></tr>
<tr><td>36</td><td>Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?</td><td>Related manufacturing area, equipment, personnel and utilities can be rated as GMP compliant.</td></tr>
<tr><td>37</td><td>Any other query raised by the Pharmaceutical Evaluation Cell?<br>An intense peak was observed for batch no. Lab-02 in both standard and sample at Retention time between 50min and 60mins. The firm provided the following justification that “Due to system behaviour extra peak appears on both standard and samples shall</td><td>1. The panel observed a peak of similar nature in mobile phase run at same retention time, this type of peak is also observed in other runs too. However, the peak area is very less as compared to the mentioned peak.<br>2. The panel disagrees with the firm’s response and conclude the peak to be of mobile phase.</td></tr>
</table>

| | | |
|---|---|---|
| | mean this peak is due to system response, not due to degradation". | |

**Conclusions:**

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Iburo 800mg/8ml Injection (Ibuprofen) is verifiable to satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are compliant and are suited for the manufacturing of Iburo 800mg/8ml Injection.

**Decision: Registration Board after thorough deliberation deferred the case for submission of documented analytical evidence wherein it has been identified that an intense peak observed in both standard and sample at retention time between 50min and 60mins is of mobile phase.**

**Evaluator PEC-VIII**

| | | |
|---|---|---|
| 1242. | Name and address of manufacturer / Applicant | M/s. Global Pharmaceuticals, Islamabad. |
| | Brand Name +Dosage Form + Strength | Tamsol S Tablets 0.4mg/6.0mg |
| | Composition | Each bilayer modified release tablet contains:<br>Tamsulosin hydrochloride…0.4mg<br>Solifenacin succinate… 6.0mg |
| | Diary No. Date of R& I & fee | Duplicate Dossier |
| | Pharmacological Group | Alpha-adrenoreceptor antagonists/Muscarinic Antagonist. |
| | Type of Form | Form-5D |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 10's : As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in MHRA |
| | Me-too status (with strength and dosage form) | N/A |
| | GMP status | ---- |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Tamsol S Tablets 0.4mg/6.0mg | | |
| Name of Manufacturer | M/s. Global Pharmaceuticals, Islamabad. | | |
| Manufacturer of API | **Tamsulosin hydrochloride(granules):** M/s Alphamed, Telangana State, India.<br>**Solifenacinsuccinate(granules):**M/s Alphamed, Telangana State, India. | | |
| API Lot No. | Tamsulosin hydrochloride: 8000173-041(A)<br>Solifenacin succinate: 8000173-041(B) | | |
| Description of Pack (Container closure system) | 10's : alu/alu blister | | |
| Stability Storage Condition | Real Time: 30°C ± 2°C / 65% ± 5%RH<br>Accelerated:40°C ±2°C / 75% ± 5%RH | | |
| Time Period | Real Time: 06 Months<br>Accelerated:06Months | | |
| Frequency | Real Time: Initial,3,6 Months(on going)<br>Accelerated: Initial,1,2,3,4,6 Months<br>(Only Identification, Appearance & Assay have been carried out at (1st, 2nd& 4th month) | | |
| Batch No. | T01 | T02 | T03 |
| Batch Size | 25000 tablets | 25000 tablets | 25000 tablets |

| | | | |
|---|---|---|---|
| Manufacturing Date | 09-2017 | 09-2017 | 09-2017 |
| Date of Initiation | 10-10-2017 | 10-10-2017 | 10-10-2017 |
| No. of Batches | 03 | | |
| Date of Submission | Duplicate dossier | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Not 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. | Copy of GMP certificate having a number 9267/E (M) TS/2017 issued M/s Alphamed, Telangana State by DCA Government of Telangana valid for a period of two years from date of issue 07-2017.<br>(This certification is for export of drugs only) |
| 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. | Yes |
| 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[2]**

The panel is requested to seek clarification by the firm for the following:
Why the dissolution test at 1st, 2nd& 4th month of accelerated Stability studies has not been carried out by the firm for all three trials (Batch No. T01, T02, T03).

**Report on Inspection of Authenticity / Genuineness of data submitted for registration of bilayer modified release Tamsol-S (Tamsulosin hydrochloride…..0.4 mg Solifenacin succinate……..6.0 mg) Tablets by M/s. Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad.**

**Inspection Date and Time:** 14th &21st January, 2019
**Inspection Site:** M/s. Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad.

**Background:**
M/s. Global Pharmaceuticals (Pvt.) Ltd., Plot No. 204-205, Industrial Estate Triangle, Kahuta Road, Model Town, Islamabad applied for registration of Tamsol-S with following composition:
**Tamsol-S Tablet**
**Each bilayer modified release tablet contains:-**
**Tamsulosin hydrochloride…..0.4 mg**
**Solifenacin succinate…….6.0 mg**

Chairman Registration Board constituted a three member panel for on-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents, import of API, quality, specification, test analysis, facilities etc. Panel was requested to conduct inspection of the firm to verify the submitted data by the firm and to submit a report on approved format for further consideration of case by the Registration Board alongwith the clarification of following point.

a) Why the dissolution test at 1st 2nd and 4th month of accelerated stability has not been carried out by the

firm for all three trials of Tamsol S tablet 0.4mg/6.0mg (Batch # T-01, T-02 & T-03).

**Composition of Panel:**

1. Additional Director, QA & LT, DRAP, Islamabad.
2. Area FID, Islamabad.
3. Mr. Arsalan Tariq, Assistant Director, QA & LT, DRAP, Islamabad.

**Scope of Inspection:**

On-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents, import of API, quality, specification, test analysis, facilities

**Tools for Inspection:**

The Inspection was conducted by using a structured questionnaire approved by DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of inspection is summarized as under:

**Detail of Inspection:**

| Q. No. | Question | Observation by panel |
|---|---|---|
| 1. | Do you have documents confirming the import of API including approval from DRAP? | **Solifenacin Succinate Granules 6 % w/w:**<br><br>**Invoice Number:** 034/2017-18 dated 11.07.2017<br>**ADC attestation date:** 04.08.2017<br>**Exporter/manufacturer:**M/s Alphamed Formulations (Pvt.) Ltd.,Survey No. 225, Sampanbole (Village) Shameerpet (Mandal). Medchal –Malkajgiri Dist. -500078, Telangana State, India.<br>Batch No. 8000173-041 (B)<br>Mfg. Date: May, 2017<br>Exp. Date: April, 2019<br>Quantity: 1 Kg<br><br>**Tamsulosin Hydrochloride:**<br>**Invoice Number:** 034/2017-18 dated 11.07.2017<br>**ADC attestation date:** 04.08.2017<br>**Exporter/Manufacturer:**M/s Alphamed Formulations (Pvt.) Ltd.,Survey No. 225, Sampanbole (Village) Shameerpet (Mandal). Medchal –Malkajgiri Dist. -500078, Telangana State, India.<br>Batch No. 8000173-041 (A)<br>Mfg. Date: May, 2017<br>Exp. Date: April, 2019<br>Quantity: 2.25 Kg |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | The firm has submitted a comparison sheet showing different parameters to compare among 4 different sources and the conclusion based upon which the applicant selected the API manufacturer that is M/s Alphamed Formulations (Pvt.) Ltd.,Survey No. 225, Sampanbole (Village) Shameerpet (Mandal). Medchal –Malkajgiri Dist. -500078, Telangana State, India. |
| 3. | Do you have documents confirming the import of reference standard of Solifenacin Succinate and Tamsulosin Hydrochloride and impurity standards? | The firm imported following working standards from MSN Laboratories Pvt. Ltd. Sun Pharma:<br>✓ Solifenacin succinate working standard<br>o (B#SF0090816)<br>o Date of Standardization: 19th May, 2017<br>o Validity Date: 18 May, 2018<br>✓ Tamsulosin hydrochloride working standard<br>o Batch No. (B#PNOTMSFL005)<br>o Date of Standardization : 16th November, 2016<br>o Validity Date: 15 November, 2017<br>✓ Tamsulosin hydrochloride working standard<br>o Batch No. (B#PNOTMSFL006)<br>o Date of Standardization: 6th October, 2017 |

<table>
<tr><td></td><td></td><td>o Validity Date: 5th October, 2018</td></tr>
<tr><td>4.</td><td>Do you have certificate of Analysis of the API, reference standards and impurity standards?</td><td>The firm has submitted COAs of following APIs as obtained from source mentioned below:<br>✓ Solifenacin Succinate Granules 6 % w/w<br>✓ Solifenacin succinate working standard<br>✓ Tamsulosin Hydrochloride Granules 0.2 % w/w<br>✓ Tamsulosin hydrochloride working standard</td></tr>
<tr><td>5.</td><td>Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?</td><td>The firm has submitted copy of GMP certificate in the name of Manufacturer that is “M/s Alphamed Formulations (Pvt.) Ltd.,Survey No. 225, Sampanbole (Village) Shameerpet (Mandal). Medchal –Malkajgiri Dist. -500078, Telangana State, India.”<br>Valid upto: 19.12.2018</td></tr>
<tr><td>6.</td><td>Do you use API manufacturer’s method of testing for testing API?</td><td>The firm stated that they have used API testing method of source that is M/s Alphamed Formulations (Pvt.) Ltd.,Survey No. 225, Sampanbole (Village) Shameerpet (Mandal). Medchal –Malkajgiri Dist. -500078, Telangana State, India.</td></tr>
<tr><td>7.</td><td>Do you have stability studies reports on API?</td><td>Firm has submitted data of long term stability studies at 30 C°± 2 C° & 65 % RH ± 5 % of three batches namely 8000173-039(A)(Mfg: February, 2017), 8000173-045(A)(Mfg: March, 2017) & 8000173-046(A)(Mfg: March, 2017) up to 12 months and accelerated data at 40 C°± 2 C° & 75 % RH ± 5 % up to 6 months of Tamsulosin Hydrochloride Granules 0.2 % w/w and long term stability studies at 30 C°± 2 C° & 65 % RH ± 5 % of three batchesof Solifenacin Succinate Granules 6 % w/w 8000173-039(B)(Mfg: February, 2017), 8000173-045(B)(Mfg: March, 2017) & 8000173-046(B)(Mfg: March, 2017) up to 12 months and accelerated data at 40 C°± 2 C° & 75 % RH ± 5 %up to 6 months<br>Remarks:<br>✓ The stability data shows various observations like:<br>o The data mentions 3 months difference between manufacturing date and testing date at 0 time point (T0). There is need to ask from source by the applicant for hold-time studies ensuring storage condition and quality of granules.</td></tr>
<tr><td>8.</td><td>If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?</td><td>The firm has submitted the stability testing data of source showing testing of unknown impurities.</td></tr>
<tr><td>9.</td><td>Do you have method for quantifying the impurities in the API?</td><td>The firm has method for calculating/quantify unknown impurities in API.</td></tr>
<tr><td>10.</td><td>Do you have some remaining quantities of the API, its reference standard and impurities standards?</td><td>The firm has submitted remaining quantities of the API, reference standard and impurities standards as per details below:
<table>
<tr><th>S #</th><th>Entity Name</th><th>Batch No.</th><th>Received amount</th><th>Consumption Details</th><th>Consumed amount</th><th>Remaining amount (approx..)</th></tr>
<tr><td rowspan="3">1</td><td rowspan="3">Solifenacin Granules</td><td rowspan="3">8000173-041(B)</td><td rowspan="3">1kg</td><td>Raw material Testing</td><td>5g</td><td>995gm</td></tr>
<tr><td>Pre formulation trial</td><td>150g</td><td>845gm</td></tr>
<tr><td>Three Stability Batches T-01,T-02,T-03</td><td>750g</td><td>95gm</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Tamsulosin Granules</td><td rowspan="2">8000173-041(A)</td><td rowspan="2">2.25kg</td><td>Raw material Testing</td><td>5g</td><td>2245gm</td></tr>
<tr><td>Pre</td><td>300</td><td>1945gm</td></tr>
</table></td></tr>
</table>

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | formulation trial | | |
| | | | | | Three Stability Batches T-01,T-02,T-03 | 1500 | 445gm |
| | | 3 | Solifenacin (Working. Standard ) | SF0090816 | 500mg | • Raw material Testing<br>• Stability Testing | Approx: 150mg | 350mg |
| | | 4 | Tamsulosin (Working. Standard ) | PNOTMSFL005 | 500mg | • Raw material Testing g<br>• Stability Testing | Approx: 100mg | 400mg |
| | | 5 | Tamsulosin (Working. Standard ) | PNOTMSFL006 | 500mg | • Stability Testing | Approx: 50mg | 450mg |
| 11. | Have you used pharmaceutical grade excipients? | The firm has used pharmaceutical grade excipients as indicated from the COAs of excipients submitted by firm. | | | | | |
| 12. | Do you have documents confirming the import of the used excipients? | The firm imported the excipient used in the applied formulation:<br>✓ **Magnesium Stearate** (Batch No.20160220) from M/s Hangzhou Zhongbao Import and Export Corporation., Ltd. Hangzhou, China.<br>✓ **Tabcoat TC Red (**Batch No.SH589925) from M/s Colorcon Ltd. England. | | | | | |
| 13. | Do you have test reports and other records on the excipients used? | The firm has performed tests on above mentioned excipients and has test reports and other records on the excipients used. | | | | | |
| 14. | Do you have written and authorized protocols for the development of Tamsol-S Tablet (Tamsulosin hydrochloride…..0.4 mg Solifenacin succinate……..6.0 mg)? | The firm has written and authorized protocols for the development of Tamsol-S Tablet (Tamsulosin hydrochloride…..0.4 mg Solifenacin succinate……..6.0 mg). But submitted documented was not in accordance with ICH Q-8 which pertains to Pharmaceutical Development. The firm was advised to improve the submitted protocol in the light of said document. | | | | | |
| 15. | Have you performed Drug-excipients compatibility studies? | The firm has not performed Drug-Excipients compatibility studies as the firm claims that their formulation (API & Excipients) is similar/comparable to that of the Vesomni 6 mg/0.4 mg modified release tablets approved by Netherland. | | | | | |
| 16. | Have you performed comparative dissolution studies? | The firm has performed comparative dissolution studies at three pH values that is 1.2, 4.5 and 6.8. The results show $F_2$ values greater than 50 that is 86.2. | | | | | |
| 17. | Do you have product development (R&D) section | The firm possesses an approved Research & Development (R&D) and Validation Department for product development studies issued by DRAP vide letter No. F. 1-1/69-Lic.(Vol-II) dated 13-06-2017. | | | | | |
| 18. | Do you have necessary equipment available in product development section for development of Tamsol-S Tablet? | Yes, the firm has following necessary equipment in R & D section though compression for the development of Tamsol-S Tablet has been carried in General Production Tablet Section of the firm having commercial scale double layer rotary tablet compression machine (Model: ZP-26; Make: Shanghai-China; Equipment ID – GL/PRD/545; IQ-290/01-15;OQ-291/01-15 & PQ-292/01-15) | | | | | |

| | | |
|---|---|---|
| | | **Research & Development**<br>Machine /Equipment Name \| Machine ID # \| Model/Make \| Capacity \| Location \| Qualification No. \| Calibration Date \| Calibration Due Date<br>Multifunctional Experimental Machine \| GL/R&D/698 \| SD-1/STC-China \| 1.00kg \| R&D \| IQ-234/08-10 OQ-235/08-10 PQ-236/08-10 \| N/A \| N/A<br>Manual Capsule Filling Machine \| GL/R&D/668 \| Manual/Pakistan \| 600cap/Hr. \| R&D \| IQ-237/03-13 OQ-238/03-13 PQ-239/03-13 \| N/A \| N/A<br>Magnetic Stirrer \| GL/R&D/738 \| 78HW1/China \| -- \| R&D \| IQ-317/09-15 OQ-318/09-15 \| N/A \| N/A<br>Disintegration Apparatus \| GL/R&D/755 \| BJ-2/Guoming-china \| Double Basket \| R&D \| IQ-338/02-16 OQ-339/03-16 \| 20-08-2017 \| 20-08-2018<br>Precision Balance \| GL/R&D/878 \| TX-300/Akura-Japan \| 300gm \| R&D \| IQ-249/03-13 OQ-250/03-15 \| 20-08-2017 \| 20-08-2018<br>Weighing Balance \| GL/R&D/001 \| SBZ/Pakistan \| 10.0 Kg \| R&D \| IQ-523/03-17 OQ-524/03-17 \| 20-08-2017 \| 20-08-2018<br>Stability Chamber (Accelerated) \| GL/R&D/655 \| I-01/Instromed/Pakistan \| 100 Packs \| R&D \| IQ-244/03-13 OQ-245/03-13 PQ-246/03-13 \| 18-08-2017 \| 18-08-2018<br>Stability Chamber(Real Time) \| GL/R&D/054 \| R1-201/Rasell/Pakistan \| 200 Packs \| R&D \| IQ-110/05-08 OQ-111/05-08 PQ-112/05-18 \| 19-08-2017 \| 19-08-2018<br>Dissolution Apparatus \| GL/R&D/777 \| RC-8/Guoming-China \| 8 Vessels \| R&D \| IQ-594/08-17 OQ-595/08-17 \| 20-08-2017 \| 20-08-2018<br>HPLC \| GL/R&D/753 \| Hitachi \| -- \| R&D \| External \| 28-07-2017 \| 28-07-2018<br>HPLC \| GL/R&D/819 \| Hitachi \| -- \| R&D \| External \| 13-08-2018 \| 13-08-2019<br>Stability Chamber(Real Time) \| GL/R&D/033 \| Thermolab / India \| - \| R&D \| IQ-110/05-08 OQ-111/05-08 PQ-356/04-16 \| 17-08-2017 \| 17-08-2018<br>Stability Chamber(Real Time) \| GL/R&D/768 \| SC750L / Instrumentl \| - \| R&D \| - \| 05-09-2018 \| 05-09-2019 |
| 19. | Are the equipment in product development section qualified? | The equipment used in production and analysis of trial batches are qualified as per details mentioned in reply of above question # 18. |
| 20. | Do you have proper maintenance/calibration/re-qualification program for the equipment used in PD section? | The firm has calibration program for the equipment used in production and QC as per details mentioned in reply of question 18. |
| 21. | Do you have qualified staff in product development section with proper knowledge and training in product development? | The firm has appointed a team of following technical personnel:<br>**Sr. #.** \| Employee Name \| **Designation** \| **Qualification** \| **Experience**<br>7. \| Mr Muhammad Jamil \| Manager R&D \| M. Sc. Analytical Chemistry \| 17 years<br>8. \| Dr. Tanseer Abbas \| Executive \| Pharm -D \| 06 Years<br>9. \| Atifali \| Executive \| M. Sc. Chemistry \| 5 years<br>10 \| Dr. AnasUllah \| Senior analyst \| Pharm D \| 4.5 years<br>11 \| Muhammad Zubair \| Analyst \| M. Sc. Chemistry \| 1.5 Years<br>12 \| Miss kainat Zahra \| Pharmacist \| Pharm D \| 06 month |
| 22. | Have you manufactured three stability batches for the stability studies of **Tamsol-S Tablet** as required? | The firm has manufactured following three stability batches for the stability studies of **Tamsol-S Tablet**:<br>**S. No.** \| **Stability Batches** \| **Batch Sizes**<br>d. \| T-01 \| 2,500<br>e. \| T-02 \| 2,500<br>f. \| T-03 \| 2,500 |
| 23. | Do you have any criteria for fixing the batch size of stability batches? | The firm has set the criteria for fixing the batch size of stability batches as/& derived the quantity sufficient for the studies both in accelerated and real time studies to cover all testing time points as per details below:<br>**S. No.** \| **Packs for real time studies** \| **Packs for accelerated studies** \| **Total packs per batch required**<br>1. \| 35 \| 30 \| 35 + 30= 65<br>Batch size = 10 x 1 x 250 = 2,500 tablets. |
| 24. | Do you have complete record of production of stability batches? | The firm has complete record of production of stability batches. Starting from Raw Material manufacturing order sheet assuring the traceability of manufacturing and analysis of all the three stability |

| | | |
|---|---|---|
| | | batches. |
| 25. | Do you have protocols for stability testing of stability batches? | The firm has controlled protocol of testing of stability batches of applied formulation at 30 C°± 2 C° & 65 % RH ± 5 % with them for real time studies and at 40 C°± 2 C° & 75 % RH ± 5 % for accelerated studies. |
| 26. | Do you have developed and validated the method for testing of stability batches? | The firm has developed an In-house method for testing of finished product which has been used in the stability studies. The firm has also submitted a report verifying the validation studies of the analytical method covering following parameters of validation:<br>i. Specificity<br>ii. Linearity and Range<br>iii. Accuracy and Recovery<br>iv. Precision<br>a. Repeatability<br>v. Ruggedness<br>vi. Robustness<br>**Remarks:**<br>The firm has not derived sensitivity studies covering LOD (Limit of Detection) and LOQ (limit of Quantification). However, firm submitted statistically calculated values of LOD & LOQ for Tamsol-S Tablet (Tamsulosin hydrochloride…..0.4 mg Solifenacin succinate……..6.0 mg) from linearity studies as follows:<br>**Solifenacin Succinate Tamsulosin HCl**<br>LOD 0.569mcg/ml 0.044mcg/ml<br>LOQ 1.72mcg/ml 0.133mcg/ml |
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | The firm has not conducted method transfer studies. According to the firm they have developed their method of testing in their own laboratory hence no need of such method transfer studies. |
| 28. | Do you have documents confirming the qualification of equipments/instruments being used in the test and analysis of APIs and the finished drug | The firm showed documents confirming the qualification of equipment / instruments being used in the test and analysis of APIs and the finished drug. |
| 29. | Do your method of analysis stability indicating? | The firm method of testing is stability indicating which has been used in stability studies of their finished product. The firm has conducted impurity testing one time at 6 month time point it was suggested to conduct the impurity testing at 0 and 6 time point to get an exact verification of impurity profiling. |
| 30. | Do your HPLC software is 21CFR compliant? | Firm has 1 HPLC dedicated for R&D testing at the time of studies conducted (now they have 2) and it is 21 CFR compliant. This HPLC system is used for stability studies of **Tamsol-S Tablet**. The HPLC used for the stability studies is 21-CFR compliant. However, the record from logbooks, analytical test reports was randomly found verifiable onsite. A complete trail of such testing was found available and verifiable. |
| 31. | Can you show Audit Trail reports on **Tamsol-S Tablet** testing? | A complete trail of such testing was found available and verifiable from log books and software of HPLC as well. |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of stability batches as per following details:<br>**Reconciliation sheet**<br>S# \| Product Name \| Batch No. \| Total packs \| Sample for Accelerated study \| Sample for Real Time Study \| Remaining Packs<br>1 \| Tamsol S 6mg/0.4mg Tablet \| T-01 \| 230 \| 30 \| 35 \| 165<br>T-02 \| 231 \| 30 \| 35 \| 166<br>T-03 \| 237 \| 30 \| 35 \| 172 |
| 33. | Do you have stability batches kept on stability testing? | The firm has completed the accelerated stability testing on the three stability batches of **Tamsol-S Tablet**. Also the firm has |

| | | |
|---|---|---|
| | | completed the real time stability testing up to 12 months on all three batches with satisfactory results. |
| 34. | Do you have valid calibration status for the equipments used in production and analysis? | The firm has valid calibration status for the equipments used in production and analysis of **Tamsol-S Tablet** as per record available during onsite visit and as per details mentioned in reply of above question # 18. |
| 35. | Do proper and continuous monitoring and control are available for stability chamber? | Continuous power supply and monitoring with back up from generator and UPS are available for stability chamber to address the problem of interrupted power supply or load shedding. Portable digital data loggers are available for continuous monitoring of temperature and humidity conditions of stability chamber. The data of temperature and humidity conditions of stability chambers used for accelerated and real time studies date-wise for every next hour has been verified from record. |
| 36. | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The related manufacturing area, equipment, personnel and utilities are rated as GMP compliant. The firm has valid GMP certificate issued by Drug Regulatory Authority of Pakistan with validity period as 24-10-2018 till 23-10-2021. |
| 37. | Why the dissolution test at 1st, 2nd& 4th month of accelerated stability studies has not carried out by the firm for all three trials of Tamsol-S tables 0.4mg/6.0mg (Batch No. T01, T02, T03). | The firm has performed complete testing including dissolution at 0, 3 and 6 month time points for all three trials of Tamsol-S tables 0.4mg/6.0mg (Batch No. T01, T02, T03) in compliance to ICH Q1A(R2) guidelines. However, at time point 1 and 2 the firm has performed appearance, identification and assay while relying on dissolution profile performed at 0 and 3 time point.<br>Furthermore, the decision regarding time points for Accelerated stability studies i.e. (0, 1st, 2nd, 3rd, 4th& 6th months) was taken in 276th Meeting of Registration Board held on 22-25 Nov, 2017 (date of confirmation of minutes 27-29th Dec, 2017), while manufacturing of trial batches and finalization of respective study plan has been carried out in September, 2017.<br>The firm assured to strictly comply in future the approved guidelines of Registration Board for stability studies. |

**Conclusion & Recommendations:**

1. On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Tamsol-S Tablet is verifiable to a satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are GMP compliant and suitable for the manufacturing of Tamsol-S Tablet, therefore, the panel recommends the registration of Tamsol-S Tablet in the name of the manufacturer.

**Decision: Registration Board decided to approve registration of "Tamsol-S Tablet 0.4mg/6mg" by M/s Global pharmaceuticals Islamabad. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**

| | | |
|---|---|---|
| 1243. | Name and address of manufacturer / Applicant | M/s Sami Pharmaceuticals (Pvt) Limited. F-95 S.I.T.E. Karachi. |
| | Brand Name +Dosage Form + Strength | Tefod Tablets 25mg |
| | Composition | Each film coated tablet contains:<br>Tenofovir Alafenamide ( as fumarate)… 25mg |
| | Diary No. Date of R& I & fee | Dy No.35096; 23-10-2018: 50,000/- (15-10-15) |
| | Pharmacological Group | Nucleotide reverse transcriptase inhibitor (Anti-Viral) |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's Specifications |
| | Pack size & Demanded Price | 10's, 20's, 30's ; Rs. 1700/-, 3400/-, 5000/- respectively |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA<br>(VEMLIDY tablet 25mg of Gilead Sciences) |
| | Me-too status | N/A |
| | GMP status | |

| STABILITY STUDY DATA | | | |
|---|---|---|---|
| Drug | Tefod Tablets 25mg | | |
| Name of Manufacturer | M/s Sami Pharmaceuticals (Pvt) Limited. F-95 S.I.T.E. Karachi. | | |
| Manufacturer of API | M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China | | |
| API Lot No. | Lot #: HCS171610-01 , Quantity; 600g | | |
| Description of Pack (Container closure system) | Alu/AluBlister Pack | | |
| Stability Storage Condition | Accelerated:40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 6 (Months)<br>Real Time: 6 (Months) | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (Months)<br>Real Time: 0,3,6,9,12,18,24 (Months) | | |
| Batch No. | Lab#01 | Lab#02 | Lab#03 |
| Batch Size | 2500 tablets | 2500 tablets | 2500 tablets |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | 05-01-2018 | December 2017 | 09-02-2018 |
| No. of Batches | 03 | | |
| Date of Submission | 31557 (18-09-2018) | | |

| DOCUMENTS / DATA PROVIDED BY THE APPLICANT | | |
|---|---|---|
| **Sr. No.** | **Documents To Be Provided** | **Status** |
| 1. | COA of API. | Copy of COA (batch #20170203) from M/s Zhuhai Rundu Pharmaceutical 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. | Following things have been submitted by the firm:<br>**Copy of GMP certificate**:<br>**Issued To:**Yichang HEC Changjiang pharmaceutical co., Ltd.<br>**Issued by:**Yichang Food and Drug Administration, China.<br>**Validity:**up to 15-05-2015<br>(It is written on this GMP Certificate that *TenofovirAlafenamideFumarate* has been manufactured for export purpose to Korea, Taiwan, Egypt, Iran, Pakistan, Bangladesh, India, Vietnam, Algeria, Argentina)<br>(Lot # of API is not mentioned on Commercial Invoice) |
| 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. | Following things have been submitted by the firm:<br>• Copy of Licence to import Drug (*TenofovirAlafenamideFumarate*) for Clinical Trials/Examination/Test/Analysis dated 06-12-2017.<br>• Copy of commercial invoice dated 29-11-2017 stating 600g of API*(TenofovirAlafenamideFumarate)*attested by ADC on 06-12-2017, DRAP, Islamabad |

| | | |
|---|---|---|
| 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 panel is requested to report the confirmation by the firm for the following:

1. Confirmation regarding the storage conditions at which the API was kept before manufacturing of batches, and the facility of cold room for storage of the API during manufacturing of the commercial batches, since this API is to be stored between 2 to 8oC.
2. Confirmation of dissolution test results for all three Trial Batches (Lab#01, Lab#02, & Lab #03) on US-FDA Recommended Dissolution Parameters which are Apparatus; Paddle, rpm; 50, Medium; 0.1NHCl, Volume; 900ml & Time; 30 Minutes. Because initially they adopted a different dissolution method by mistake & now they have performed dissolution test for their product according to US-FDA recommended dissolution method & found it satisfactory as per their recent information.

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Tefod (TenofovirAlafenamidehemifumarate) 25mg Tablets by M/s Sami Pharmaceuticals Pvt. Limited, Karachi.**

**Reference No:** F.13-11/2017-PEC (Pt) dated 23rd January, 2019.
**Investigation Date and Time:** 28th January, 2019. (Forenoon)
**Investigation Site:** Factory premises of M/s Sami Pharmaceuticals Pvt. Ltd. Karachi.

**Background:**

Chairman Registration Board considered the applications of M/s. Sami Pharmaceuticals (Pvt.) Ltd., Karachi for registration of Tefod (TenofovirAlafenamidehemifumarate) 25mg Tabletsand constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

1. Confirmation regarding the storage conditions at which the API was kept before manufacturing of batches, and the facility of cold room for storage of API during manufacturing of commercial batches, since this API is to be stored between 2°C to 8°C.
2. Confirmation of dissolution test results for all three trial batches on USFDA recommended dissolution parameters which are Apparatus: Paddle, rpm:50, Medium: 0.1M HCl, Volume: 900ml and Time: 30mins. Because they initially adopted a different dissolution method by mistake and now they have performed dissolution test for their product according to USFDA recommended dissolution method & found it satisfactory as per their recent information

**Composition of Panel:**

1. Dr. Rafeeq Alam, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board.
2. Mr.Aslam Shah, Sr. Manager Pharmacy Services, Indus Hospital, Karachi, Member Registration Board.
3. Dr.Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

**Details of Investigation:**

| S.No. | Description | Observation by panel |
|---|---|---|
| 1 | Do you have documents confirming the import of API including approval from DRAP? | The firm has imported 600.0g TenofovirAlafenamidehemifumarate raw material from M/S WIS Pharmatech Co. Ltd. Manufactured by M/s Yichang HCE Changjian Pharmaceutical Co. Ltd. China vide invoice no. WIS170115 dated 29-11-2017 and has obtained approval from DRAP Karachi.<br>Batch No. \| Quantity Imported<br>HCS171610-01 \| 600.0 g |
| 2 | Do you have any rationale behind selecting the particular manufacturer | There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through:<br>• Desktop Audit checklist<br>• GMP approval by competent authority |
| 3 | Do you have documents confirming the Import of Reference standard and Impurities standards? | The firm has imported 100mg of working standard and 10mg impurity standard from, the API manufacturer China. |
| 4 | Do you have certificate of analysis of the API reference standard and impurities standards? | The firm has Certificate of Analysis for API, working standards and impurity standard. |
| 5 | Do you have any approval of API or GMP certificate of manufacturer issued by regulatory authority of country of origin? | The firm has provided copy of GMP certificate issued by Yichang Food and Drug Administration |
| 6 | Do you use API manufacturer method of Testing for testing of API? | The firm has used API Manufacturer's method of testing |
| 7 | Do you have stability Studies Report on API? | The firm has stability studies report of API TenofovirAlafenamideHemifumarateconducted by API manufacturer. |
| 8 | If Yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified.? | The manufacturer of API has performed the stability studies of API as per SIM Method and the Related Substance have been quantified by the API manufacturer |
| 9 | Do you have method for quantifying the impurities in the API? | The firm has methods for quantifying the impurities in API. |
| 10 | Do you have some remaining quantities of the API, Its reference standard and impurities standard? | The firm has 320g API TenofovirAlafenamideHemifumaratebut have consumed all working standard and impurity standard. |
| 11 | Have you used pharmaceutical grade excipients? | The firm has used pharmaceutical grade excipients.<br>Lactose Monohydrate, Microcrystalline cellulose, Croscarmellose Sodium and Magnesium Stearate. Sheffcoat has been used for coating. |
| 12 | Do you have documents confirming the import of the used excipients | The firm has documents confirming the import of the used excipients. |
| 13 | Do you have test reports and other records on the excipients? | The firm has test reports and other records on the excipients. |
| 14 | Do you have written and authorized protocols for the development of Tefod 25mg tablets? | The firm has written and authorized protocol for the development of Tefod 25mg Tablets. |
| 15 | Have you performed Drug-Excipient compatibility studies? | Since firm has used same excipients as used by the innovator. Therefore, compatibility studies were not performed. |

<table>
<tr><td>16</td><td>Have you performed comparative studies?</td><td>Firm has performed comparative studies with innovator Vemlidy 25mg tablets manufactured by Gilead Sciences, Inc, Foster City, CA 94404, Canada.</td></tr>
<tr><td>17</td><td>Do you have Product Development / R&D Section?</td><td>The firm has product development (R&D) Section with the facility of manufacturing and Analysis of R&D products.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment's available in product development section for development of Tefod 25mg tablets?</td><td>The firm has necessary equipment available in product development section for development ofTefod Tablets 25mg.</td></tr>
<tr><td>19</td><td>Are the equipment's in product development qualified?</td><td>The available equipment in Product Development are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD?</td><td>There is proper maintenance / calibration program for the equipment used in PD.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has 08 Pharmacists and 02 Chemists for Product Development Formulation and 6 Pharmacist and 4 Chemists in Analytical side.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Tefod 25mg tablets as required?</td><td>The firm has manufactured three stability batches of each 2500 tablets.<br>Tefod 25mg tablets<br><table><tr><td>Batch No</td><td>Date of Mfg.</td><td>Expiry Date</td></tr><tr><td>Lab-01</td><td>01-18</td><td>12-19</td></tr><tr><td>Lab-02</td><td>01-18</td><td>12-19</td></tr><tr><td>Lab-03</td><td>01-18</td><td>12-19</td></tr></table></td></tr>
<tr><td>23</td><td>Do you have any criteria for fixing the batch size of stability of batches?</td><td>The criteria for fixing the batch size of stability batches is the number of Tablets per testing frequencies.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record for the stability batches of Tefod 25mg tablets.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches</td><td>The firm has protocols for testing of stability batches.</td></tr>
<tr><td>26</td><td>Do you have developed and validated the method for testing of stability batches</td><td>The firm has developed and validated method of testing of finish product Tefod 25mg Tablets, based on method of testing of API.</td></tr>
<tr><td>27</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is by any other lab.</td><td>Method transfer studies is not applicable as the firm developed and validated their own method.</td></tr>
<tr><td>28</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of the product's API and product Tefod 25mg tablets?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the Tefod 25mg tablets.</td></tr>
<tr><td>29</td><td>Do your method of analysis Stability indicating?</td><td>The firm's Method of analysis is Stability indicating.</td></tr>
<tr><td>30</td><td>Do your HPLC software 21CFR compliant?</td><td>The HPLC software is 21CFR compliant.</td></tr>
<tr><td>31</td><td>Can you show audit trail reports on Tefod 25mg Tablets testing?</td><td>The firm has audit trail Reports on testing.</td></tr>
<tr><td>32</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm has some remaining quantities of stability batches only.</td></tr>
<tr><td>33</td><td>Do you have batches kept on stability testing?</td><td>The firm has three stability batches kept on stability for Real time stability testing. 9 Months Real Time and 6 months Accelerated stability studies has been completed.</td></tr>
</table>

| | | |
|---|---|---|
| 34 | Do you have valid calibration status for the equipment's used in Tefod 25mg tablets production and analysis? | The firm has valid calibration status for the equipment used in Tefod 25mg tablets production and analysis. |
| 35 | Do Proper and Continuous monitoring and control are available for stability chamber? | Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software 21CFR compliance. |
| 36 | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | Related manufacturing area, equipment, personnel and utilities can be rated as GMP compliant. |
| 37 | Any other query raised by the Pharmaceutical Evaluation Cell?<br>1. Confirmation regarding the storage conditions at which the API was kept before manufacturing of batches, and the facility of cold room for storage of API during manufacturing of commercial batches, since this API is to be stored between 2°C to 8°C.<br>2. Confirmation of dissolution test results for all three trial batches on USFDA recommended dissolution parameters which are Apparatus: Paddle, rpm:50, Medium: 0.1M HCl, Volume: 900ml and Time: 30mins. Because they initially adopted a different dissolution method by mistake and now they have performed dissolution test for their product according to USFDA recommended dissolution method & found it satisfactory as per their recent information | 1. The firm has cold storage in their product development section as well as in their routine raw material store.<br>2. The firm has performed dissolution testing as per USFDA method. |

**Conclusions:**

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Tefod 25mg Tablets (Tenofoviralafenamide) is verifiable to highly satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are compliant are suited for the manufacturing of Tefod 25mg Tablets.

**Decision: Registration Board decided to approve registration of "Tefod 25mg Tablets (Tenofovir alafenamide)" by M/s Sami pharmaceuticals Karachi Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

**Evaluator PEC-XII**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1244. | **M/s Highnoon Laboratories,**<br>17.5km, Multan Road, Lahore. | **Daplozmet Tablets 5mg/850mg**<br><br>Each film coated tablet contains:<br>Dapagliflozin (as propanediol monohydrate) …5mg<br>Metformin hydrochloride …850mg<br><br>(Combinations of oral blood glucose lowering drugs)<br><br>Manufacturer's Specifications. | Form 5-D<br><br>Dairy No. 21945 dated 23-11-2017.<br>Rs.50,000/- dated 23-11-2017.<br><br>As per SRO, for 14's.<br>As per SRO, for 28's.<br>As per SRO, for 56's. | Ebymect 5 mg/850 mg film-coated tablets by M/s AstraZeneca AB (EMA approved)<br><br>Last GMP inspection dated 06-07-2017; firm is considered to be operating at Good level of compliance of GMP Requirements at the time of inspection. |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Daplozmet Tablets 5mg/850mg<br>(Dapagliflozin and Metformin hydrochloride) | | |
| Name of Manufacturer | M/s Highnoon laboratories,<br>17.5km, Multan Road, Lahore. | | |
| Manufacturer of API | Dapagliflozin : MSN Laboratories Pvt Ltd, Sy NO. 317 & 323, Rudraram (Vill), Patancheru (Mandal), Medak District, Telangana, India.<br>Metformin: Ipca Laboratories Limited, H-4, M.I.D.C, Waluj Industrial Area, Aurangabad, India. | | |
| API Lot No. | Dapagliflozin : DQ0010217<br>Metformin: 17180ML2JMI | | |
| Description of Pack (Container closure system) | Alu/Alu blister | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 24 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,3,6 (Months)<br>Real Time: 0,3,6 (Months) | | |
| Batch No. | RD 18069 | RD 18070 | RD 18071 |
| Batch Size | 2500 Tablets | 2500 Tablets | 2500 Tablets |
| Manufacturing Date | April 2018 | April 2018 | April 2018 |
| Date of Initiation | April 2018 | April 2018 | April 2018 |
| No. of Batches | 03 | | |
| Date of Submission | 05-11-2018 (Dy. No. 36509) | | |
| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | | |

| Sr. No. | Documents to Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA for Dapagliflozin propanediol from M/s MSN Laboratories Pvt Ltd, India has been submitted.<br>Copy of COA for Metformin hydrochloride from M/s Ipca Laboratories Limited, Aurangabad, India has been 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. | Dapagliflozin propanediol: Photocopy of GMP Certificate No. 10162/E(R)/TS/2017 for MSN Laboratories Pvt Ltd, India issued by DCA, Govt. of Telangana is submitted. Valid till 16-10-2019.<br>Metformin hydrochloride: Photocopy of GMP Certificate No. NEW-WHO-GMP/CERT/AD67318/2018/11/24741 for Ipca Laboratories Limited, Aurangabad, India issued by FDA, Maharashtra is submitted. Valid till 27-08-2021. |
| 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. | Dapagliflozin propanediol: Photocopy of ADC (Lahore) attested Commercial Invoice containing batch details of Batch No. DQ0010217 is submitted. Quantity: 5kg<br>Metformin hydrochloride: Photocopy of ADC (Lahore) attested Commercial Invoice containing batch details of Batch No. 17180ML2JMI is submitted. Quantity: 5000kg |
| 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 |

**Evaluation by PEC:**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1245. | M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore. | Daplozmet Tablets 5mg/1000mg<br><br>Each film coated tablet contains:<br>Dapagliflozin (as propanediol monohydrate) …5mg<br>Metformin | Form 5-D<br><br>Dairy No. 21946 dated 23-11-2017.<br>Rs.50,000/- dated 23-11-2017.<br><br>As per SRO, for 14's.<br>As per SRO, for 28's. | Ebymect 5 mg/1000 mg film-coated tablets by M/s AstraZeneca AB (EMA approved)<br><br>Last GMP inspection dated 06-07-2017; firm is considered to be operating at Good level |

| | | | | |
|---|---|---|---|---|
| | | hydrochloride …1000mg<br><br>(Combinations of oral blood glucose lowering drugs)<br><br>Manufacturer's Specifications. | As per SRO, for 56's. | of compliance of GMP Requirements at the time of inspection. |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Daplozmet Tablets 5mg/1000mg<br>(Dapagliflozin and Metformin hydrochloride) | | |
| Name of Manufacturer | M/s Highnoon laboratories,<br>17.5km, Multan Road, Lahore. | | |
| Manufacturer of API | Dapagliflozin : MSN Laboratories Pvt Ltd, Sy NO. 317 & 323, Rudraram (Vill), Patancheru (Mandal), Medak District, Telangana, India.<br>Metformin: Ipca Laboratories Limited, H-4, M.I.D.C, Waluj Industrial Area, Aurangabad, India. | | |
| API Lot No. | Dapagliflozin : DQ0010217<br>Metformin: 17180ML2JMI | | |
| Description of Pack (Container closure system) | Alu/Alu blister | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 24 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,3,6 (Months)<br>Real Time: 0,3,6 (Months) | | |
| Batch No. | RD 18072 | RD 18073 | RD 18074 |
| Batch Size | 2500 Tablets | 2500 Tablets | 2500 Tablets |
| Manufacturing Date | April 2018 | April 2018 | April 2018 |
| Date of Initiation | April 2018 | April 2018 | April 2018 |
| No. of Batches | 03 | | |
| Date of Submission | 05-11-2018 (Dy. No. 36510) | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr. No.** | **Documents to Be Provided** | **Status** |
| 1. | COA of API | Copy of COA for Dapagliflozin propanediol from M/s MSN Laboratories Pvt Ltd, India has been submitted.<br>Copy of COA for Metformin hydrochloride from M/s Ipca Laboratories Limited, Aurangabad, India has been 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. | Dapagliflozin propanediol: Photocopy of GMP Certificate No. 10162/E(R)/TS/2017 for MSN Laboratories Pvt Ltd, India issued by DCA, Govt. of Telangana is submitted. Valid till 16-10-2019.<br>Metformin hydrochloride: Photocopy of GMP Certificate No. NEW-WHO-GMP/CERT/AD67318/2018/11/24741 for Ipca Laboratories Limited, Aurangabad, India issued by FDA, Maharashtra is submitted. Valid till 27-08- |

| | | |
|---|---|---|
| | | 2021. |
| 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. | Dapagliflozin propanediol: Photocopy of ADC (Lahore) attested Commercial Invoice containing batch details of Batch No. DQ0010217 is submitted. Quantity: 5kg<br>Metformin hydrochloride: Photocopy of ADC (Lahore) attested Commercial Invoice containing batch details of Batch No. 17180ML2JMI is submitted. Quantity: 5000kg |
| 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 |

**Evaluation by PEC:**

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Daplozmet Tablets 5mg/850mg & Daplozmet Tablets 5mg/1000mg by M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore.**

**Reference No:** 175/2019/FID (VIII**)** dated 2nd January, 2019.

**Investigation Date and Time:** 1st January, 2019.

**Investigation Site:** Factory premises of M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore.

**Composition of Panel:**

- Mr Asim Rauf (Additional Director, DRAP, Lahore)
- Ms Uzma Barkat (Area Federal Inspector of Drugs, Lahore)
- Mr Shahrukh Ali (Assistant Director, DRAP, Lahore)

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

**Details of Inspection**

**DAPLOZMET TABLETS 5mg/850mg (Dapagliflozin as propanediol monohydrate + Metformin HCl)**

| Sr. No. | Question | Observation by the panel |
|---|---|---|
| 1. | Do you have documents confirming the import of API? | Firm had imported Dapagliflozin propanediol from M/s MSN Laboratories, India, and Metformin HCl from M/s IPCA Laboratories, India. Invoices for import attested by AD (I&E) were also seen. |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | Firm has a vendor approval system and according to the firm, the rationale behind selecting the manufacturer is its GMP status and evaluation as per SOP for vendor |

| | | |
|---|---|---|
| | | approval. (Firm is using Metformin HCl from same source in their other products also.) |
| 3. | Do you have documents confirming the import of reference standard and impurity standards? | Firm had Dapagliflozin working standard and four impurity standards (obtained from MSN, India). Reference standards of Metformin HCl, its two impurities and two related substances were also procured. Documentary evidence related to purchase was seen. |
| 4. | Do you have certificate of Analysis of the API, reference standards and impurity standards? | Relevant COAs from principal manufacturer were seen. |
| 5. | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | Yes, firm had GMP certificate of both API manufacturers issued by regulatory authority of the country of origin. |
| 6. | Do you use API manufacturer method of testing? | Yes, firm used API manufacturer`s method of testing for Dapagliflozin and compendial method for Metformin HCl.. |
| 7. | Do you have stability studies reports on API? | Yes, firm had stability studies reports on API as provided by the manufacturer |
| 8. | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | Yes, stability testing had been performed as per Stability Indicating Method (SIM) and impurities/ related substances/degradation products had been quantified. |
| 9. | Do you have method for quantifying the impurities in the API? | Yes, firm had method for quantifying the impurities in the API. Dapagliflozin propanediol was tested accordingly. However, results of impurity and related substances of Metformin HCl were taken from manufacturer's COA. |
| 10. | Do you have some remaining quantities of the API, its reference standard and impurities standards? | Yes, some remaining quantities of the APIs, reference standards, impurity standards and working standards were available. |
| 11. | Have you used pharmaceutical grade excipients? | Yes, firm had used pharmaceutical grade excipients. |
| 12. | Do you have documents confirming the import of the used excipients? | Yes, firm had necessary documents confirming the import of the excipients used in product. |
| 13. | Do you have test reports and other records on the excipients used? | Yes, the firm had test reports and other record of the excipients used. |
| 14. | Do you have written and authorized protocols for the development of the product? | Yes, the firm had written and authorized protocols for the development of the product. . |
| 15. | Have you performed Drug-excipient compatibility studies? | Yes, firm had performed drug excipient compatibility studies and all excipients were found compatible with the APIs as per the report provided. |
| 16. | Have you performed comparative dissolution studies? | Yes, firm has performed comparative dissolution studies and the product showed comparable results. |
| 17. | Do you have product development (R&D) section? | Yes, firm had a product development (PD) department. |
| 18. | Do you have necessary equipments available in product development section for development of the product? | Yes, firm had necessary equipment available in product development section for development of the product. Remarks: Firm was advised to upgrade PD laboratory. Firm's management informed that revamping and upgradation of the facility is already under planning. |
| 19. | Are the equipments in product development section qualified? | The equipment in product development section were qualified as informed by the firm. Equipment qualification protocols were available. Two protocols were randomly selected and scrutinized. |
| 20. | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | Yes, firm had a maintenance / calibration / re-qualification program for the whole facility including equipment used in PD section. |
| 21. | Do you have qualified staff in product development section with proper | Yes, firm had qualified and trained staff in product development section. Training record was seen for the year |

| | | |
|---|---|---|
| | knowledge and training in product development? | 2018. |
| 22. | Have you manufactured three stability batches for the stability studies of the product as required? | Firm had manufactured three stability batches for the stability studies of Daplozmet Tablets 5mg/850mg with Batch No. RD-18069, RD-18070 & RD-18071 (batch size of 2500 tablets). |
| 23. | What was the criteria for fixing the batch size of stability batches? | The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tablets per testing frequency and number of testing frequencies / intervals), minimum working capacity of equipment and DRAP guidelines. |
| 24. | Do you have complete record of production of stability batches? | Yes, firm had complete record of production of stability batches. |
| 25. | Do you have protocols for stability testing of stability batches? | Yes, firm had protocols for stability testing of stability batches. |
| 26. | Do you have developed and validated the method for testing of stability batches? | Yes, firm had developed method for testing of stability batches. Test method validation protocol and report for identification, assay and content uniformity was available. |
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | The method for testing of the product was developed and validated in the firm's premises. |
| 28. | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug? | Yes, firm had documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug product. |
| 29. | Is your method of analysis stability indicating? | Yes, firm's method of analysis was stability indicating and the record of testing of stability batches was available. |
| 30. | Is your HPLC software 21CFR compliant? | Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available. |
| 31. | Can you show Audit Trail reports on product testing? | Audit trail reports were available and randomly checked. |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of some impurity standards and stability batches. |
| 33. | Do you have stability batches kept on stability testing? | The stability studies of trial batches kept at 30˚C/65% RH were on going. |
| 34. | Do you have valid calibration status for the equipments used in production and analysis? | Firm had valid calibration status for the equipment used in production and analysis of the product. |
| 35. | Is proper and continuous monitoring and control available for stability chamber? | Yes, monitoring and control was available for the stability chambers provided.<br>Firm was advised to install alarm system in stability chamber and perform challenge test. |
| 36. | Can related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The related facilities of Highnoon Laboratories Ltd., Lahore were GMP compliant. |
| **DAPLOZMET TABLETS 5mg/1000mg (Dapagliflozin as propanediol monohydrate + Metformin HCl)** | | |
| **Sr. No.** | **Question** | **Observation by the panel** |
| 1. | Do you have documents confirming the import of API? | Firm had imported Dapagliflozin propanediol from M/s MSN Laboratories, India, and Metformin HCl from M/s IPCA Laboratories, India. Invoices for import attested by AD (I&E) were also seen. |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | Firm has a vendor approval system and according to the firm, the rationale behind selecting the manufacturer is its GMP status and evaluation as per SOP for vendor approval. (Firm is using Metformin HCl from same source |

| | | |
|---|---|---|
| | | in their other products also.) |
| 3. | Do you have documents confirming the import of reference standard and impurity standards? | Firm had Dapagliflozin working standard and four impurity standards (obtained from MSN, India). Reference standards of Metformin HCl, its two impurities and two related substances were also procured. Documentary evidence related to purchase was seen. |
| 4 | Do you have certificate of Analysis of the API, reference standards and impurity standards? | Relevant COAs from principal manufacturer were seen. |
| 5 | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | Yes, firm had GMP certificate of both API manufacturers issued by regulatory authority of the country of origin. |
| 6 | Do you use API manufacturer method of testing? | Firm used API manufacturer`s method of testing for Dapagliflozin and compendial method for Metformin HCl. |
| 7 | Do you have stability studies reports on API? | Yes, firm had stability studies reports on API as provided by the manufacturer |
| 8 | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | Yes, stability testing had been performed as per Stability Indicating Method (SIM) and impurities/ related substances/degradation products had been quantified. |
| 9 | Do you have method for quantifying the impurities in the API? | Yes, firm had method for quantifying the impurities in the API. Dapagliflozin propanediol was tested accordingly. However, results of impurity and related substances of Metformin HCl were taken from manufacturer's COA. |
| 10 | Do you have some remaining quantities of the API, its reference standard and impurities standards? | Yes, some remaining quantities of the APIs, reference standards, impurity standards and working standards were available. |
| 11 | Have you used pharmaceutical grade excipients? | Yes, firm had used pharmaceutical grade excipients. |
| 12 | Do you have documents confirming the import of the used excipients? | Yes, firm had necessary documents confirming the import of the excipients used in product. |
| 13 | Do you have test reports and other records on the excipients used? | Yes, the firm had test reports and other record of the excipients used. |
| 14 | Do you have written and authorized protocols for the development of the product? | Yes, the firm had written and authorized protocols for the development of the product. . |
| 15 | Have you performed Drug-excipient compatibility studies? | Yes, firm had performed drug excipient compatibility studies and all excipients were found compatible with the APIs as per the report provided. |
| 16 | Have you performed comparative dissolution studies? | Yes, firm has performed comparative dissolution studies and the product showed comparable results. |
| 17 | Do you have product development (R&D) section? | Yes, firm had a product development (PD) department. |
| 18 | Do you have necessary equipments available in product development section for development of the product? | Yes, firm had necessary equipment available in product development section for development of the product. Remarks: Firm was advised to upgrade PD laboratory. Firm's management informed that revamping and upgradation of the facility is already under planning. |
| 19 | Are the equipments in product development section qualified? | The equipment in product development section were qualified as informed by the firm. Equipment qualification protocols were available. Two protocols were randomly selected and scrutinized. |
| 20 | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | Yes, firm had a maintenance / calibration / re-qualification program for the whole facility including equipment used in PD section. |
| 21 | Do you have qualified staff in product development section with proper knowledge and training in product development? | Yes, firm had qualified and trained staff in product development section. Training record was seen for the year 2018. |
| 22 | Have you manufactured three stability | Firm had manufactured three stability batches for the |

| | | |
|---|---|---|
| | batches for the stability studies of the product as required? | stability studies of Daplozmet Tablets 5mg/1000mg with Batch No. RD-18072, RD-18073 & RD-18074 (batch size of 2500 tablets). |
| 23 | What was the criteria for fixing the batch size of stability batches? | The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tablets per testing frequency and number of testing frequencies / intervals), minimum working capacity of equipment and DRAP guidelines. |
| 24 | Do you have complete record of production of stability batches? | Yes, firm had complete record of production of stability batches. |
| 25 | Do you have protocols for stability testing of stability batches? | Yes, firm had protocols for stability testing of stability batches. |
| 26 | Do you have developed and validated the method for testing of stability batches? | Yes, firm had developed method used for testing of stability batches. Test method validation protocol and report for identification, assay and content uniformity was available. |
| 27 | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | The method for testing of the product was developed and validated in the firm's premises. |
| 28 | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug? | Yes, firm had documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug product. |
| 29 | Is your method of analysis stability indicating? | Yes, firm's method of analysis was stability indicating and the record of testing of stability batches was available. |
| 30 | Is your HPLC software 21CFR compliant? | Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available. |
| 31 | Can you show Audit Trail reports on product testing? | Audit trail reports were available and randomly checked. |
| 32 | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of some impurity standards and stability batches. |
| 33 | Do you have stability batches kept on stability testing? | The stability studies of trial batches kept at 30˚C/65% RH were on going. |
| 34 | Do you have valid calibration status for the equipments used in production and analysis? | Firm had valid calibration status for the equipment used in production and analysis of the product. |
| 35 | Is proper and continuous monitoring and control available for stability chamber? | Yes, monitoring and control was available for the stability chambers provided.<br>Firm was advised to install alarm system in stability chamber and perform challenge test. |
| 36 | Can related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The related facilities of Highnoon Laboratories Ltd., Lahore were GMP compliant. |

**Conclusion:**

Based on the documents reviewed, areas inspected and technical personnel met, and considering the findings of the inspection, the panel is of the view that stability studies were conducted by the firm M/s Highnoon Laboratories Ltd., 17.5 km Multan Road, Lahore, and relevant data of the products Daplozmet Tablets 5mg/850mg and Daplozmet Tablets 5mg/1000mg (Dapagliflozin as propanediol monohydrate + Metformin HCl) provided by the firm was verified.

**Decision: Registration Board decided to approve registration of "Daplozmet Tablets 5mg/850mg and Daplozmet Tablets 5mg/1000mg (Dapagliflozin as propanediol monohydrate + Metformin HCl)" by M/s Highnoon Laboratories Ltd., 17.5 km Multan Road, Lahore, Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1246. | M/s Bosch Pharmaceuticals (Pvt) Limited,<br>Bosch House, 221, Sector 23, Korangi Industrial Area, Karachi. | Dovir Tablets 30mg<br>Each film coated tablet contains:<br>Daclatasvir (as dihydrochloride) …… 30mg<br>Direct Acting Antivirals (Antivirals for treatment of HCV infections)<br>Manufacturer's Specifications. | Form 5-D<br><br>Dairy No. 2847, Dated 15-12-2016.<br>Rs.50,000/-, Dated 15-12-2016.<br><br>28's/ As per PRC | DAKLINZA daclatasvir tablets by M/s Gilead Sciences, Inc (USFDA approved)<br><br>21-09-2017 GMP and follow up inspection Firm is operating at acceptable level of GMP compliance. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Dovir Tablets 30mg (Daclatasvir) | | |
| Name of Manufacturer | M/s Bosch Pharmaceuticals (Pvt) Limited,<br>Bosch House, 221, Sector 23, Korangi Industrial Area, Karachi. | | |
| Manufacturer of API | M/s Optimus Drugs Private Limited,<br>Survey No. 239 & 240 Dothigudem (V), Pochampally (M), Nalgonda (D), 508284, Telangana, India. | | |
| API Lot No. | DP-850-S3-006/16 | | |
| Description of Pack (Container closure system) | Alu/ alu blister packing. | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 6 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,3,6 (Months)<br>Real Time: 0,3,6 (Months) | | |
| Batch No. | TR-DV-02 | TR-DV-03 | TR-DV-04 |
| Batch Size | 800 Tablets | 800 Tablets | 800 Tablets |
| Manufacturing Date | Nov 2017 | Nov 2017 | Nov 2017 |
| Date of Initiation | 30-11-2017 | 30-11-2017 | 30-11-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 26-07-2018 (Dy. No. 25801) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents to Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA for Daclatasvir (as dihydrochloride) from M/s Optimus Drugs Private Limited, Telangana, India. Has been submitted. |
| 2. | Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer | Firm has submitted copy of the document 'List of products approved under WHO GMP Certification |

| | | |
|---|---|---|
| | issued by regulatory authority of country of origin. | Scehme for Export purpose' issued by DCA Yelangana. Which states the name of Daclatasvir hydrochloride.<br>Document confirms that the firm is GMP compliant.<br>Document is valid till 03-01-2018 |
| 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. | Firm has submitted copy of receipt of Daclatasvir. Firm has imported Daclatasvir from M/s. Optimus drugs (Pvt.) Ltd via FedEx. Batch number: DP-850-S3-006/16 and Quantity: 500gms.<br>Firm has submitted copy of from 6 attested by ADC Karachi confirming import of API.. |
| 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**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1247. | **M/s Bosch Pharmaceuticals (Pvt) Limited,**<br>Bosch House, 221, Sector 23, Korangi Industrial Area, Karachi. | **Dovir Tablets 60mg**<br>Each film coated tablet contains:<br>Daclatasvir (as dihydrochloride) …… 60mg<br><br>Direct Acting Antivirals (Antivirals for treatment of HCV infections)<br>Manufacturer's Specifications. | Form 5-D<br><br>Dairy No. 2850, Dated 15-12-2016.<br>Rs.50,000/-, Dated 15-12-2016.<br><br>28's/ As per PRC | DAKLINZA daclatasvir tablets by M/s Gilead Sciences, Inc (USFDA approved)<br><br>21-09-2017 GMP and follow up inspection Firm is operating at acceptable level of GMP compliance. |

**STABILITY STUDY DATA**

| | |
|---|---|
| Drug | Dovir Tablets 60mg (Daclatasvir) |
| Name of Manufacturer | M/s Bosch Pharmaceuticals (Pvt) Limited,<br>Bosch House, 221, Sector 23, Korangi Industrial Area, Karachi. |
| Manufacturer of API | M/s Optimus Drugs Private Limited,<br>Survey No. 239 & 240 Dothigudem (V), Pochampally (M), Nalgonda (D), 508284, Telangana, India. |
| API Lot No. | DP-850-S3-006/16 |

| | | | |
|---|---|---|---|
| Description of Pack (Container closure system) | Alu/ alu blister packing. | | |
| Stability Storage Condition | Accelerated: 40°C ± 2°C & 75±5%RH<br>Real Time: 30°C ± 2°C & 65±5%RH | | |
| Time Period | Accelerated: 6 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,3,6 (Months)<br>Real Time: 0,3,6 (Months) | | |
| Batch No. | TR-DV-05 | TR-DV-06 | TR-DV-07 |
| Batch Size | 800 Tablets | 800 Tablets | 800 Tablets |
| Manufacturing Date | Nov 2017 | Nov 2017 | Nov 2017 |
| Date of Initiation | 09-12-2017 | 09-12-2017 | 09-12-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 26-07-2018 (Dy. No. 25802) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents to Be Provided | Status |
|---|---|---|
| 1. | COA of API | **Status** |
| 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. | Copy of COA for Daclatasvir (as dihydrochloride) from M/s Optimus Drugs Private Limited, Telangana, India. Has been submitted. |
| 3. | Protocols followed for conduction of stability study and details of tests. | Firm has submitted copy of the document 'List of products approved under WHO GMP Certification Scehme for Export purpose' issued by DCA Yelangana. Which states the name of Daclatasvir hydrochloride.<br>Document confirms that the firm is GMP compliant.<br>Document is valid till 03-01-2018 |
| 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. | Yes |
| 6. | All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents. | Firm has submitted copy of receipt of Daclatasvir. Firm has imported Daclatasvir from M/s. Optimus drugs (Pvt.) Ltd via FedEx. Batch number: DP-850-S3-006/16 and Quantity: 500gms.<br>Firm has submitted copy of from 6 attested by ADC Karachi confirming import of API.. |
| 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**

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Dovir 30mg & 60mg Tablets (Daclatasvir) Tablets by M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.**

**Reference No:** F.13-11/2017-PEC(Pt) dated 10th, December, 2018.
**Investigation Date and Time:** 25th January, 2019 (Afternoon).
**Investigation Site:** Factory premises of M/s. Bosch Pharmaceuticals, Korangi Industrial Area, Karachi.

**Background:**

Chairman Registration Board considered the applications of M/s Bosch Pharmaceutical, Bosch House 221, Sector 23, Korangi Industrial Area, Karachi for registration of Dovir 30mg & 60mg (Daclatasvir) Tablets and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

**Composition of Panel:**

7. Dr. Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Women, Karachi. (Member Registration Board)
8. Dr. Najam us Saquib, Federal Inspector of Drugs, DRAP, Karachi.
9. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under::

**Details of Inspection**

**DOVIR 30MG & 60MG TABLETS**

| S.No. | Question | Observation by panel |
|---|---|---|
| 1 | Do you have documents confirming the import of API ? | The firm has imported 0.5Kg Daclatasvir Batch no: DP-850-S3-006-16 from M/s Optimus Drug Pvt Ltd India and has taken approval from DRAP-Karachi for import |
| 2 | What was the rationale behind selecting the particular manufacturer of API? | There is proper vendor qualification being implemented by the firm which includes GMP Status, provision of DMF, reference standard, impurity standards etc. |
| 3 | Do you have documents confirming the import of API reference standard and impurity standards? | The firm has documents confirming the import of API of said batches working standards and their impurities standards. |
| 4 | Do you have certificate of Analysis of the API, reference standards and impurity standards? | The firm has certificates of analysis for both APIs, working standards and their impurities. |
| 5 | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | The firm has GMP certificate of the manufacturer issued by Drug Control Administration, Govt of Telangana, India |
| 6 | Do you use API manufacturer method of testing? | The firm has used API manufacturer method of testing for both APIs. |
| 7 | Do you have stability studies reports on API? | The firm has stability studies reports on API. |
| 8 | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | The stability testing has been performed as per SIM method and degradation products have been quantified. |
| 9 | Do you have method for quantifying the impurities in the API? | The firm has method for quantifying the impurities in the API. |
| 10 | Do you have some remaining quantities of the API, its reference standard and impurities standards? | The firm has remaining quantities of API, reference standard and impurity standards. |
| 11 | Have you used pharmaceutical grade excipients? | The firm has used pharmaceutical grade excipients. |
| 12 | Do you have documents confirming the import of the used excipients? | The firm has documents confirming the import of all excipients used. |
| 13 | Do you have test reports and other records on the excipients used? | The firm has test reports and other records on the excipients used. |
| 14 | Do you have written and authorized protocols for the development of API tablets? | The firm has written and authorized protocols for the development of Dovir (Daclatasvir) 30mg & 60mg tablets. |

| S.No. | Question | Observation by panel |
|---|---|---|
| 15 | Have you performed Drug-excipient compatibility studies? | Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator. |
| 16 | Have you performed comparative dissolution studies? | The firm has performed comparative dissolution studies and their product has shown comparable dissolution profile. |
| 17 | Do you have product development (R&D) section | The firm has product development (R&D) section with equipment for manufacturing of tablet dosage form and analytical lab for test/ analysis of R&D and stability batches. |
| 18 | Do you have necessary equipment available in product development section for development of API tablets? | The firm has necessary equipment for product development of Dovir tablets. |
| 19 | Are the equipment in product development section qualified? | The available equipment in product development section are qualified. |
| 20 | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | The firm has SOP for the maintenance/calibration/requalification of equipment used on PD section. |
| 21 | Do you have qualified staff in product development section with proper knowledge and training in product development? | The firm has qualified staff in product development section with relevant work experience. |
| 22 | Have you manufactured three stability batches for the stability studies of API tablets as required? | The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Dovir tablet<br>Dovir Tablet 30mg ( TR-DV-02 , TR-DV-03 , TR-DV-04 )<br>Dovir Tablet 60mg ( TR-DV-05, TR-DV-06, TR-DV-07 ) |
| 23 | What was the criteria for fixing the batch size of stability batches? | The criteria for fixing the batch size of stability batches is the number of tablets per testing and the number of tablets required for whole stability testing. |
| 24 | Do you have complete record of production of stability batches? | The firm has complete record of production of stability batches. Necessary log books of equipment used has been available with the firm. |
| 25 | Do you have protocols for stability testing of stability batches? | The firm has detailed protocol for stability testing of stability batches. |
| 26 | Do you have developed and validated the method for testing of stability batches? | The firm has developed and validated their own method for testing of stability batches. The method is supported by impurities standards spiking studies and forced degradation, hence capable of quantifying the degradation products in their tablets kept on stability testing. |
| 27 | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | Not Applicable |
| 28 | Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug? | The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug. |
| 29 | Do your method of analysis stability indicating? | The firm's method of analytical testing has stability indicating parameters. |
| 30 | Do your HPLC software is 21CFR compliant? | The HPLC software is 21CFR Compliant as per record available with the firm. |
| 31 | Can you show Audit Trail reports on API testing? | The firm showed the audit trail reports on API testing. |
| 32 | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of stability batches. |

| S.No. | Question | Observation by panel |
|---|---|---|
| 33 | Do you have commitment batches kept on stability testing? | The firm has completed accelerated stability testing on the three stability batches of both strengths. The real time stability testing is in progress on all the three stability batches. |
| 34 | Do you have valid calibration status for the equipment used in API tablets production in analysis? | The firm has valid calibration status for the equipment used in Dovir tablets production and analysis. |
| 35 | Do proper and continuous monitoring and control are available for stability chamber? | Continuous power supply and monitoring are available for stability chambers. |
| 36 | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant. |

**Conclusions:**

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Dovir 30mg & 60mg (Daclatasvir) Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Dovir 30mg & 60mg Tablets.

**Recommendations**:

**1.** The firm may kindly be granted necessary registration of Dovir 30mg & 60mg tablets**.**

**Decision: Registration Board decided to approve registration of "Dovir 30mg Tablets & Dovir 60mg Tablets (Daclatasvir (as dihydrochloride) Tablets" by M/s Bosch Pharmaceuticals (Pvt) Ltd.,Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

**Evaluator PEC-XIV**

| 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<br><br>GMP Inspection Report Date & Remarks | Previous DRB Decision / Remarks (if any) |
|---|---|---|---|---|---|
| 1248. | M/s Highnoon Laboratories limited. 17.5 Kilometer, Multan Road, Lahore | Nebvax 5/80 mg Tablet<br>Each film coated tablet contains:<br>Nebivolol as Hydrochloride.....5mg<br>Valsartan ……80mg<br>Anti-Hypertensive<br><br>(Manufacturers specifications) | Form 5D<br>Dy. No.21689<br>21-06-2018<br>Rs.50,000/-,<br><br>(Duplicate Dossier)<br><br>14's, 30's, 60's;<br>As per SRO | Byvalson of M/s Allergan sales, **USFDA**<br><br>**N/A**<br>Last GMP inspection dated 06-07-2017; firm is considered to be operating at Good level of compliance of GMP requirements at the time of inspection. | The firm has claimed Manufacturer's Specifications. |

| STABILITY STUDY DATA | |
|---|---|
| Drug | Nebvax 5/80 mg Tablet |
| Name of Manufacturer | M/S Highnoon Laboratories limited |
| Manufacturer of API | Valsartan: M/s. Zhejiang Tianyu Pharmaceuticals Co. Ltd. China<br>Nebivolol HCl: M/s. Cadila Pharmaceuticals Ltd, 294, G.I.D.C, Estate Ankleshawar-3293002, Gujrat India |
| API Lot No. | Valsartan: 10230-161204<br>Valsartan: 10230-161117<br>Valsartan: 10230-161116 |

| | | | |
|---|---|---|---|
| | Nebivolol HCl: 17NV011 | | |
| Description of Pack (Container closure system) | Alu/Alu Blister in outer unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months<br>Real Time: 09 Months | | |
| Frequency | Accelerated: 0,3,6 (Months)<br>Real Time: 0,3,6,9 (Months) | | |
| Batch No. | RD 17091 | RD 17092 | RD 17093 |
| Batch Size | 4000 Tablets | 4000 Tablets | 4000 Tablets |
| Manufacturing Date | August-2017 | August-2017 | August-2017 |
| Date of Initiation | September-2017 | September-2017 | September-2017 |
| No. of Batches | 3 | | |
| Date of Submission | 21-06-2018 (Dy. No. 21689) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | **Valsartan:** Copy of COA from M/s Zhejiang Tiianyu Pharmaceuticals, China is submitted<br>**Nebivolol HCl:** Copy of COA from M/s Cadila Pharmaceuticals Ltd, India 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. | **Valsartan:** Copy of GMP of M/s Zhejiang Tianyu Pharmaceuticals, China (Certificate No. ZJ20130111) issued by State Food and Drug Administration has been submitted.<br>**Nebivolol HCl:** Copy of GMP of M/s Cadila Pharmaceuticals Certificate No.16061158 6078745 issued by Food & Drug control Adminstration, Gujarat Estate. India is submitted |
| 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. | **Valsartan:** Copy of ADC (Lahore) attested dated: 27-04-2017 Commercial Invoice No TY117257 Dated: 17-05-2017 issued by M/s Zhejiang Tianyu Pharmaceuticals is submitted.<br>**Nebivolol HCl:** Copy of ADC (Lahore) attested dated: 16-06-2017 Commercial Invoice No CPL/BD/123/17-18 Dated: 14-06-2017 issued by M/s Cadila Pharmaceuticals Ltd is submitted. |
| 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(VI)**

- The firm has provided 06 Months Accelerated and 09 Months Real Time Stability Data for 03 Batches.
- The firm has procured Valsartan from M/s Zhejiang Tianyu Pharmaceuticals, China.
- EMA has updated on medicines containing valsartan from Zhejiang Tianyu, China.
  "*Company no longer authorised to manufacture valsartan active substance for EU medicines due to presence of NDMA".*
  https://www.ema.europa.eu/documents/press-release/update-medicines-containing-valsartan-zhejiang-tianyu_en.pdf

**Previous Decision:** Registration Board deferred the case for impurity profiling for identification of NDMA levels in the procured valsartan from Zhejiang Tianyu, China. **(M-285)**

- The firm has submitted calculation comparison for maximum level of NDMA in finished product Nebvax 5/80mg tablet as well as FDA acceptable intake limit by consuming finished products as shown in table below;

| **Calculations for Maximum Level of NDMA in finished product Nebvax 5/80mg Tablet** | |
|---|---|
| **NDMA in Valsartan (API)** | |
| Provisional Acceptable Limit of NDMA in API (Valsartan) | 0.3ppm or 0.3 µg/g or 0.3 nanogram/mg<br>1ppm = 1 µg/g = 1 nanogram /mg |
| Max NDMA in Valsartan from API Manufacturer Zhejiang Tianyu Pharmaceutical Co. Ltd., China | NMT 0.3 ppm<br>(NMT 0.3 ppm or 0.3 µg/ g or 0.3 nanogram/mg) |
| FDA acceptable intake Limit of NDMA by consuming Finished products | 0.096 µg/Day or 96 nanogram/day |
| Quantity of Valsartan in Nebvax 5/80mg Tablet | 80mg /Tablet |
| Maximum daily dose of Nebvax 5/80mg Tablet | 1 Tablet / Day |
| Daily intake of Valsartan by consuming maximum dose of Nebvax 5/80mg Tablet | 80mg / Day |
| Maximum Qty of NDMA in Valsartan as confirmed by API manufacturer | 1 Tablet / Day |
| Maximum daily intake of NDMA by consuming Nebvax 5/80mg Tablets | 80 mg × 0.3 nanogram/mg = 24 nanogram |
| Conclusion | Per day quantity of NDMA in Nebvax tablet is 1/4$^{th}$ of FDA acceptable limit. |

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**INSPECTION REPORT OF HIGHNOON LABORATORIES LTD, LAHORE**

**General Information**

| | |
|---|---|
| **Name of Manufacturer** | M/s Highnoon Laboratories Ltd. |
| **Physical Address** | 17.5 km Multan Road, Lahore |
| **DML No. and Validity** | DML by way of formulation. No. 00155<br>Date of renewal: 20-08-2015 |
| **Date of Inspection** | 1$^{st}$ January, 2019 |
| **Purpose of Inspection** | Panel inspection for verification of authenticity of stability data for purpose of registration of drugs with reference to DRAP Islamabad letter No. F.13-11/2017-PEC (Pt) dated 14$^{th}$ December, 2018 |
| **Name of Inspectors** | Mr Asim Rauf (Additional Director, DRAP, Lahore)<br>Ms Uzma Barkat (Area Federal Inspector of Drugs, Lahore)<br>Mr Shahrukh Ali (Assistant Director, DRAP, Lahore) |
| **Name of firm representatives accompanying during inspection** | Dr Saleem Akhter (Director, Quality Operations)<br>Ms Azia Zafar (Head of Quality Control & Validation)<br>Ms Irum Naila (Head of Regulatory Affairs)<br>Ms Noureen Afzal (Head of Product Development)<br>Dr Muhammad Saqlain Tahir (Head of Quality Assurance)<br>Mr Shahid Rashid (Head of Compliance & Audit)<br>Mr Muhammad Asif (Manager Quality Control)<br>Mr Fahd Ali (Manager Stability) |

**Focus of Inspection**

The inspection of M/s Highnoon Laboratories Ltd., Lahore was conducted with reference to DRAP Islamabad letter no. F.13-11/2017-PEC (Pt) dated 14$^{th}$ December, 2018, for verification of authenticity of stability data of product namely Nebvax Tablets 5mg/80mg. The panel evaluated the relevant documentation and also visited the production area, product development laboratory and quality control laboratory of the company.

The data of was evaluated in accordance with the checklist provided as given below.

**Details of Investigation**

**NEBVAX TABLETS 5/80mg (Nebivolol as HCl + Valsartan)**

| Sr. No. | Question | Observation by the panel |
|---|---|---|
| 1. | Do you have documents confirming the import of API? | Firm had imported Nebivolol HCl from M/s Cadila Pharmaceutical, India and Valsartan from M/s Zhejiang |

| | | |
|---|---|---|
| | | Tianyu Pharmaceutical, China. Invoices for import attested by AD (I&E) were also seen. |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | Firm has a vendor approval system and according to the firm, the rationale behind selecting the manufacturer is its GMP status and evaluation as per SOP for vendor approval. (Firm was using Nebivolol HCl and Valsartan from same sources in their other products also.) |
| 3. | Do you have documents confirming the import of reference standard and impurity standards? | Documentary evidence related to purchase of reference standard was available. Impurity standards were not procured yet. |
| 4. | Do you have certificate of Analysis of the API, reference standards and impurity standards? | Relevant COAs from principal manufacturer were seen. |
| 5. | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | Yes, firm had GMP certificate of both API manufacturers issued by regulatory authority of their respective country of origin. |
| 6. | Do you use API manufacturer method of testing? | Yes, firm used API manufacturer`s method of testing for Nebivolol HCl and compendial method for Valsartan. |
| 7. | Do you have stability studies reports on API? | Yes, firm had stability studies reports on API as provided by the manufacturer |
| 8. | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | Yes, stability testing had been performed as per Stability Indicating Method (SIM) and impurities/ related substances/degradation products had been quantified. |
| 9. | Do you have method for quantifying the impurities in the API? | Yes, firm had method for quantifying the impurities in the API.<br>However, firm had taken specific results of related substances A, B and C of Valsartan from manufacturer's COA. Firm had performed test for assessing individual and total percentage of related substances by area normalization method and results were found to be within limits prescribed in USP.<br>Impurities in Nebivolol HCl were assessed by using relative retention time given by the API manufacturer.<br>The firm informed that clarification for N-NDMA presence in Valsartan from the said source had been submitted to the concerned division by the firm and had been evaluated by concerned division as given in summary of case provided by PE&R Division alongwith the inspection letter No. F.13-11/2017-PEC (Pt) dated 14th December, 2018. |
| 10. | Do you have some remaining quantities of the API, its reference standard and impurities standards? | Yes, APIs were available however, no remaining quantities of reference standards were available. |
| 11. | Have you used pharmaceutical grade excipients? | Yes, firm had used pharmaceutical grade excipients. |
| 12. | Do you have documents confirming the import of the used excipients? | Yes, firm had necessary documents confirming the import of the excipients used in product. |
| 13. | Do you have test reports and other records on the excipients used? | Yes, the firm had test reports and other record of the excipients used. |
| 14. | Do you have written and authorized protocols for the development of the product? | Yes, the firm had written and authorized protocols for the development of the product. |
| 15. | Have you performed Drug-excipient compatibility studies? | Yes, firm had performed drug excipient compatibility studies and all excipients were found compatible with the APIs as per the report provided. |
| 16. | Have you performed comparative dissolution studies? | Yes, firm has performed comparative dissolution studies and the product showed comparable results. |
| 17. | Do you have product development (R&D) section? | Yes, firm had a product development (PD) department. |

| | | |
|---|---|---|
| 18. | Do you have necessary equipments available in product development section for development of the product? | Yes, firm had necessary equipment available in product development section for development of the product.<br>Remarks: Firm was advised to upgrade PD laboratory. Firm's management informed that revamping and upgradation of the facility is already under planning. |
| 19. | Are the equipments in product development section qualified? | The equipment in product development section were qualified as informed by the firm. Equipment qualification protocols were available. Two protocols were randomly selected and scrutinized. |
| 20. | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | Yes, firm had a maintenance / calibration / re-qualification program for the whole facility including equipment used in PD section. |
| 21. | Do you have qualified staff in product development section with proper knowledge and training in product development? | Yes, firm had qualified and trained staff in product development section. Training record was seen for the year 2018. |
| 22. | Have you manufactured three stability batches for the stability studies of the product as required? | Firm had manufactured three stability batches for the stability studies of Nebvax Tablets 5mg/80mg with Batch No. RD-17091, RD-17092 & RD-17093 (batch size of 4000 tablets). |
| 23. | What was the criteria for fixing the batch size of stability batches? | The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tablets per testing frequency and number of testing frequencies / intervals), minimum working capacity of equipment and DRAP guidelines. |
| 24. | Do you have complete record of production of stability batches? | Yes, firm had complete record of production of stability batches. |
| 25. | Do you have protocols for stability testing of stability batches? | Yes, firm had protocols for stability testing of stability batches. |
| 26. | Do you have developed and validated the method for testing of stability batches? | Yes, firm had developed method for testing of stability batches. Test method validation protocol and report for identification, assay and content uniformity was available. |
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | The method for testing of the product was developed and validated in the firm's premises. |
| 28. | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug? | Yes, firm had documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug product. |
| 29. | Is your method of analysis stability indicating? | Yes, firm's method of analysis was stability indicating and the record of testing of stability batches was available. |
| 30. | Is your HPLC software 21CFR compliant? | Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available. |
| 31. | Can you show Audit Trail reports on product testing? | Audit trail reports were available and randomly checked. |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | The firm had remaining quantities of stability batches. |
| 33. | Do you have stability batches kept on stability testing? | The stability studies of trial batches kept at 30˚C/65% RH were on going. |
| 34. | Do you have valid calibration status for the equipments used in production and analysis? | Firm had valid calibration status for the equipment used in production and analysis of the product. |
| 35. | Is proper and continuous monitoring and control available for stability chamber? | Yes, monitoring and control was available for the stability chambers provided.<br>Firm was advised to install alarm system in stability chamber and perform challenge test. |

| | | |
|---|---|---|
| 36. | Can related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The related facilities of Highnoon Laboratories Ltd., Lahore were GMP compliant. |

**CONCLUSION**

Based on the documents reviewed, areas inspected and technical personnel met, and considering the findings of the inspection, the panel is of the view that stability studies were conducted by the firm M/s Highnoon Laboratories Ltd., 17.5 km Multan Road, Lahore, and relevant data of the product Nebvax Tablets 5mg/80mg (Nebivolol as Hydrochloride + Valsartan) provided by the firm was verified.

**Decision: Registration Board decided to approve registration of "Nebvax Tablets 5mg/80mg (Nebivolol as Hydrochloride + Valsartan)" by M/s Highnoon Laboratories Ltd., 17.5 km Multan Road, Lahore. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1. | M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore, Pakistan. | Zaniprill Tablets 10/10mg<br>Each film coated tablet contains:<br>Enalapril maleate….10mg<br>Lercanidipine HCl….10mg<br>(ACE Inhibitor/CCB) | Form 5-D<br>13-5-2016<br>PKR 50,000/-<br>(DUPLICATE)<br>1x10's<br>(As per SRO) | Zaneril Tablets by Recordati Pharmaceuticals (**MHRA** Approved)<br><br>13-4-2017: Panel recommends renewal of DML |

**Remarks of Evaluator:**
The firm has submitted stability study data along with required documents as per checklist approved in 251st meeting of Registration Board. Detailsof submitted data are as under:
**(Dy.# 2566 dated 19-1-2018)**

**STABILITY STUDY DATA**

| | | |
|---|---|---|
| Drug | Zaniprill Tablets 10/10mg | |
| Name of Manufacturer | M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore, Pakistan. | |
| Manufacturer of API | **Enalapril Maleate:** | Zhejiang Huahai Pharmaceutical Co. Ltd., China |
| | **Lercanidipine hydrochloride:** | Recordati Industria Chimica E Farmaceutica S.p.A. Mfg site: Campoverde Via Mediana Cisterna, 4 04011 Campoverde Di Aprilia, Italy. |
| API Lot No. | **Enalapril Maleate:** | 5112-17-059 |
| | **Lercanidipine hydrochloride:** | 17100694 |
| Description of Pack (Container closure system) | Opaque PVDC blisters sealed with aluminium foil | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 65% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | |
| Time Period | Real time: 26 weeks<br>Accelerated: 26 weeks | |

| | | | |
|---|---|---|---|
| Frequency | Accelerated: 0,1,2,3,4,6,8,10,12,16,20,24,26 (Weeks)<br>Real Time: 0,1,2,3,4,6,8,10,12,16,20,24,26 (Weeks) | | |
| Batch No. | T0106M | T0206M | T0306M |
| Batch Size | 10,000 Tablet | 10,000 Tablet | 10,000 Tablet |
| Manufacturing Date | June-2017 | June-2017 | June-2017 |
| Date of Initiation | 26-02-2018 | 26-02-2018 | 26-02-2018 |
| No. of Batches | 03 | | |
| Date of Submission | **Dy.# 24476 dated 14-12-2017** | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| # | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | **Enalapril Maleate:** Copy of GMP certificate issued by State Food & Drug Administration, China valid upto 25-09-2019 has been submitted for Enalapril. |
| | | **Lercanidipine hydrochloride:** Firm has submitted copy of Eudra GMP certificate based on inspection conducted on 16-9-2016. The certificate has been verified online from Eudra GMP database. |
| 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. | **Enalapril Maleate:** Firm has submitted invoice of Gudia (Pvt) Ltd stating that their vendor has brought the substance from China and have not submitted any ADC attested invoice. |
| | | **Lercanidipine hydrochloride:** Firm has submitted ADC attested commercial invoice dated 12-02-2016, confirming import of API (micronized) 5Kg. |
| 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**

- Firm has initially submitted ADC attested invoice for import of Lercanidipine hydrochloride dated 30-3-2018, later the firm has submitted another invoice of Lercenadipine hydrochloride which was cleared on 12-02-2016. Panel may be requested to verify the exact batch of API used from the dispensing and quality control log books.
- Firm has manufactured the stability batches in June 2017 and the stability studies were initiated in February 2018. The Panel may verify the exact temperature and humidity conditions at which the batches were kept during this time period before initiation of stability studies.
- Firm has initially submitted invoice of Gudia (Private) Limited Ref No. ZHP/008/2017 dated 3rd June 2017 confirming import of 500g enalapril maleate Batch No. 5112-17-059 and 100mg working standard Batch No. 2014-199 through DHL. Upon clarification of DHL invoice without ADC clearance and provision of tracking number of DHL, the firm submitted that their supplier took the material from principal in their China visit. The firm submitted another copy of invoice of Gudia (Private) Limited with same details of batch number and quantity but without any reference number, date and with different signatures. The panel may be requested to verify the details of the import of enalapril maleate including batch number of the imported API along with

exact date of import.

- Firm has used different dissolution media for both API as per the following details:

| API | **Specifications provided by the firm** | **USP specification** |
|---|---|---|
| Enalapril maleate | **Apparatus:** Paddle<br>**Speed:** 50rpm<br>**Medium:** RO Water<br>**Volume:** 900ml<br>**Time:** 30 mins<br>**Acceptance criteria:** NLT 70% in 30 min | **Apparatus:** Paddle<br>**Speed:** 50rpm<br>**Medium:** pH 6.8 phosphate buffer<br>**Volume:** 900ml<br>**Time:** 30 mins<br>**Acceptance criteria:** NLT 80% (Q) of labelled amount of $C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$ in 30 min |
| Lercanidipine hydrochloride | **Apparatus:** Paddle<br>**Speed:** 50rpm<br>**Medium:** 0.3% w/v polysorbate 80 in 0.1N HCl (freshly prepared)<br>**Volume:** 900ml<br>**Time:** 45 mins<br>**Acceptance criteria:** NLT 70% in 45 min | Not available in any official pharmacopoeia |

- While the USP general chapter <1092> The Dissolution Procedure: Development and Validation states that "Purified water is often used as the dissolution medium, but is not ideal for several reasons. First, the quality of water can vary depending on the source of the water, and the pH value of the water is not controlled. Second, the pH value can vary from day to day and can also change during the run, depending on the active substance and excipients". Further it recommends that solubility of the drug along with profiling of drug release in the dissolution media needs to be performed for selection of suitable dissolution medium. The panel may determine the scientific rationale behind selection of two different dissolution media and its scientific and regulatory importance in predicting the in vivo drug release properties.
- Scientific rational behind adaptation of acceptance criteria as NLT 70% while the USP general chapter <1092> The Dissolution Procedure: Development and Validation states that " Typical acceptance criteria for the amount of active ingredient dissolved, expressed as a percentage of the labeled content (Q), are in the range of 75% to 80% dissolved"

| **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**<br><br>**GMP Inspection Report Date & Remarks** |
|---|---|---|---|---|
| 2. | M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore, Pakistan. | Zaniprill Tablets 20/10mg<br>Each film coated tablet contains:<br>Enalapril maleate….20mg<br>Lercanidipine HCl….10mg<br>(ACE Inhibitor/CCB) | Form 5-D<br>13-5-2016<br>PKR 50,000/-<br>(DUPLICATE)<br>2x7's, 4x7's<br>(As per SRO) | Zaneril Tablets by Recordati Pharmaceuticals (**MHRA** Approved)<br><br>13-4-2017: Panel recommends renewal of DML |
| | **Remarks of Evaluator:**<br>The firm has submitted stability study data along with required documents as per checklist approved in 251st meeting of Registration Board. Detailsof submitted data are as under:<br>**(Dy.# 2565 dated 19-1-2018)** | | | |

**STABILITY STUDY DATA**

| | | |
|---|---|---|
| Drug | Zaniprill Tablets 20/10mg | |
| Name of Manufacturer | M/s Pacific Pharmaceuticals Ltd., 30 Km Multan Road, Lahore, Pakistan. | |
| Manufacturer of API | **Enalapril Maleate:** | Zhejiang Huahai Pharmaceutical Co. Ltd., China |

| | | | |
|---|---|---|---|
| | **Lercanidipine hydrochloride:** | Recordati Industria Chimica E Farmaceutica S.p.A. Mfg site: Campoverde Via Mediana Cisterna, 4 04011 Campoverde Di Aprilia, Italy. | |
| API Lot No. | **Enalapril Maleate:** | 5112-17-059 | |
| | **Lercanidipine hydrochloride:** | 17100694 | |
| Description of Pack (Container closure system) | Opaque PVDC blisters sealed with aluminum foil | | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 65% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| Time Period | Real time: 26 weeks<br>Accelerated: 26 weeks | | |
| Frequency | Accelerated: 0,1,2,3,4,6,8,10,12,16,20,24,26 (Weeks)<br>Real Time: 0,1,2,3,4,6,8,10,12,16,20,24,26 (Weeks) | | |
| Batch No. | T0106M | T0206M | T0306M |
| Batch Size | 10,000 Tablet | 10,000 Tablet | 10,000 Tablet |
| Manufacturing Date | Jun-2017 | Jun-2017 | Jun-2017 |
| Date of Initiation | 26-02-2018 | 26-02-2018 | 26-02-2018 |
| No. of Batches | 03 | | |
| Date of Submission | **Dy.# 24476 dated 14-12-2017** | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| # | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | **Enalapril Maleate:** Copy of GMP certificate issued by State Food & Drug Administration, China valid upto 25-09-2019 has been submitted for Enalapril. |
| | | **Lercanidipine hydrochloride:** Firm has submitted copy of Eudra GMP certificate based on inspection conducted on 16-9-2016. The certificate has been verified online from Eudra GMP database. |
| 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. | **Enalapril Maleate:** Firm has submitted invoice of Gudia (Pvt) Ltd stating that their vendor has brought the substance from China and have not submitted any ADC attested invoice. |
| | | **Lercanidipine hydrochloride:** Firm has submitted ADC attested commercial invoice dated 12-02-2016, confirming import of API (micronized) 5Kg. |
| 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, | Yes |

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|---|---|---|
| | 1978. | |

**REMARKS OF EVALUATOR**

- Firm has initially submitted ADC attested invoice for import of Lercanidipine hydrochloride dated 30-3-2018, later the firm has submitted another invoice of Lercanadipine hydrochloride which was cleared on 12-02-2016. Panel may be requested to verify the exact batch of API used from the dispensing and quality control log books.
- Firm has manufactured the stability batches in June 2017 and the stability studies were initiated in February 2018. The Panel may verify the exact temperature and humidity conditions at which the batches were kept during this time period before initiation of stability studies.
- Firm has initially submitted invoice of Gudia (Private) Limited Ref No. ZHP/008/2017 dated 3rd June 2017 confirming import of 500g Enalapril maleate Batch No. 5112-17-059 and 100mg working standard Batch No. 2014-199 through DHL. Upon clarification of DHL invoice without ADC clearance and provision of tracking number of DHL, the firm submitted that their supplier took the material from principal in their China visit. The firm submitted another copy of invoice of Gudia (Private) Limited with same details of batch number and quantity but without any reference number, date and with different signatures. The panel may be requested to verify the details of the import of enalapril maleate including batch number of the imported API along with exact date of import.
- Firm has used different dissolution media for both API as per the following details:

| API | Specifications provided by the firm | USP specification |
|---|---|---|
| Enalapril maleate | **Apparatus:** Paddle<br>**Speed:** 50rpm<br>**Medium:** RO Water<br>**Volume:** 900ml<br>**Time:** 30 mins<br>**Acceptance criteria:** NLT 70% in 30 min | **Apparatus:** Paddle<br>**Speed:** 50rpm<br>**Medium:** pH 6.8 phosphate buffer<br>**Volume:** 900ml<br>**Time:** 30 mins<br>**Acceptance criteria:** NLT 80% (Q) of labelled amount of $C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$ in 30 min |
| Lercanidipine hydrochloride | **Apparatus:** Paddle<br>**Speed:** 50rpm<br>**Medium:** 0.3% w/v polysorbate 80 in 0.1N HCl (freshly prepared)<br>**Volume:** 900ml<br>**Time:** 45 mins<br>**Acceptance criteria:** NLT 70% in 45 min | Not available in any official pharmacopoeia |

- While the USP general chapter <1092> The Dissolution Procedure: Development and Validation states that "Purified water is often used as the dissolution medium, but is not ideal for several reasons. First, the quality of water can vary depending on the source of the water, and the pH value of the water is not controlled. Second, the pH value can vary from day to day and can also change during the run, depending on the active substance and excipients". Further it recommends that solubility of the drug along with profiling of drug release in the dissolution media needs to be performed for selection of suitable dissolution medium. The panel may determine the scientific rationale behind selection of two different dissolution media and its scientific and regulatory importance in predicting the in vivo drug release properties.
- Scientific rational behind adaptation of acceptance criteria as NLT 70% while the USP general chapter <1092> The Dissolution Procedure: Development and Validation states that " Typical acceptance criteria for the amount of active ingredient dissolved, expressed as a percentage of the labeled content (Q), are in the range of 75% to 80% dissolved"

**INSPECTION REPORT OF PACIFIC PHARMACEUTICALS LTD, LAHORE**

**General Information**

| | |
|---|---|
| **Name of Manufacturer** | M/s Pacific Pharmaceuticals Ltd. |
| **Physical Address** | 30 km Multan Road, Lahore |
| **DML No. and Validity** | DML by way of formulation. No. 000295 |
| **Date of Inspection** | 28th January, 2019 |
| **Purpose of Inspection** | Panel inspection for verification of authenticity of stability data for purpose of registration of drugs with reference to DRAP Islamabad letter No. F.13-11/2017-PEC (Pt) dated 4th December, 2018 |

| | |
|---|---|
| **Name of Inspectors** | Mr Asim Rauf (Additional Director, DRAP, Lahore)<br>Ms Uzma Barkat (Area Federal Inspector of Drugs, Lahore)<br>Mr Hafiz Ahsan (Assistant Director,PEC, DRAP, Islamabad) |
| **Name of firm representatives accompanying during inspection** | Mr Ahmad Junaid (Quality Control In charge)<br>Mr Ghazi Mustansar Riaz (Quality Assurance In charge)<br>Mr Farhan Bhatti (Dy. Compliance Manager) |

**Focus of Inspection**

The inspection of M/s Pacific Pharmaceuticals Ltd., Lahore was conducted with reference to DRAP Islamabad letter no. F.13-11/2017-PEC (Pt) dated 4th December, 2018, for verification of authenticity of stability data of products namely Zaniprill Tablets 10/10mg and Zaniprill Tablets 10/20mg. The panel evaluated the relevant documentation and also visited the production area, product development laboratory and quality control laboratory of the company. The data of both products was evaluated in accordance with the checklist provided as given below.

**Details of Investigation**

**A. ZANIPRILL TABLETS 10/10mg (Lercanidipine HCl and Enalapril maleate)**

| Sr. No. | Question | Observation by the panel |
|---|---|---|
| 1. | Do you have documents confirming the import of API? | Firm had imported Lercanidipine HCl from M/s Recordati, Ireland and Enalapril maleate from M/s Zhejiang Huahai Pharmaceutical Co. Ltd., China. Copy of invoice for import attested by AD (I&E), DRAP, Lahore issue no. 2355/2016-DRAP dated 15-02-2016 was provided by firm. Enalapril Maleate was imported through M/s Gudia Pvt Ltd, Lahore and firm showed copy of a letter from M/s Gudia whereby it was stated that the principal handed over Enalapril maleate sample 1000gm and working standard 100mg to them for onward submission to M/s Pacific Pharmaceuticals, Lahore. No other document related to import was available. It was counter checked from QC sample incoming log book. |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | Firm had been importing Lercanidipine from the same manufacturer since many years for use in their registered product.<br>Firm's management informed that the manufacturer for Enalapril maleate was selected through their vendor approval system. |
| 3. | Do you have documents confirming the import of reference standard and impurity standards? | Firm had Lercanidipine working standard and impurity standards (obtained from Recordati, Ireland).<br>Working standard of Enalapril was obtained from the principal manufacturer through Gudia Private whereas secondary standard was obtained from Sigma-Aldrich. Impurity standards of Enalapril maleate were not procured. |
| 4. | Do you have certificate of Analysis of the API, reference standards and impurity standards? | Relevant COAs from principal manufacturer were seen. |
| 5. | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | Yes, firm had GMP certificate of both API manufacturers issued by regulatory authority of the country of origin. |
| 6. | Do you use API manufacturer method of testing? | Firm used API manufacturer`s method of testing for Lercanidipine. Firm imported Enalapril maleate USP but method of testing applied was from BP monograph. |
| 7. | Do you have stability studies reports on API? | Firm had stability studies reports on API as provided by the manufacturer.<br>However, for Lercanidipine 12 months accelerated and 24 months real time stability studies report was available. For Enalapril 6 months accelerated and 18 months real time stability studies report was available. |

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|---|---|---|
| 8. | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | Yes, stability testing had been performed by the manufacturer as per Stability Indicating Method (SIM) and degradation products had been quantified. |
| 9. | Do you have method for quantifying the impurities in the API? | Yes, firm had method obtained from manufacturer for quantifying the impurities in the API. Lercanidipine was tested accordingly.<br>However, impurity testing was not performed for Enalapril maleate by the firm. |
| 10. | Do you have some remaining quantities of the API, its reference standard and impurities standards? | Yes, some remaining quantities of the working standards and impurity standards of Lercanidipine were available. |
| 11. | Have you used pharmaceutical grade excipients? | Yes, firm had used pharmaceutical grade excipients. |
| 12. | Do you have documents confirming the import of the used excipients? | Yes, firm had necessary documents confirming the import of the excipients used in product. |
| 13. | Do you have test reports and other records on the excipients used? | Yes, the firm had test reports and other record of the excipients used. |
| 14. | Do you have written and authorized protocols for the development of the product? | The firm had written and authorized formulation development report available for the product. |
| 15. | Have you performed Drug-excipient compatibility studies? | Yes, firm had performed drug-excipient compatibility studies and excipients were found compatible with the APIs as per the report provided. |
| 16. | Have you performed comparative dissolution studies? | No, firm had not performed comparative dissolution studies. |
| 17. | Do you have product development (R&D) section? | Yes, firm had R&D department. |
| 18. | Do you have necessary equipments available in product development section for development of the product? | At the time of inspection, renovation/upgradation was in progress in the R&D lab and relevant equipment were not installed. However, firm's management informed that they had the necessary equipment which were currently decommissioned due to revovation of the lab. |
| 19. | Are the equipments in product development section qualified? | At the time of inspection, renovation/upgradation was in progress in the R&D lab and relevant equipment were not installed. |
| 20. | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | Yes, firm informed that they had a maintenance / calibration / re-qualification program for the whole facility including equipment used in PD section. |
| 21. | Do you have qualified staff in product development section with proper knowledge and training in product development? | Yes, firm had qualified and trained staff in product development section. Training record was available..<br>Firm was advised to further impart product development specific training to their R&D team. |
| 22. | Have you manufactured three stability batches for the stability studies of the product as required? | Firm had manufactured three stability batches for the stability studies of Zaniprill Tablets 10/10mg with Batch No T0106M, T0206M and T0306M. (batch size of 10,000 tablets). |
| 23. | What was the criteria for fixing the batch size of stability batches? | The criteria for fixing the batch size of stability batches, as informed by the firm was one tenth of proposed commercial size batch. |
| 24. | Do you have complete record of production of stability batches? | Yes, firm had complete record of production of stability batches. |
| 25. | Do you have protocols for stability testing of stability batches? | Yes, firm had protocols for stability testing of stability batches. |
| 26. | Do you have developed and validated the method for testing of stability batches? | Firm had taken method for assay and dissolution testing from the method of their existing product Lercanidipine tablets having method and acceptance limits provided by M/s Recordati.<br>For assay of Enalapril maleate in tablets, testing method was taken from BP monograph of Enalapril maleate |

| | | |
|---|---|---|
| | | tablets. Parameters for dissolution and acceptance criteria were taken from BP monograph of Enalapril maleate tablets but quantification was done through UV/VIS spectrophotometry using in house developed method.<br>Four analytical method validation reports were available. One each for quantitative assay of Lercanidipine HCl and Enalapril maleate and one each for dissolution of each API in finished product. The parameter of robustness of method was not mentioned in validation reports. |
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | The method transfer studies were not available. |
| 28. | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug? | Yes, firm had documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug product. |
| 29. | Is your method of analysis stability indicating? | The BP monograph of Enalapril tablets gives a stability indicating method but it was seen that BP monograph of Enalapril tablets was not completely adopted by the firm for finished product testing. Related substances testing had not been done during stability studies as given in the monograph. No acceptance criteria for related substances had been given or defined in finished product specifications. However, in the stability studies protocol (initiated on 26-02-2018), Limit of degradation was given as NMT 2.0% in specifications.<br>Firm had taken method for assay and dissolution testing from the method of their existing product Lercanidipine tablets having method and acceptance limits provided by M/s Recordati No acceptance criteria for related substances had been given or defined in finished product specifications. However, in the stability studies protocol (initiated on 26-02-2018), Limit of degradation was given as NMT 2.0% in specifications. |
| 30. | Is your HPLC software 21CFR compliant? | Four HPLC systems were used. Audit trail was not installed on HPLC systems used at the time of method validation and stability studies. |
| 31. | Can you show Audit Trail reports on product testing? | Data could only be verified from one system by tracing it through manual log book. In rest three there was some technical IT related issue due to which back up data was not available at the time of inspection. Relevant entries were randomly checked from manual log books for these systems. |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of some impurity standards and stability batches. |
| 33. | Do you have stability batches kept on stability testing? | The stability studies of trial batches kept at 30˚C/65% RH were on going. |
| 34. | Do you have valid calibration status for the equipments used in production and ana ysis? | Firm had valid calibration status for the equipment used in analysis of the product. However, renovation/upgradation was in progress in the production area and R&D lab at the time of inspection and the area was shut down. |
| 35. | Is proper and continuous monitoring and control available for stability chamber? | Yes, monitoring and control was available for the stability chambers provided. Digital data loggers were provided and record was randomly checked.<br>Firm was advised to install alarm system in stability chambers and perform challenge test. |
| 36. | Can related manufacturing area, equipment, personnel and utilities be rated as GMP | The QC laboratory was found to be GMP compliant at the time of inspection. Renovation/upgradation was in |

| | | |
|---|---|---|
| | compliant? | progress in the production area and R&D lab at the time of inspection and the area was shut down. |

**B. ZANIPRILL TABLETS 10/20mg (Lercanidipine HCl and Enalapril maleate)**

| Sr. No. | Question | Observation by the panel |
|---|---|---|
| 1. | Do you have documents confirming the import of API? | Firm had imported Lercanidipine HCl from M/s Recordati, Ireland and Enalapril maleate from M/s Zhejiang Huahai Pharmaceutical Co. Ltd., China. Copy of invoice for import attested by AD (I&E), DRAP, Lahore issue no. 2355/2016-DRAP dated 15-02-2016 was provided by firm. Enalapril Maleate was imported through M/s Gudia Pvt Ltd, Lahore and firm showed copy of a letter from M/s Gudia whereby it was stated that the principal handed over Enalapril maleate sample 1000gm and working standard 100mg to them for onward submission to M/s Pacific Pharmaceuticals, Lahore. No other document related to import was available. It was counter checked from QC sample incoming log book. |
| 2. | What was the rationale behind selecting the particular manufacturer of API? | Firm had been importing Lercanidipine from the same manufacturer since many years for use in their registered product.<br>Firm's management informed that the manufacturer for Enalapril maleate was selected through their vendor approval system. |
| 3. | Do you have documents confirming the import of reference standard and impurity standards? | Firm had Lercanidipine working standard and impurity standards (obtained from Recordati, Ireland).<br>Working standard of Enalapril was obtained from the principal manufacturer through Gudia Private whereas secondary standard was obtained from Sigma-Aldrich. Impurity standards of Enalapril maleate were not procured. |
| 4. | Do you have certificate of Analysis of the API, reference standards and impurity standards? | Relevant COAs from principal manufacturer were seen. |
| 5. | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | Yes, firm had GMP certificate of both API manufacturers issued by regulatory authority of the country of origin. |
| 6. | Do you use API manufacturer method of testing? | Firm used API manufacturer`s method of testing for Lercanidipine. Firm imported Enalapril maleate USP but method of testing applied was from BP monograph. |
| 7. | Do you have stability studies reports on API? | Firm had stability studies reports on API as provided by the manufacturer.<br>However, for Lercanidipine 12 months accelerated and 24 months real time stability studies report was available. For Enalapril 6 months accelerated and 18 months real time stability studies report was available. |
| 8. | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | Yes, stability testing had been performed by the manufacturer as per Stability Indicating Method (SIM) and degradation products had been quantified. |
| 9. | Do you have method for quantifying the impurities in the API? | Yes, firm had method obtained from manufacturer for quantifying the impurities in the API. Lercanidipine was tested accordingly.<br>However, impurity testing was not performed for Enalapril maleate by the firm. |
| 10. | Do you have some remaining quantities of the API, its reference standard and impurities standards? | Yes, some remaining quantities of the working standards and impurity standards of Lercanidipine were available. |

| | | |
|---|---|---|
| 11. | Have you used pharmaceutical grade excipients? | Yes, firm had used pharmaceutical grade excipients. |
| 12. | Do you have documents confirming the import of the used excipients? | Yes, firm had necessary documents confirming the import of the excipients used in product. |
| 13. | Do you have test reports and other records on the excipients used? | Yes, the firm had test reports and other record of the excipients used. |
| 14. | Do you have written and authorized protocols for the development of the product? | The firm had written and authorized formulation development report available for the product. |
| 15. | Have you performed Drug-excipient compatibility studies? | Yes, firm had performed drug-excipient compatibility studies and excipients were found compatible with the APIs as per the report provided. |
| 16. | Have you performed comparative dissolution studies? | No, firm had not performed comparative dissolution studies. |
| 17. | Do you have product development (R&D) section? | Yes, firm had R&D department. |
| 18. | Do you have necessary equipments available in product development section for development of the product? | At the time of inspection, renovation/upgradation was in progress in the R&D lab and relevant equipment were not installed. However, firm's management informed that they had the necessary equipment which were currently decommissioned due to revovation of the lab. |
| 19. | Are the equipments in product development section qualified? | At the time of inspection, renovation/upgradation was in progress in the R&D lab and relevant equipment were not installed. |
| 20. | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | Yes, firm informed that they had a maintenance / calibration / re-qualification program for the whole facility including equipment used in PD section. |
| 21. | Do you have qualified staff in product development section with proper knowledge and training in product development? | Yes, firm had qualified and trained staff in product development section. Training record was available..<br>Firm was advised to further impart product development specific training to their R&D team. |
| 22. | Have you manufactured three stability batches for the stability studies of the product as required? | Firm had manufactured three stability batches for the stability studies of Zaniprill Tablets 10/20mg with Batch No T0106M, T0206M and T0306M. (batch size of 10,000 tablets). |
| 23. | What was the criteria for fixing the batch size of stability batches? | The criteria for fixing the batch size of stability batches, as informed by the firm was one tenth of proposed commercial size batch. |
| 24. | Do you have complete record of production of stability batches? | Yes, firm had complete record of production of stability batches. |
| 25. | Do you have protocols for stability testing of stability batches? | Yes, firm had protocols for stability testing of stability batches. |
| 26. | Do you have developed and validated the method for testing of stability batches? | Firm had taken method for assay and dissolution testing from the method of their existing product Lercanidipine tablets having method and acceptance limits provided by M/s Recordati.<br>For assay of Enalapril maleate in tablets, testing method was taken from BP monograph of Enalapril maleate tablets. Parameters for dissolution and acceptance criteria were taken from BP monograph of Enalapril maleate tablets but quantification was done through UV/VIS spectrophotometry using in house developed method.<br>Four analytical method validation reports were available. One each for quantitative assay of Lercanidipine HCl and Enalapril maleate and one each for dissolution of each API in finished product. The parameter of robustness of method was not mentioned in validation reports. |
| 27. | Do you have method transfer studies in case when the method of testing being used by | The method transfer studies were not available. |

| | | |
|---|---|---|
| | your firm is given by any other lab? | |
| 28. | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug? | Yes, firm had documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug product. |
| 29. | Is your method of analysis stability indicating? | The BP monograph of Enalapril tablets gives a stability indicating method but it was seen that BP monograph of Enalapril tablets was not completely adopted by the firm for finished product testing. Related substances testing had not been done during stability studies as given in the monograph. No acceptance criteria for related substances had been given or defined in finished product specifications. However, in the stability studies protocol (initiated on 26-02-2018), Limit of degradation was given as NMT 2.0% in specifications.<br>Firm had taken method for assay and dissolution testing from the method of their existing product Lercanidipine tablets having method and acceptance limits provided by M/s Recordati No acceptance criteria for related substances had been given or defined in finished product specifications. However, in the stability studies protocol (initiated on 26-02-2018), Limit of degradation was given as NMT 2.0% in specifications. |
| 30. | Is your HPLC software 21CFR compliant? | Four HPLC systems were used. Audit trail was not installed on HPLC systems used at the time of method validation and stability studies. |
| 31. | Can you show Audit Trail reports on product testing? | Data could only be verified from one system by tracing it through manual log book. In rest three there was some technical IT related issue due to which back up data was not available at the time of inspection. Relevant entries were randomly checked from manual log books for these systems. |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of some impurity standards and stability batches. |
| 33. | Do you have stability batches kept on stability testing? | The stability studies of trial batches kept at 30˚C/65% RH were on going. |
| 34. | Do you have valid calibration status for the equipments used in production and analysis? | Firm had valid calibration status for the equipment used in analysis of the product. However, renovation/upgradation was in progress in the production area and R&D lab at the time of inspection and the area was shut down. |
| 35. | Is proper and continuous monitoring and control available for stability chamber? | Yes, monitoring and control was available for the stability chambers provided. Digital data loggers were provided and record was randomly checked.<br>Firm was advised to install alarm system in stability chambers and perform challenge test. |
| 36. | Can related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The QC laboratory was found to be GMP compliant at the time of inspection. Renovation/upgradation was in progress in the production area and R&D lab at the time of inspection and the area was shut down. |

**CONCLUSION**

During the course of inspection, the documents provided by the firm were reviewed, relevant areas were visited and technical personnel were met and interviewed. Details of the evaluation have been given in the questionnaire and the queries of the assessor have been addressed by the panel of inspectors for further review and necessary action.

**Decision: Registration Board deferred the case for submission of stability data at next time point of long term stability studies, wherein assay and dissolution analysis for Enalapril maleate in applied formulation shall be performed as per BP monograph of Enalapril tablets.**

**d. Exemption from onsite verification of stability data**

**Evaluator PEC-II**

| Sr.# | 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 | REMARKS (IF ANY) |
|---|---|---|---|---|---|
| 1249. | "M/s Werrick Pharmaceuticals, Islamabad." | Glad tablets 80mg<br>"Each tablet contains: Azilsartan medoxomil (as potassium)…..80mg<br>(Angiotensin II receptor Inhibitor) | Form-5D (Photocopy) Dy. dated 07-05-2011<br>Rs. 8,000/- Dated 07-05-2011 (photocopy)<br>Rs. 7000/- dated 07-05-2011 (photocopy)<br>Rs. 5,000/ dated 28-12-2018<br>Rs. 30,000/- dated 25-01-2019<br>10's,20's,30's | Approved by USFDA<br>Last GMP inspection conducted on 07-12-2017 concluding good level of GMP compliance. | The firm has claimed Manufacturer's Specifications. |

| **STABILITY STUDY DATA SUBMITTED INITIALLY** | | | |
|---|---|---|---|
| Drug | Glad tablets 40mg | | |
| Name of Manufacturer | M/s Werrick Pharmaceuticals, Islamabad. | | |
| Manufacturer of API | M/s Ami Lifesciences Pvt Ltd, Block No. 82B, ECP Road, AT & Post Karakhadi, Taluka, Padra, Dist: Baroda, State Gujarat, India. | | |
| API Lot No. | AZP/50310517 | | |
| Description of Pack (Container closure system) | Alu-Alu blister foil with unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C / 75% ± 5%RH<br>Real Time: 30˚C ± 2˚C / 65% ± 5%RH | | |
| Time Period | Accelerated: 6 Months<br>Real Time: 6 Months | | |
| Frequency | Real Time: 0,3 & 6 (months)<br>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 | 16-03-2018 | 16-03-2018 | 16-03-2018 |
| Date of Initiation | 17-04-2018 | 17-04-2018 | 17-04-2018 |
| No. of Batches | 03 | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY** | | |
|---|---|---|
| **Sr.#** | **Documents To Be Provided** | **Status** |
| **i.** | COA of API | Yes |
| **ii.** | Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate (Certificate#. S-GMP/1704043) issued from Food and Drug Administration Gandhinagar, Gujarat state, India and is valid until 26-4-2019. |
| **iii.** | Protocols followed for conduction of stability study and details of tests. | Yes |

| | | |
|---|---|---|
| **iv.** | Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc. | Yes |
| **v.** | Documents confirming import of API etc. | Copy of Commercial invoice (invoice# EXP/A/137/2017-18) dated 31-07-2017, from M/s Ami Lifesciences Pvt. Ltd. in the name of M/s Werrick Pharmaceuticals, Islamabad for Azilsartan Medoxomil Potassium. Form 3 & Form 7 from M/s Ami Lifesciences Pvt. Ltd. in the name of M/s Werrick Pharmaceuticals, Islamabad with following details: |

| **Batch No.** | **Mfg. Date** | **Quantity Imported.** |
|---|---|---|
| AZP/50310517 | 05-2017 | 0.9603Kg |

| | | |
|---|---|---|
| **vi.** | All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents. | Yes |
| **vii.** | Commitment to continue real time stability study till assigned shelf life of the product. | Yes |
| **viii.** | Commitment to follow Drug Specification Rules, 1978. | Yes |

**REMARKS OF EVALUATOR[2]**

- The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

| **Sr.#** | **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** | **REMARKS (IF ANY)** |
|---|---|---|---|---|---|
| 1250. | "M/s Werrick Pharmaceuticals, Islamabad." | Glad tablets 40mg<br>"Each tablet contains:<br>Azilsartan medoxomil (as potassium)…..40mg<br>(Angiotensin II receptor Inhibitor) | Form-5D (Photocopy) Dy. dated 07-05-2011<br>Rs. 8,000/- Dated 07-05-2011 (photocopy)<br>Rs. 7000/- dated 07-05-2011 (photocopy)<br>Rs. 5,000/ dated 28-12-2018<br>Rs. 30,000/- dated 25-01-2019<br>10's,20's,30's | Approved by USFDA<br>Last GMP inspection conducted on 07-12-2017 concluding good level of GMP compliance. | The firm has claimed Manufacturer's Specifications. |

**STABILITY STUDY DATA SUBMITTED INITIALLY**

| | |
|---|---|
| Drug | Glad tablets 40mg |
| Name of Manufacturer | M/s Werrick Pharmaceuticals, Islamabad. |
| Manufacturer of API | M/s Ami Lifesciences Pvt Ltd, Block No. 82B, ECP Road, AT & Post Karakhadi, Taluka, Padra, Dist: Baroda, State Gujarat, India. |
| API Lot No. | AZP/50310517 |

| | | | |
|---|---|---|---|
| Description of Pack (Container closure system) | Alu-Alu blister foil with unit carton | | |
| Stability Storage Condition | Accelerated: 40°C ± 2°C / 75% ± 5%RH<br>Real Time: 30°C ± 2°C / 65% ± 5%RH | | |
| Time Period | Accelerated: 6 Months<br>Real Time: 6 Months | | |
| Frequency | Real Time: 0,3 & 6 (months)<br>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 | 22-02-2018 | 13-03-2018 | 15-03-2018 |
| Date of Initiation | 16-04-2018 | 16-04-2018 | 16-04-2018 |
| No. of Batches | 03 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY**

| Sr.# | Documents To Be Provided | Status |
|---|---|---|
| **i.** | COA of API | Yes |
| **ii.** | Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate (Certificate#. S-GMP/1704043) issued from Food and Drug Administration Gandhinagar, Gujarat state, India and is valid until 26-4-2019. |
| **iii.** | Protocols followed for conduction of stability study and details of tests. | Yes |
| **iv.** | Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc. | Yes |
| **v.** | Documents confirming import of API etc. | Copy of Commercial invoice (invoice# EXP/A/137/2017-18) dated 31-07-2017, from M/s Ami Lifesciences Pvt. Ltd. in the name of M/s Werrick Pharmaceuticals, Islamabad for Azilsartan Medoxomil Potassium. Form 3 & Form 7 from M/s Ami Lifesciences Pvt. Ltd. in the name of M/s Werrick Pharmaceuticals, Islamabad with following details: |
| **vi.** | All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents. | Yes |
| **vii.** | Commitment to continue real time stability study till assigned shelf life of the product. | Yes |
| **viii.** | Commitment to follow Drug Specification Rules, 1978. | Yes |

| **Batch No.** | **Mfg. Date** | **Quantity Imported.** |
|---|---|---|
| AZP/50310517 | 05-2017 | 0.9603Kg |

**REMARKS OF EVALUATOR[2]**

- The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

**REQUEST OF EXEMPTION FROM ON SITE INSPECTION**

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Glad 40mg & Glad 80 mg tablets vide Letter no. WP/RGA-482/1218 and WP/RGA-483/1218 respectively dated 27-

12-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
(Date of submission: 28-12-2018 vide diary no. 44302 & 44301)

**Administrative Portion**

| | | |
|---|---|---|
| **1.** | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Firm has referred to onsite inspection reports of their product "Cell-Tab tablets (Sofosbuvir +400 mg)", which was presented in 276th meeting of Registration Board held on 27-28th April, 2017<br>Observations: Keeping in view improvements made by the firm as identified in the previous inspection, panel recommends that facilities of the firm for production of Cell-Tab (Sofosbuvir 400mg) Tablets rate as good.<br><br>Decision: Registration Board decided to approve registration of "Cell-Tab (Sofosbuvir 400mg)" by M/s Werrick Pharmaceuticals, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. |
| **2.** | Documents for the procurement of API with approval from DRAP (in case of import). | Copy of Commercial invoice (invoice# EXP/A/137/2017-18) dated 31-07-2017, from M/s Ami Lifesciences Pvt. Ltd. in the name of M/s Werrick Pharmaceuticals, Islamabad for Azilsartan Medoxomil Potassium. Form 3 & Form 7 from M/s Ami Lifesciences Pvt. Ltd. in the name of M/s Werrick Pharmaceuticals, Islamabad with following details:<br><br>**Batch No.** / **Mfg. Date** / **Quantity Imported.**<br>AZP/50310517 / 05-2017 / 0.9603Kg |
| **3.** | Documents for the procurement of reference standard and impurity standards. | Firm has submitted a copy of invoice (invoice# EXP/A/sample/2017-18) dated 18-08-2017, from M/s Ami Lifesciences Pvt. Ltd. in the name of M/s Morgan chemicals, Karachi for Azilsartan (WRS) & Azilsartan (Impurity) detailed as under:<br><br>**Name** / **Batch No.** / **Quantity Imported.**<br>Azilsartan (WRS) / AZP/WRS/IH/03 / 100mg<br>Azilsartan (Impurity) / RD/16/A/AZI/03 / 80mg |
| **4.** | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate (Certificate#. S-GMP/1704043) issued from Food and Drug Administration Gandhinagar, Gujarat state, India and is valid until 26-4-2019. |
| **5.** | Mechanism for Vendor pre-qualification | • The firm has submitted Work instruction for Evaluation of Suppliers and vendors. |
| **6.** | Certificate of analysis of the API, reference standards and impurity standards | Photocopy of COA of Batch No. AZP/50310517 by M/s Ami lifesciences, India is submitted.<br>**Working standards**: Photocopy of COA of Batch No. AZP/50170217 & Batch No. AZR/RD/60121118 by M/s Ami lifesciences, India is submitted.<br>**Impurity Standard**: Photocopy of COA of Batch No. RD/16/A/AZI/03 by M/s Ami Lifesciences, India is submitted. |
| **7.** | Documents for the procurement of excipients used in product development? | The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development of Flozin tablet |

<table>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development comprising of 10 members.</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 SOP for development of Glad 40mg & 80mg tablet & Stability protocol.</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 Record and Batch Packaging Record of three stability batches for the stability studies of Glad 80mg Tablet & Glad 40mg Tablet, such as.
<table>
<tr><th colspan="3">Glad 80mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>16-03-2018</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>16-03-2018</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>16-03-2018</td><td>1500 Tablets</td></tr>
</table>
<table>
<tr><th colspan="3">Glad 40mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>Trial# 01</td><td>22-02-2018</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 02</td><td>13-03-2018</td><td>1500 Tablets</td></tr>
<tr><td>Trial# 03</td><td>15-03-2018</td><td>1500 Tablets</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th colspan="2">Glad 80mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>Trial# 01</td><td>33 packs (30’s)</td></tr>
<tr><td>Trial# 02</td><td>34 packs (30’s)</td></tr>
<tr><td>Trial# 03</td><td>34 packs (30’s)</td></tr>
</table>
<table>
<tr><th colspan="2">Glad 40mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>Trial# 01</td><td>33 packs (30’s)</td></tr>
<tr><td>Trial# 02</td><td>32 packs (30’s)</td></tr>
<tr><td>Trial# 03</td><td>31 packs (30’s)</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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>The firm has submitted photocopies of digital printouts for Real Time and Accelerated Conditions for complete stability studies of applied formulations.</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 for Azilsartan Medoxomil Potassium.</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 Glad 80mg Tablet & Glad 40mg Tablet along with Stability Study Report of stability batches, chromatograms, lab reports, raw data sheets etc.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Azilsartan Medoxomil Potassium salt for both Accelerated (30˚C ± 2˚C /65% ± 5%RH) for 18 months & Long term (5˚C ± 3˚C) conditions for 6 months from manufacturer.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Glad tablets.</td></tr>
</table>

<table>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has reported that no Physical & Chemical incompatibilities were found on the basis of various literatures.<br>• The firm has also mentioned as under:<br>“Stability studies (Accelerated & Real time) are indicative of chemical and physical compatibility with the drug product.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative Dissolution Profile protocol & reports. The details of reference product & Sample product are as follows:
<table>
<tr><th colspan="3">Glad 80mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Werrick</th></tr>
<tr><td>Brand name</td><td>Edarbi 80mg tablet</td><td>Glad 80mg tablet</td></tr>
<tr><td>Batch No.</td><td>68110</td><td>Trial# 01</td></tr>
<tr><td>Expiry date</td><td>08-2022</td><td>--</td></tr>
<tr><th colspan="3">Glad 40mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Werrick</th></tr>
<tr><td>Brand name</td><td>Edarbi 40mg tablet</td><td>Glad 80mg tablet</td></tr>
<tr><td>Batch No.</td><td>66621</td><td>Trial# 01</td></tr>
<tr><td>Expiry date</td><td>06-2022</td><td>--</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:<br>a. pH 1.2 HCl buffer<br>b. pH 4.5 Acetate buffer<br>c. pH 6.8 Phosphate buffer<br>• Firm has submitted relevant chromatograms and results for the CDP study showing comparable results of reference and applied product.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
<tr><td colspan="3">Remarks of Evaluator:
<table>
<tr><th>Observations/Queries</th><th>Response by Firm</th></tr>
<tr><td>Copy of invoice submitted for import of working standard and impurity standard has also been previously submitted in case of Azan tablets of M/s Scottmann.</td><td>The supplier of M/s Werrick & M/s Scottmann is same i.e., Morgan chemicals hence same invoice was submitted.</td></tr>
</table>
• Submitted COA of API recommends storage at 2ºC to 8ºC.<br>• Firm has submitted stability studies of API from supplier at Accelerated i.e., 30˚C ± 2˚C /65% ± 5%RH & Long term conditions i.e., 5˚C ± 3˚C, whereas innovator has performed stability of API at 25°C/60% RH and 40°C/75% RH. Clarification shall be submitted in this regard.<br>• Applied formulation is a BCS class IV drug.<br>Decision: Registration Board decided to constitute panel for onsite investigation to confirm genuineness / authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc., along with following observations:<br>• Use of working stadards (batch# AZP/WRS/IH/03) & impurity standards (batch#. RD/16/A/AZI/03) in the stability studies of applied formulation, since copy of invoice submitted for import of working standard and impurity standard has also been previously submitted in case of Azan tablets of M/s Scotmann.<br>• Clarification/justification for performance of stability studies of API from supplier at Accelerated i.e., 30˚C ± 2˚C /65% ± 5%RH & Long term conditions i.e., 5˚C ± 3˚C, since innovator has performed stability of API at 25°C/60% RH and 40°C/75% RH.</td></tr>
</table>

| 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<br><br>GMP Inspection Report Date | Remarks |
|---|---|---|---|---|---|
| 1251 | M/s. Highnoon Laboratories 17.5 Km, Multan Road, Lahore | Daploz 5mg Tablet<br>Each film coated tablet contains:<br>Dapagliflozin (as propanediol monohydrate) .....5mg<br><br>Anti-diabetic rugs<br>Manufacturer's specification | Form 5D<br><br>Dairy No. 896 dated 11-4-2016<br><br>Rs.50,000/- dated 11-04-2016<br><br>14's As per SRO | Farxiga Tablets by Astrazaneca<br>**USFDA**<br><br>GMP Inspection dated 27-9-2018 confirms good compliance to GMP | |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Daploz 5mg Tablet | | |
| Name of Manufacturer | M/s. Highnoon Laboratories 17.5 Km, Multan Road, Lahore | | |
| Manufacturer of API | MSN Laboratories Pvt Ltd. India | | |
| API Lot No. | DQ0010217 | | |
| Description of Pack (Container closure system) | Alu-Alu Blister | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 6 (months)<br>Real Time: 6 (months) | | |
| Frequency | Accelerated:0,3,6 (months)<br>Real Time: 0,3,6 (months) | | |
| Batch No. | RD 18013 | RD 18014 | RD 18015 |
| Batch Size | 6666 tablets | 6666 tablets | 6666 tablets |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | 02-2018 | 02-2018 | 02-2018 |
| No. of Batches | 03 | | |
| Date of Submission | 42168 (10-12-2018) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | Yes |
| 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. | Copy of GMP certificate issued by Drugs Controlo Administration Government of Telangana dated 16-10-2017. |
| 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. | Firm has submitted copy of commercial invoice attested by AD (I&E) DRAP Lahore dated 28-03-2017 confirming import of 5kg dapagliflozin |
| 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 |

**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:

| | | |
|---|---|---|
| | **Administrative Portion** | |
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Firm has referred to their recent inspection report for the product Nebvax 5/80mg Tablet which was conducted on 1st January 2019. This product has not yet considered in any meeting of Registration Board. The inspection report is added in the same meeting and firm has requested to grant them exemption on the basis of same report which is being considered in the instant meeting. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | Firm has submitted copy of commercial invoice attested by AD (I&E) DRAP Lahore dated 28-03-2017 confirming import of 5kg dapagliflozin. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copy of pre-shipment sample invoice for working standard and impurity standards. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate issued by Drugs Controlo Administration Government of Telangana dated 16-10-2017. |
| 5. | Mechanism for Vendor pre-qualification | The firm has submitted process flow of source approval. |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | Firm has submitted copy of COA of API, reference standard and impurity standards. |
| 7. | Documents for the procurement of excipients used in product development? | The firm has submitted copy of Commercial invoices/COAs of 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 R&D department. |
| | **Production Data** | |
| 9. | Authorized Protocols/SOP for the development & stability testing of trial batches. | The firm has submitted copy of product design and development SOP's. |
| 10. | Complete batch manufacturing record of three stability batches. | The firm has submitted copy of Batch Manufacturing Records of all the three Batches |
| 11. | Record of remaining quantities of stability batches. | Firm has submitted record of remaining quantities of the stability batches |
| | **QA / QC DATA** | |
| 12. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated). | Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing |

| | | |
|---|---|---|
| 13. | Method used for analysis of API along with COA. | The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA. |
| 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 copy of Finished Product Testing Procedure and specification. |
| 15. | Reports of stability studies of API from manufacturer. | The firm has submitted stability study data of API but not as per the conditions of Zone IV-A. |
| 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 submitted drug excipient compatibility study results. |
| 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 Farxiga Tablets. The firm‘s product results are comparable to that of the innovator product. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Audit trail on testing reports of Daploz tablet has been submitted by the firm. |

Remarks of the evaluator:

- The inspection report initially submitted by the firm for exemption did not confirmed audit trail reports and 21CFR compliant HPLC. Later the firm has referred to their recent inspection report for the product Nebvax 5/80mg Tablet which was conducted on 1st January 2019. This product has not yet considered in any meeting of Registration Board. The inspection report is added in the instant meeting and firm has requested to grant them exemption on the basis of same report which is being considered in the instant meeting.

| Observations | Reply by the firm |
|---|---|
| Real-time stability study data of API as per the requirements of zone IV-A needs to be submitted, since the submitted data is not as per the conditions of zone IV-A. | Firm has submitted that the API manufacturer recommends storage conditions of 25ºC and the raw material was stored at same conditions in Highnoon Laboratories. As API is used in manufacture for finished product at Highnoon Lab and it is not used by the patients, therefore we request you to accept the long term stability data of API as 25ºC.<br>Firm has referred to WHO technical report series No. 1010, 2018 Annex 10 titled “Stability testing of pharmaceutical ingredients and finished pharmaceutical product” |
| Justify the dissolution limits of NLT 80% (Q) after 30 minutes, while the dissolution time point used by the reference product i.e. Farxiga Tablets is 15 minutes (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/202293Orig1s000ClinPharmR.pdf). | Firm has submitted that dissolution limit of NLT 80% (Q) after 30 mins is selected based on FDA “guidance for industry, dissolution testing of immediate release oral dosage forms”. According to this document “For rapidly dissolving drugs (BSC Class 1, 3) a single point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less is sufficient. We have performed a dissolution test of reference drug Forxiga Tablet and our product Daploz Tablet. It has been noted that in reference NDA document of Forxiga the applicant have submitted the dissolution profile with sampling times 15, 30, and 60 mins in support of his request. |

**Decision: Registration Board decided to deferre the case for following:**

- **Submission of stability data of API from supplier as per Zone-IVA conditions.**
- **Submission of stability data at next time point of long term stability conditions wherein dissolution analysis shall be performed with release limits of NLT 80% (Q) after 15 minutes.**

| 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<br><br>GMP Inspection Report Date | Remarks |
|---|---|---|---|---|---|
| 1252 | M/s. Highnoon Laboratories 17.5 Km, Multan Road, Lahore | Daploz 10mg Tablet<br>Each film coated tablet contains:<br>Dapagliflozin (as propanediol monohydrate)…..10mg<br><br>Anti-diabetic rugs<br>Manufacturer's specification | Form 5D<br><br>Dairy No. 895 dated 11-04-2016<br><br>Rs.50,000/- dated 11-04-2016<br><br>14's As per SRO | Farxiga Tablets by Astrazaneca<br>**USFDA**<br><br>GMP Inspection dated 27-9-2018 confirms good compliance to GMP | |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Daploz 10mg Tablet | | |
| Name of Manufacturer | M/s. Highnoon Laboratories 17.5 Km, Multan Road, Lahore | | |
| Manufacturer of API | MSN Laboratories Pvt Ltd. India | | |
| API Lot No. | DQ0010217 | | |
| Description of Pack (Container closure system) | Alu-Alu Blister | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 6 (months)<br>Real Time: 6 (months) | | |
| Frequency | Accelerated:0,3,6 (months)<br>Real Time: 0,3,6 (months) | | |
| Batch No. | RD 18016 | RD 18017 | RD 18018 |
| Batch Size | 3333 tablets | 3333 tablets | 3333 tablets |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | 02-2018 | 02-2018 | 02-2018 |
| No. of Batches | 03 | | |
| Date of Submission | 42168 (10-12-2018) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | Yes |
| 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. | Copy of GMP certificate issued by Drugs Controlo Administration Government of Telangana dated 16-10-2017. |
| 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. | Firm has submitted copy of commercial invoice attested by AD (I&E) DRAP Lahore dated 28-03-2017 confirming import of 5kg dapagliflozin |
| 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 |

**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:

| | | |
|---|---|---|
| | **Administrative Portion** | |
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Firm has referred to their recent inspection report for the product Nebvax 5/80mg Tablet which was conducted on 1st January 2019. This product has not yet considered in any meeting of Registration Board. The inspection report is added in the same meeting and firm has requested to grant them exemption on the basis of same report which is being considered in the instant meeting. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | Firm has submitted copy of commercial invoice attested by AD (I&E) DRAP Lahore dated 28-03-2017 confirming import of 5kg dapagliflozin. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copy of pre-shipment sample invoice for working standard and impurity standards. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate issued by Drugs Controlo Administration Government of Telangana dated 16-10-2017. |
| 5. | Mechanism for Vendor pre-qualification | The firm has submitted process flow of source approval. |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | Firm has submitted copy of COA of API, reference standard and impurity standards. |
| 7. | Documents for the procurement of excipients used in product development? | The firm has submitted copy of Commercial invoices/COAs of 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 R&D department. |
| | **Production Data** | |
| 9. | Authorized Protocols/SOP for the development & stability testing of trial batches. | The firm has submitted copy of product design and development SOP's. |
| 10. | Complete batch manufacturing record of three stability batches. | The firm has submitted copy of Batch Manufacturing Records of all the three Batches |
| 11. | Record of remaining quantities of stability batches. | Firm has submitted record of remaining quantities of the stability batches |
| | **QA / QC DATA** | |
| 12. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing |
| 13. | Method used for analysis of API along with COA. | The firm has submitted copy of Raw Material Specifications, Raw Material Testing Procedures along with COA. |

| | | |
|---|---|---|
| 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 copy of Finished Product Testing Procedure and specification. |
| 15. | Reports of stability studies of API from manufacturer. | The firm has submitted stability study data of API but not as per the conditions of Zone IV-A. |
| 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 submitted drug excipient compatibility study results. |
| 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 Farxiga Tablets. The firm's product results are comparable to that of the innovator product. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Audit trail on testing reports of Daploz tablet has been submitted by the firm. |

**Remarks of the evaluator:**

- The inspection report initially submitted by the firm for exemption did not confirmed audit trail reports and 21CFR compliant HPLC. Later the firm has referred to their recent inspection report for the product Nebvax 5/80mg Tablet which was conducted on 1st January 2019. This product has not yet considered in any meeting of Registration Board. The inspection report is added in the instant meeting and firm has requested to grant them exemption on the basis of same report which is being considered in the instant meeting.

| Observations | Reply by the firm |
|---|---|
| Real-time stability study data of API as per the requirements of zone IV-A needs to be submitted, since the submitted data is not as per the conditions of zone IV-A. | Firm has submitted that the API manufacturer recommends storage conditions of 25ºC and the raw material was stored at same conditions in Highnoon Laboratories. As API is used in manufacture for finished product at Highnoon Lab and it is not used by the patients, therefore we request you to accept the long term stability data of API as 25ºC.<br>Firm has referred to WHO technical report series No. 1010, 2018 Annex 10 titled "Stability testing of pharmaceutical ingredients and finished pharmaceutical product" |
| Justify the dissolution limits of NLT 80% (Q) after 30 minutes, while the dissolution time point used by the reference product i.e. Farxiga Tablets is 15 minutes (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/202293Orig1s000ClinPharmR.pdf). | Firm has submitted that dissolution limit of NLT 80% (Q) after 30 mins is selected based on FDA "guidance for industry, dissolution testing of immediate release oral dosage forms". According to this document "For rapidly dissolving drugs (BSC Class 1, 3) a single point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less is sufficient. We have performed a dissolution test of reference drug Forxiga Tablet and our product Daploz Tablet. It has been noted that in reference NDA document of Forxiga the applicant have submitted the dissolution profile with sampling times 15, 30, and 60 mins in support of his request. |

**Decision: Registration Board decided to deferre the case for following:**

- **Submission of stability data of API from supplier as per Zone-IVA conditions.**
- **Submission of stability data at next time point of long term stability conditions wherein dissolution analysis shall be performed with release limits of NLT 80% (Q) after 15 minutes.**

| 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<br><br>GMP Inspection Report Date | Remarks |
|---|---|---|---|---|---|
| 1253 | M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad. | Sacuval Tablets 24/26mg<br><br>Each film coated tablet contains:<br>Sacubitril……..24mg<br>Valsartan…..…26mg<br>Angiotensin II receptor blocker<br>Manufacturer's specification | Form 5<br><br>Dairy No. 39647 dated 03-12-2018<br><br>Rs.20,000/- dated 03-12-2018<br><br>4x5's, 4x7's, 2x10's; As per SRO | Entresto Tablet of Novartis pharms, **USFDA**<br><br>GMP Inspection conducted on 10-10-2018 & 17-10-2018 concluded that the panel unanimously recommended for the grant of cGMP certificate. | The firm had initially applied with Brand name of "Enscot Tablets 24/26mg". Later on the firm has requested to change the brand name as "Sacuval Tablets 24/26mg." |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Sacuval Tablet 24/26mg | | |
| Name of Manufacturer | M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad. | | |
| Manufacturer of API | M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China | | |
| API Lot No. | 20170203 | | |
| Description of Pack (Container closure system) | Alu Alu Blister Pack in Unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 26 (weeks)<br>Real Time: 26 (weeks) | | |
| Frequency | Accelerated:0,1,2,3,4,6,8,12,16,20,24,26 (weeks)<br>Real Time: 0,1,2,3,4,6,8,12,16,20,24,26 (weeks) | | |
| Batch No. | Trial #01 | Trial #02 | Trial #03 |
| Batch Size | 1500 tablets | 1500 tablets | 1500 tablets |
| Manufacturing Date | 08-2017 | 08-2017 | 08-2017 |
| Date of Initiation | 16-08-2017 | 16-08-2017 | 21-08-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 39850 (04-12-2018) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | Copy of COA (batch #20170203) from M/s Zhuhai Rundu Pharmaceutical 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. | Copy of GMP certificate (certificate No. GD20170777) issued by China Food & Drugs Administration, China. It is valid until 24-12-2022. |
| 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, | Yes |

| | | |
|---|---|---|
| | laboratory reports, data sheets etc. | |
| 5. | Documents confirming import of API etc. | Firm has submitted following:<br>• Copy of License to import drugs (Form 6) dated 09-05-2017.<br>• Copy of commercial invoice dated 14-06-2017 attested by ADC, DRAP, Islamabad<br>• Copy of clearance certificate dated 14-06-2017 |
| 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 |

**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:

| **Administrative Portion** | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Registration Board decided to approve registration of "DASCOT 30 mg Tablets (Daclatasvir 30 mg)" & "DASCOT 60 mg Tablets (Daclatasvir 60 mg)" as well as VELSCOT 400mg/100mg Tablet by M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.<br>Date of Inspection: 26-01-2018.<br>• The HPLC software is 21 CFR compliant.<br>• The firm has demonstrated all audit trail reports for DASCOT 30 & 60mg tablet. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | Copy of commercial invoice has been submitted attested by ADC, DRAP Islamabad. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copies of invoices for the procurement of following working standard substances:<br>Sacubitril sodium: 99.4 %<br>Valsartan Related compound C: 92 %<br>Valsartan Related compound B: 99.5 %<br>Valsartan : 100 % |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | The firm has submitted copy of GMP certificate (Certificate No.GD20170777) for M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China issued by Zhuhai Food & Drug Administration, Guangdong Province, China valid upto 24-12-2022. |
| 5. | Mechanism for Vendor pre-qualification | 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 API (Batch # 20170203) from M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China has been submitted.<br>• Copy of COA of reference standard has been submitted |
| 7. | Documents for the procurement of excipients used in product development? | The firm has submitted photocopy of Commercial invoices/COAs of all 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 R&D department. |

| | | |
|---|---|---|
| **Production Data** | | |
| 9. | Authorized Protocols/SOP for the development & stability testing of trial batches. | The firm has submitted photocopy of "Protocols/SOP for the Development of SACUVAL Tablets |
| 10. | Complete batch manufacturing record of three stability batches. | The firm has submitted photocopy of Batch Manufacturing Records of all the three Batches |
| 11. | Record of remaining quantities of stability batches. | Firm has submitted record of remaining quantities of the stability batches |
| **QA / QC DATA** | | |
| 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 stability chambers with real time and accelerated stability testing |
| 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 Sacubitril/Valsartan Complex. |
| 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 Sacuval Tablets along with Stability Study Reports. |
| 15. | Reports of stability studies of API from manufacturer. | The firm has submitted photocopy of 06 Months Accelerated and 24 Months Real Time Stability Study Data of 03 Batches of Sacubitril/Valsartan from M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China. |
| 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 Entresto Tablets. The firm's product results are comparable to that of the comparator product. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Audit trail on testing reports of Sacubitril/Valsartan from has been submitted by the firm. |

**Remarks of the evaluator:**

- The dissolution acceptance criteria adopted by the firm is NLT 85% in phosphate buffer pH 4.5 after 45 minutes, while the USFDA recommended time point for dissolution testing is after 25 minutes (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207620Orig1s000ChemR.pdf)
  The dissolution results for comparative dissolution profile at pH 6.8 phosphate buffer at 15 and 30 minutes are as follows:Phase-I

| Drug | Time point (min) | Dissolution results (%) |
|---|---|---|
| Valsartan | 15 | 63.58 |
| | 30 | **80.34** |
| Sacubitril | 15 | 61.97 |
| | 30 | **79.59** |

Phase-II

| Drug | Time point (min) | Dissolution results (%) |
|---|---|---|
| Valsartan | 15 | 67.08 |
| | 30 | 83.57 |
| Sacubitril | 15 | 65.78 |
| | 30 | 82.95 |

- Firm has used valsartan API manufactured by Zhejiang Rundu Pharmaceuticals, China. The applicant has not performed impurity testing for NDMA or NDEA. The COA provided by the API manufacturer do not confirm impurity testing for NDMA or NDEA as well.

**Decision: Registration Board deferred the case for Following:**

- **Impurity profiling for identification of NDMA levels in the procured valsartan from Zhejiang Tianyu, China.**
- **Submission of stability data at next time point of long term stability conditions wherein**

**dissolution analysis shall be performed with release limits of NLT 80% (Q) after 25 minutes in phosphate buffer pH 4.5 as recommende dby USFDA**

**Evaluator PEC-V**

| | | |
|---|---|---|
| 1254 | Name and address of manufacturer / Applicant | M/s Ferozsons Laboratories Limited, Amangarh Nowshera, KPK |
| | Brand Name +Dosage Form + Strength | Hexigard Gel 4% |
| | Composition | Each g contains:<br>Chlorhexidine …40mg<br>Chlorhexidine gluconate 7.1% eq. to chlorhexidine 4% |
| | Diary No. Date of R& I & fee | Dy. No. 26247; 31-07-2018; Rs. 50,000/-, 30-07-2018 |
| | Pharmacological Group | Antiseptic and disinfectant |
| | Type of Form | Form-5D |
| | Finished product Specifications | BP specs. |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Umbipro<br>WHO approved formulation |
| | Me-too status (with strength and dosage form) | N/A |
| | GMP status | 10-01-2018<br>Recommends issuance of GMP. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Hexigard Gel 4% | | |
| Name of Manufacturer | M/s Ferozsons Laboratories Limited | | |
| Manufacturer of API | M/s Smaart Pharmaceuticals, India | | |
| API Lot No. | SMAART/CHG/2017/063 | | |
| Description of Pack<br>(Container closure system) | 10g gel filled in Al tube, crimped and sealed. | | |
| Stability Storage Condition | Real Time: 30ºC ± 2ºC / 65% ± 5%RH<br>Accelerated:40ºC ±2ºC / 75% ± 5%RH | | |
| Time Period | Real Time: 06 Months<br>Accelerated: 06 Months | | |
| Frequency | Real Time: 0,3,6 Months(on going)<br>Accelerated: 0,1,2,3,4,6 Months | | |
| Batch No. | CHGel-001 | CHGel-002 | CHGel-003 |
| Batch Size | 6.5 kg | 6.5 kg | 6.5 kg |
| Manufacturing Date | Dec 2017 | Dec 2017 | Dec 2017 |
| Date of Initiation | Jan 2018 | Jan 2018 | Jan 2018 |
| No. of Batches | 03 | | |
| Date of Submission | Dy. No. 26247; 31-07-2018 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes<br>Lot number: SMAART/CHG/2017/063 |
| 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. | Certificate No. 6079163<br>Valid up to 25-12-2018<br>Issued by FDA, Maharashtra State |
| 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. | Yes<br>Invoice No: E-020<br>Not attested by ADC Attested<br>Quantity: 50 Kg<br>Form 6 ADC attested dated: 01-06-2017 and batch no. not mentioned. |
| 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**

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 "Quench Plus Cream", which was conducted on 02nd May, 2018 and was presented in 283rd meeting of Registration Board held on 27-29th June, 2018.<br>Following two observations were reported in the report:<br>i. The HPLC software is 21CFR Compliant.<br>ii. Firm has shown all Audit trail reports.<br>iii. Adequate monitoring and control are available for stability chambers. Data Loggers are also placed in stability chambers for monitoring |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | • Copy of Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 01-06-2017, for the import of Chlorhexidine gluconate 20% solution BP, quantity of drug 50.00kg has been submitted.<br>• Copy of Commercial Invoice (invoice no. E-020) not attested by ADC has been submitted.<br>Batch No SMAART/CHG/2017/063. |
| 3. | Documents for the procurement of reference standard and impurity standards. | Firm has submitted DHL of Chlorhexidine Acetate but receiver is Neon Chemicals.<br>Firm has submitted that:<br>Neon Chemicals is authorized distributor of Smart Pharmaceuticals in Pakistan. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Certificate No. 6079163<br>Valid up to 25-12-2018<br>Issued by FDA, Maharashtra State |
| 5. | Mechanism for Vendor pre-qualification | The firm has submitted SOP for the induction of new vendor of raw material and packaging material in order to ensure that the selected supplier will meet the supply and quality requirements.<br>I. Material Management department will provide samples of API in three different lots with new vendor assessment form to quality control department.<br>II. The samples will be analyzed in Lab against the currant specifications and report will be provided |

<table>
<tr><td></td><td></td><td>to material management Department. In case of non-compliance, MQC will return the form to MM Department with remarks.<br>III. After approval of samples by the QC department the material Management Department will arrange adequate quantity of API along with stability studies and DMF where possible to conduct a trial batch of the Finished Product. The performance of the material supplied will be judged by the results of QC analysis of the stability samples.<br>IV. On the basis of the stability results successful trials and vendor sample assessment, the supplier will be accepted and rejected.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of API have been submitted, detailed as under:<table><tr><th>API</th><th>Batch. #</th><th>Quantity</th></tr><tr><td>Chlorhexidine Gluconate 20 % Solution</td><td>SMAART/CHG /2017/063.</td><td>50 Kg</td></tr><tr><td>Chlorhexidine Acetate Working standard</td><td>SMAART/QC/CH A/WS/2017/002</td><td>0.5g</td></tr></table></td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted commercial invoices from relevant manufacturers.<table><tr><td>Excipient</td><td>Manufacturer</td><td>Batch No.</td></tr><tr><td>Benzalkonium Chloride</td><td>Sigma</td><td>020M6884 500ml</td></tr><tr><td>Guar Gum Super Gel 200 2Kg</td><td>Pakistan Gum and Chemical</td><td>037105 2 kg</td></tr></table></td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff along with their training record involved in product development.</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 SOP of Product development and protocol for stability studies.</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 Record and BPR of the following 03 Batches.<table><tr><th>Batch No.</th><th>Batch Size</th><th>Yield</th></tr><tr><td>001</td><td>6.5Kg</td><td>6.2 Kg</td></tr><tr><td>002</td><td>6.5 Kg</td><td>6.250 Kg</td></tr><tr><td>003</td><td></td><td>6.3 Kg</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td><table><tr><th>Batch No.</th><th>Batch Produced</th><th>Stability Samples</th></tr><tr><td>001</td><td>479</td><td>85</td></tr><tr><td>002</td><td>495</td><td>85</td></tr><tr><td>003</td><td>480</td><td>856</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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>• The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 30-08-2018 to 31-08-2018 that shows excursions (54.6%RH ) .</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Firm has submitted as follows:<br>When the doors of the climatic chamber are opened for loading or unloading of the samples, there can be a momentarily change in temperature and humidity. However when the doors are shut, the set values are recovered quickly.<br>Data logger values on 31/08/2018 at 08:53 am & 12:53 pm due to open of door at that moment. This momentarily change has no influence on the stability studies.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has claimed BP method for analysis of API but has not performed analysis accordingly.<br>Chlorhexidine Gluconate 20%
<table>
<tr><th>BP</th><th>Firm specs.</th></tr>
<tr><td>Appearance<br>Almost colourless or pale-yellowish liquid</td><td>Almost white liquid</td></tr>
<tr><td>First identification A, B.<br>Second identification B, C, D</td><td>A,C D</td></tr>
<tr><td>pH (2.2.3)<br>5.5 to 7.0.</td><td>5.5-5.7</td></tr>
<tr><td>Impurity P (chloroaniline)</td><td>Not performed</td></tr>
<tr><td>Related substances</td><td>Not performed</td></tr>
</table></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 claimed BP method for analysis of FP but has not performed analysis accordingly.<br>Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copies of reports of 06 Months Accelerated and 48 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of its own Analytical reports for all excipients used in product development.
<table>
<tr><th>Tests</th><th>BP</th><th>Firm</th></tr>
<tr><td>Identification</td><td>Ist :B,E<br>2nd :A,C,D,E</td><td>A, E</td></tr>
<tr><td>Appearance of solution</td><td>✓</td><td>X</td></tr>
<tr><td>Average relative molecular mass and ratio of alkyl components</td><td>✓</td><td>X</td></tr>
<tr><td>Impurities A, B and C</td><td>✓</td><td>X</td></tr>
<tr><td>Amines and amine salts</td><td>✓</td><td>X</td></tr>
<tr><td>Assay</td><td>✓</td><td>X</td></tr>
</table></td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>Not performed.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Not performed.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for stability studies analysis of three batches.</td></tr>
</table>

**Evaluation by PEC:**

| Sr. No | Deficiencies/Shortcomings | Reply |
|---|---|---|
| 1. | Commercial invoice is not ADC attested. | Invoice No: E-020<br>Not attested by ADC Attested<br>Quantity: 50 Kg<br>Form 6 ADC attested dated: 01-06-2017 and batch no. |

| | | |
|---|---|---|
| | | not mentioned. |
| 2. | Provide reference for assay calculation formula i.e. Assay=average sample area /average standard areax100. | For the quantitation formula, in chromatographic method, normally USP & BP recommends the peak areas, if the sample and reference concentrations are the same. Please see the attached pharmacopeia reference.<br>*"In the linear range, peak areas and peak heights are usually proportional to the quantity of compound eluting. The peak areas and peak heights are commonly measured by electronic integrators but may be determined by more classical approaches. Peak areas are generally used but may be less accurate if peak interference occurs. The components measured are separated from any interfering components. Peak tailing and fronting is minimized, and the measurement of peaks on tails of other peaks are avoided when possible."*<br>Evaluation<br>The following justification is insufficient to justify the provided formula.<br>Moreover, raw data sheets does not confirm that concentration is same. |
| 3. | Viscosity to be established after completion of stability studies. Clarify. | Viscosity is a measure of a formulation's resistance to flow and is an assessment of a rheological property of a semi solid dosage form. As viscosity limits are not identified in the BP specific drug product monograph, so we perform extra testing and study the viscosity of our Hexigard Gel, during the stability studies for six months. The viscosity limits are as follows;<br>Viscosity: 44500 – 43500 cp. |
| 4. | Injection volume in BP is 100ul whereas, you have used 20ul.Justify. | British Pharmacopeia (BP) recommends 100µl injection volume, however the General Monograph allows for Adjustment of Chromatographic Conditions accordingly. Please refer to BP 2018 general monograph (attached).<br>In our analysis development, the injection volume of 100 µl gave a very high peak response which goes to infinity (injection volume 100 µl chromatogram attached for your reference). Therefore, it was determined that injection volume 20 µl is sufficient to give a high resolution peak and the same was used for our method development. |
| **5.** | Variation in retention time of API and internal standard at different time points and same time points between standard and sample e.g. 9.2 min of standard and 7.8 min of sample of initial time point for batch no CHGel-001. Justify and clarify the variations. | The chromatographic conditions are not constant due to seasonal changes in ambient temperature. Therefore, seasonal temperature change results in variation of the retention time. However this has no effect on the testing procedure or on the accuracy of the test. |
| **6.** | Batch no 001, accelerated condition, at 4 month time point, the peak of internal standard and API are very close to each other and this trend vary from other time points i.e. the resolution is very poor. Justify and clarify the variations. | Due to extensive and detailed study of analytical method validation, HPLC column get overloaded and it need a long time to wash the column. While performing 4th month stability studies, this problem was observed and then we recover the column through very long term washing procedure so that it can maintain its actual position. The regeneration and washing of column behavior reflects in our 6th month stability data chromatograms which had been already submitted to you. |

<table>
<tr><td></td><td></td><td>Whereas low resolution is concerned, the minimum requirement of resolution in the chromatographic analysis is more than 1.50 (please see the attached highlighted references). In the 4th month stability studies, chromatograms shows two components of the sample are well separated and the resolution value of all the chromatograms is more than 1.60 (please see the attached 4th month study chromatograms with highlighted resolution).</td></tr>
<tr><td>7.</td><td>Firm has not submitted COAs of impurity standards.</td><td>Firm has submitted COA of impurity standard but has not performed impurities.</td></tr>
<tr><td>8.</td><td>The digital printouts of graphical chart for Accelerated Conditions starting from 30-08-2018 to 31-08-2018 shows excursions (as low as 54.6%RH). Provide justification.</td><td>When the doors of the climatic chamber are opened for loading or unloading of the samples, there can be a momentarily change in temperature and humidity. However when the doors are shut, the set values are recovered quickly.<br>Data logger values on 31/08/2018 at 08:53 am & 12:53 pm due to open of door at that moment. This momentarily change has no influence on the stability studies.</td></tr>
<tr><td>9.</td><td>Explanation is required regarding path case study, as mentioned in Drug-excipients compatibility studies?</td><td>Path case study is a working paper prepared for the UN Commission on Life saving commodities for women and children for appropriate Technology in Health through USAID program.</td></tr>
<tr><td>10.</td><td>Submit and justify the formula for potency adjustment for API.</td><td>Molecular Weight of Chlorhexidine Gluconate (CHXG)= 897.762<br>Molecular Weight of Chlorhexidine (CHX)= 505.452<br>Factor= 897.762/505.452 =1.777<br>We, Have 20% CHXG Solution<br>For 1ml of 7.1% CHXG Solution, we require= 7.1/20= 0.355ml (of 20% CHXG Solution)<br>7.1% CHXG= 4% CHX<br>Assay/Potency API=100.85%<br>So, for Batch Size 6.5Kg = (0.355*6.5*100)= 2.308 Kg CHXG<br>Remarks: Adjustment of potency not required since potency is more than 100%.</td></tr>
<tr><td>11.</td><td>No preservative is used in innovator formulation i.e. Umbipro whereas, you have used preservative i.e. Benzalkonium Chloride. Justify.</td><td>We followed the formulation available in working paper, prepared for the UN commission on Life-saving commodities for women and children, attached.<br>In Ferozson’s formulation, Benzalkonium Chloride is used which is most frequently used as preservative.<br>The manufacturer of Umbipro also used the antimicrobial preservative (Sodium Acetate trihydrate), which may be for any reasons suiting the manufacturer.<br>Umbipro Formulation:
<table>
<tr><th colspan="2">Umbipro Formulation:</th></tr>
<tr><th>Ingredients</th><th>Role</th></tr>
<tr><td>Chlorhexidine Gluconate</td><td>API</td></tr>
<tr><td>Guar Gum</td><td>Gelling Agent</td></tr>
<tr><td>Sodium Acetate Trihydrate</td><td>Antimicrobial Preservative</td></tr>
<tr><td>Purified Water</td><td>Solvent</td></tr>
</table>
Whereas SMPC mentions as follows:<br>Sodium acetate trihydrate was shown to result in the</td></tr>
</table>

| | | |
|---|---|---|
| | | lowest level of drug-related impurities and was selected as the pH stabiliser.<br>Moreover, the case study data provided by firm mentions the following statement regarding the safe use of benzalkonium chloride.<br>"Some manufacturers have chosen to add small amounts of 50 % benzalkonium chloride(0.10%) to CHX products as a preservative but stability tests conducted by PATH have shown that this may not be a crucial addition. |
| **12.** | **The reference for API Specs. is BP but testing** is not performed as per BP.<br>Chlorhexidine Gluconate<br>BP \| Firm specs.<br>Appearance Almost colourless or pale-yellowish liquid \| Almost white liquid<br>First identification A, B. Second identification B, C, D \| A,C D<br>pH (2.2.3) 5.5 to 7.0. \| 5.5-5.7<br>Impurity P (chloroaniline) \| Not performed<br>Related substances \| Not performed | **<u>Identification test clarification</u>**<br>BP has recommended 4 qualitative identification test A, B, C, D. We have performed 3 out of 4 qualitative tests which confirm the identity of the material. Test B was not performed due to non-availability of reference standard of Calcium gluconate by B.P.<br>**<u>Impurity P (chloroaniline)</u>**<br>British Pharmacopeia (BP) provides the impurity testing on specialized Gas Chromatograph equipped with detector ECD (Electron Capturing).<br>Since the Electron capturing Detector (ECD) cell contains a Radioactive Isotope 63Ni and it is a Radioactive source, therefore the import of this detector is prohibited by Pakistan Nuclear Regulatory Authority (PNRA) for commercial use (please see the highlighted information for your record).<br>We have the facility of Gas Chromatograph equipped with FID (Flame Ionization detector), which is most commonly used in pharmaceutical API/Excipients and product testing. |
| **13.** | **Benzalkonium Chloride**<br>**Tests** \| **BP** \| **Firm**<br>**Identification** \| **Ist :B,E 2nd:A,C,D,E** \| **A, E**<br>**Appearance of solution** \| ✓ \| **X**<br>**Average relative molecular mass and ratio of alkyl components** \| ✓ \| **X**<br>**Impurities A, B and C** \| ✓ \| **X**<br>**Amines and amine salts** \| ✓ \| **X**<br>**Assay** \| ✓ \| **X** | **<u>B</u>**P has recommended 5 qualitative identification test A, B, C, D, E. Previously, we have performed 2 out of 5 qualitative tests which confirm the identity of the material. Test C and D performed dated: 07-02-2019, See attached revised COA.<br>Test B could not performed due to non-availability of Benzalkonium chloride for system suitability CRS standard by B.P.<br>**Appearance of solution**<br>Test performed dated: 07-02-2019.<br>**Average relative molecular mass and ratio of alkyl components**<br>Test was not performed due to non-availability of Benzalkonium chloride for system suitability CRS standard<br>**Impurities A, B and**<br>Impurities not performed due to non-availability of impuirty standard A, impuirty standard B and impuirty standard C by B.P.<br>**Amines and amine salts**<br>Test performed dated: 07-02-2019.<br>**Assay**<br>Average relative molecular mass value used in the calculation of assay, whereas Average relative molecular mass test was not performed due to non-availability of Benzalkonium chloride for system suitability CRS standard |
| **14.** | The BP mentions appearance as almost colorless or pale-yellowish liquid while you | <u>Appearance clarification</u><br>It is to clarify that our analyst mistakenly wrote |

| | | |
|---|---|---|
| | have mentioned almost white liquid. Clarify | description "Almost white liquid" instead of clear colorless liquid"<br>COA of API from Smaart Pharmaceuticals is attached bearing appearance as "clear colorless liquid" and sample of API is also provided herewith our clarification for your visual inspection.<br>Copy of corrected analysis report with initials of that analyst for API. |
| **15.** | The COA of API and COA of benzalkonium chloride mentions that these raw materials are provisionally approved. Clarify and Justify the same. | New API and excipients are provisionally approved based on QC testing and Finally approved for commercial use after completing trials and stability studies to make sure product is stable during stability |
| **16.** | The SMPC of Umbipro mentions that sodium acetatae trihydrate was selected as the pH stabilizer. While you have mentioned it as an antimicrobial agent. Clarify. | Sodium acetate trihydrate has dual action i.e. As pH stabilizer as well as Preservative. |

**Decision: Registration Board decided to constitute panel for onsite investigation to confirm genuineness / authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc., along with observations presented in table above.**

**Evaluator PEC-VII**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1255. | M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad | Trapeze plus XR tablet 50/1000 mg<br>Each tablet contains:<br>Sitagliptin phosphate monohydrate eq. to Sitagliptin……50 mg<br>Metformin hydrochloride……..1000 mg (as extended release core)<br>Anti-diabetic | Form-5-D<br>Dy. No: 42024<br>Dated. 7/12/18<br>Rs.20,000/- (5-12-18)<br>7's, 2x7's, 1x10's and 10x6's<br>As per SRO | Janumet XR –USFDA approved<br><br>GMP compliant dated 10-10-2018 & 17-10-2018 concluding the panel unanimously recommends for the grant of GMP certificate. |

| **STABILITY STUDY DATA** | |
|---|---|
| Drug | Trapeze plus XR tablet 50/1000 mg |
| Name of Manufacturer | M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad. |
| Manufacturer of API | Sitagliptin phosphate monohydrate: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. No 15 Donghai avenue Zheijang provincial and medical raw material base linhai zone, Taizhou city, Zheijang province China<br>Metformin HCl: M/s Abhilasha Pharma Pvt. Ltd, INDIA |
| API Lot No. | Sitagliptin phosphate monohydrate: 12301-17030101<br>Metformin HCl: MET123/17 |
| Description of Pack (Container closure system) | Alu / Alu Blister Pack |
| Stability Storage Condition | Accelerated: 40°C ± 2°C & 75±5%RH<br>Real Time : 30°C ± 2°C & 65±5%RH |
| Time Period | Accelerated: 06 Months<br>Real Time: 06 Months |
| Frequency | Accelerated: 0, 1,2,3, 4 ,6 (Months)<br>Real Time : 0, 3 ,6 (Months) |

| | | | |
|---|---|---|---|
| Batch No. | Trail 001 | Trail 001 | Trail 001 |
| Batch Size | 1500 Tablets | 1500 Tablets | 1500 Tablets |
| Manufacturing Date | 12 - 2017 | 12 – 2017 | 12 - 2017 |
| Date of Initiation | 06-12-2017 | 06-12-2017 | 06-12-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 4/1/2019 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | **Sitagliptin phosphate monohydrate:** Copy of GMP certificate (Certificate No. ZJ20170020) for M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. No 15 Donghai avenue Zheijang provincial and medical raw material base linhai zone, Taizhou city, Zheijang province China issued by Zheijang province Food & Drug Administration, valid upto 3/28/2022.<br>**Metformin HCl:** GMP Certificate of manufacturer (#1706138) "M/s Abhilasha Pharma Pvt. Ltd, INDIA" issued by Food & Drugs Control Administration, Gandhinagar, Gujarat State, India is provided by applicant which is valid till 01/06/2019. |
| 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. | Copy of ADC attested Form 5, form 3 and commercial invoice provided for both actives.<br>Sitagliptin: Quantity 50 kg<br>Metformin: Quantity 1000 kg |
| 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**

**Data for exemption from On-site investigation of submitted stability data**

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | • Registration Board approved Dascot 30 and 60 mg Tablets and Velscot tablet conducted on 26 jan 2018 in 278 meeting.<br>• Date of Inspection: 26 jan 2018.<br>• The HPLC is 21CFR Compliant.<br>• Audit trail on the testing reports of ― Dascot 30 and 60 mg Tablets and Velscot tablet were available. |
| 2. | Documents for the procurement of API with approval from DRAP (in | **Sitagliptin phosphate monohydrate:** The firm has submitted photocopies of ADC attested document dated 3-july-2017, ADC |

<table>
<tr><td></td><td>case of import).</td><td>attested Form 5, Commercial Invoice attestation on dated 05/7/2017 for 50 kg of Sitagliptin. The firm has imported “Sitagliptin” Raw Material ,Qty ; 50 kg ; Batch # 12301-17030101<br>Metformin HCl: The firm has submitted photocopies of ADC (Islamabad) attested Form 5 and AD attested commercial invoice dated 6/9/17. Commercial Invoice is issued by M/s Abhilasha Pharma Pvt. Ltd, INDIA Moreover detail of Qty ; 1000 kg ; Batch # MET123/17 is mentioned on invoice.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted the commercial invoice of the reference standard for both metformin and setagliptin</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Sitagliptin phosphate monohydrate: Copy of GMP certificate (Certificate No. ZJ20170020) for M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. No 15 Donghai avenue Zheijang provincial and medical raw material base linhai zone, Taizhou city, Zheijang province China issued by Zheijang province Food & Drug Administration, valid upto 3/28/2022.<br>Metformin HCl: GMP Certificate of manufacturer (#1706138) “M/s Abhilasha Pharma Pvt. Ltd, INDIA” issued by Food & Drugs Control Administration, Gandhinagar, Gujarat State, India is provided by applicant which is valid till 01/06/2019</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from APIs manufacturer.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Sitagliptin API:<br>Photocopy of COA of Batch No. 12301-17030101 issued by “M/s. M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. China” is submitted.<br>• Reference standards and impurity standards:<br>The firm has submitted copy of Reference Standard<br>Metformin HCl API:<br>Photocopy of COA of Batch No. MET123/17 issued by M/s Abhilasha Pharma Pvt. Ltd, INDIA is submitted.<br>• Reference standards and impurity standards:<br>The firm has submitted copy of Working Standards (Metformin HCl),USP Reference Standard and impurity standards provided by the API Manufacturer - M/s Abhilasha Pharma Pvt. Ltd, INDIA</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of commercial invoices for the excipients used in the applied formulation.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted copy of R&D staff list.3 pharmacists and 1 MSc are present in there R &D</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 copy of SOP with the title ‘Manufacturing methodology of Sitagliptin/Metformin HCl XR tablet” and “Stability protocols of trapeze plus XR tablet”<br>Effective date 30/11/2017</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th></tr>
<tr><td>Trail#1</td><td>1500 Tabs</td><td>12-2017</td></tr>
<tr><td>Trail#2</td><td>1500 Tabs</td><td>12-2017</td></tr>
<tr><td>Trail#3</td><td>1500 Tabs</td><td>12-2017</td></tr>
</table></td></tr>
</table>

| | | |
|---|---|---|
| 11. | Record of remaining quantities of stability batches. | **Trapeze plus XR ;**<br>**Stability Pack Size :**<br>• Trail #1: Batch Size : 1500 Tablets<br>Yield 1320 Tablets ,<br>124 tablets used for testing<br>other are remaining<br>• Trail #2: Batch Size : 1500 Tablets<br>Yield 1300 Tablets ,<br>124 tablets used for testing<br>other are remaining<br>• Trail #3: Batch Size : 1500 Tablets<br>Yield 1310 Tablets ,<br>124 tablets used for testing<br>other are remaining |
| **QA/QC DATA** | | |
| 12. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | • **Previously Reported in panel inspection:**<br>The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability & for Accelerated Stability studies)<br>Now the firm has submitted copy of record of digital data logger for temperature and humidity monitoring of stability chambers. |
| 13. | Method used for analysis of API along with COA. | • The firm has submitted photocopy of method used for analysis of APIs along with COA. |
| 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 Specifications and Testing Method of applied product and its validation data.<br>• Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 months stability data (Accelerated & Real Time). |
| 15. | Reports of stability studies of API from manufacturer. | **Apixaban:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) & **long term, 24 Months** (30°C±2°C & 65±5%RH) stability study reports of 03 batches |
| 16. | Analysis reports for excipients used. | The firm has submitted copy of COAs for the excipients used in the applied formulation. |
| 17. | Drug-excipients compatibility studies. | • The firm has not submitted Drug-excipients compatibility studies and provides excipient analysis report |
| 18. | Record of comparative dissolution data. | • Firm has submitted Comparative dissolution study of their product Trapeze plus XR with Innovator's Brand "Janumet XR" conducted on following dates ;<br>• Comparative dissolution studies have been performed in following media:<br>**Sitagliptin :**<br>i. 0.01N Hydrochloric Acid Solution<br>ii. pH 4.5 Acetate buffer solution.<br>iii. pH 6.8 phosphate buffer solution.<br>**METFORMIN HCl :**<br>i. 0.01N Hydrochloric Acid Solution<br>ii. pH 4.5 Acetate buffer solution.<br>iii. pH 6.8 phosphate buffer solution.<br>• Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted copy of Audit Trail for Initial, 3rd and 6th Month Testing Intervals |

**Evaluation by PEC:**

Above observation were communicated to firm vide letter no. F.1-1/2019/PEC-DRAP (AD PEC-VII), to which firm has responded as under:
Formulation is according to innovator using wet granulation for core preparation and incorporation of sitagliptin in coating solution,
v. Firm has submitted revised finished product testing method along with stability studies data.
vi. Dissolution parameters stated in finished product testing method, submitted along with stability studies data are not as per recommended by USFDA.

| Sr.# | Deficiency/Observation | Response by Pharma. |
|---|---|---|
| i. | Why baseline is not stable in comparative dissolution chromatograms (e.g. in case of spl dissolution 30 min pH 6.8). Justify | The baseline of provided chromatograms of comparative dissolution is stable the scale was magnified to view the sitagliptin peak at the maximum because the peak high of sitagliptin is too low. |
| ii. | Documents for the procurement of impurity standards missing for sitagliptin phosphate monohydrate | Documents for impurity standard were provided |
| iii. | 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 phosphate monohydrate present in the same sample aliquot. | The specificity of UV method was performed during method development which shows that the both actives absorbs at different wavelength and do not interfere each other even placebo was also run during specificity |
| iv. | Innovator performs propyl gallate assay as propyl gallate is carcinogenic Justify the exemption of these test by API manufacturer and applicant. | The WHO has set an estimated acceptable daily limit of intake of propyl gallate at up to 1.4 mg/kg as per guideline the average 70 kg person can take 98 mg per day while we are using 1 mg per tablet in our product which is negligible to cause any carcinogenic effect. |

**Decision: Registration Board decided to approve registration of "Trapeze Plus XR 50/1000mg Tablet" by M/s Scotmann Pharmaceuticals Islamabad. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1256. | M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad | Trapeze plus XR tablet 50/500 mg<br>Each tablet contains:<br>Sitagliptin phosphate monohydrate eq. to Sitagliptin…….50mg<br>Metformin hydrochloride……...500mg<br>(as extended release core)<br>Anti-diabetic | Form-5-D<br>Dy. No: 42025<br>Dated. 7/12/18<br>Rs.20,000/- (5-12-18)<br>7's, 2x7's, 1x10's and 10x6's<br>As per SRO | Janumet XR –USFDA approved<br><br>GMP compliant dated 10-10-2018 & 17-10-2018 concluding the panel unanimously recommends for the grant of GMP certificate. |

| STABILITY STUDY DATA | |
|---|---|
| Drug | Trapeze plus XR tablet 50/500 mg |
| Name of Manufacturer | M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad. |
| Manufacturer of API | Sitagliptin phosphate monohydrate: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. No 15 Donghai avenue Zheijang provincial and medical raw material base linhai zone, Taizhou city, Zheijang province China<br>Metformin HCl : M/s Abhilasha Pharma Pvt. Ltd, INDIA |

| | | | |
|---|---|---|---|
| API Lot No. | Sitagliptin phosphate monohydrate: 12301-17030101<br>Metformin HCl: MET123/17 | | |
| Description of Pack (Container closure system) | Alu / Alu Blister Pack | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time : 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months | Real Time: | 06 Months |
| Frequency | Accelerated: 0, 1,2,3, 4 ,6 (Months)<br>Real Time : 0, 3 ,6 (Months) | | |
| Batch No. | Trail 001 | Trail 001 | Trail 001 |
| Batch Size | 1500 Tablets | 1500 Tablets | 1500 Tablets |
| Manufacturing Date | 12 - 2017 | 12 – 2017 | 12 - 2017 |
| Date of Initiation | 06-12-2017 | 06-12-2017 | 06-12-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 23/10/2018 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | **Sitagliptin phosphate monohydrate:** Copy of GMP certificate (Certificate No. ZJ20170020) for M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. No 15 Donghai avenue Zheijang provincial and medical raw material base linhai zone, Taizhou city, Zheijang province China issued by Zheijang province Food & Drug Administration, valid upto 3/28/2022.<br>**Metformin HCl:** GMP Certificate of manufacturer (#1706138) "M/s Abhilasha Pharma Pvt. Ltd, INDIA" issued by Food & Drugs Control Administration, Gandhinagar, Gujarat State, India is provided by applicant which is valid till 01/06/2019. |
| 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. | Copy of ADC attested Form 5, form 3 and commercial invoice provided for both actives.<br>Sitagliptin: Quantity 50 kg<br>Metformin: Quantity 1000 kg |
| 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 | | |
|---|---|---|
| **Data for exemption from On-site investigation of submitted stability data** | | |
| **Administrative Portion** | | |
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | • Registration Board approved Dascot 30 and 60 mg Tablets and Velscot tablet conducted on 26 jan 2018 in 278 meeting.<br>• Date of Inspection: 26 jan 2018.<br>• The HPLC is 21CFR Compliant.<br>• Audit trail on the testing reports of ― Dascot 30 and 60 mg Tablets and Velscot tablet were available. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | **Sitagliptin phosphate monohydrate:** The firm has submitted photocopies of ADC attested document dated 3-july-2017, ADC attested Form 5, Commercial Invoice attestation on dated 05/7/2017 for 50 kg of Sitagliptin. The firm has imported "Sitagliptin" Raw Material ,Qty ; 50 kg ; Batch # 12301-17030101<br>**Metformin HCl :** The firm has submitted photocopies of ADC (islamabad) attested Form 5 and AD attested commercial invoice dated 6/9/17. Commercial Invoice is issued by M/s Abhilasha Pharma Pvt. Ltd, INDIA Moreover detail of Qty ; 1000 kg ; Batch # MET123/17 is mentioned on invoice. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted the commercial invoice of the reference standard for both metformin and setagliptin |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | **Sitagliptin phosphate monohydrate:** Copy of GMP certificate (Certificate No. ZJ20170020) for M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. No 15 Donghai avenue Zheijang provincial and medical raw material base linhai zone, Taizhou city, Zheijang province China issued by Zheijang province Food & Drug Administration, valid upto 3/28/2022.<br>**Metformin HCl:** GMP Certificate of manufacturer (#1706138) "M/s Abhilasha Pharma Pvt. Ltd, INDIA" issued by Food & Drugs Control Administration, Gandhinagar, Gujarat State, India is provided by applicant which is valid till 01/06/2019 |
| 5. | Mechanism for Vendor pre-qualification | • The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from APIs manufacturer. |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | • **Sitagliptin API:**<br>Photocopy of COA of Batch No. 12301-17030101 issued by "M/s. M/s Zhejiang Tianyu Pharmaceutical Co., Ltd. China" is submitted.<br>• **Reference standards and impurity standards:**<br>The firm has submitted copy of Reference Standard<br>**Metformin HCl API:**<br>Photocopy of COA of Batch No. MET123/17 issued by M/s Abhilasha Pharma Pvt. Ltd, INDIA is submitted.<br>• **Reference standards and impurity standards:**<br>The firm has submitted copy of Working Standards (Metformin HCl),USP Reference Standard and impurity standards provided by the API Manufacturer - M/s Abhilasha Pharma Pvt. Ltd, INDIA |
| 7. | Documents for the procurement of excipients used in product development? | Firm has submitted copy of commercial invoices for the excipients used in the applied formulation. |
| 8. | List of qualified staff involved in product development with relevant experience. | Firm has submitted copy of R&D staff list.3 pharmacists and 1 MSc are present in there R &D |

<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 copy of SOP with the title ‘Manufacturing methodology of Sitagliptin/Metformin HCl XR tablet” and “Stability protocols of trapeze plus XR tablet”<br>Effective date 30/11/2017</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th></tr>
<tr><td>Trail#1</td><td>1500 Tabs</td><td>11-2017</td></tr>
<tr><td>Trail#2</td><td>1500 Tabs</td><td>11-2017</td></tr>
<tr><td>Trail#3</td><td>1500 Tabs</td><td>11-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Trapeze plus XR ;<br>Stability Pack Size :<br>• Trail #1: Batch Size : 1500 Tablets<br>Yield 1310 Tablets ,<br>126 tablets used for testing<br>other are remaining<br>• Trail #2: Batch Size : 1500 Tablets<br>Yield 1290 Tablets ,<br>126 tablets used for testing<br>other are remaining<br>• Trail #3: Batch Size : 1500 Tablets<br>Yield 1280 Tablets ,<br>126 tablets used for testing<br>other are remaining</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>• Previously Reported in panel inspection:<br>The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability & for Accelerated Stability studies)<br>Now the firm has submitted copy of record of digital data logger for temperature and humidity monitoring of stability chambers.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>• The firm has submitted photocopy of method used for analysis of APIs along with COA.</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 Specifications and Testing Method of applied product and its validation data.<br>• Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 months stability data (Accelerated & Real Time).</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5 % RH) & long term, 24 Months (30°C±2°C & 65±5%RH) stability study reports of 03 batches</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not submitted Drug-excipients compatibility studies and provides excipient analysis report</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative dissolution study of their product Trapeze plus XR with Innovator’s Brand “Janumet XR”<br>• Comparative dissolution studies have been performed in following media:<br><u>Sitagliptin</u> :<br>i. 0.01N Hydrochloric Acid Solution<br>ii. pH 4.5 Acetate buffer solution.</td></tr>
</table>

| | | |
|---|---|---|
| | | iii. pH 6.8 phosphate buffer solution.<br>**METFORMIN HCl :**<br>i. 0.01N Hydrochloric Acid Solution<br>ii. pH 4.5 Acetate buffer solution.<br>iii. pH 6.8 phosphate buffer solution.<br>• Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted copy of Audit Trail for Initial, 3rd and 6th Month Testing Intervals |

**Evaluation by PEC:**

Above observation were communicated to firm vide letter no. F.1-1/2019/PEC-DRAP (AD PEC-VII), to which firm has responded as under:

| Sr.# | Deficiency/Observation | Response by Pharma. |
|---|---|---|
| i. | Why baseline is not stable in comparative dissolution chromatograms (e.g. in case of spl dissolution 30 min pH 6.8). Justify | The baseline of provided chromatograms of comparative dissolution is stable the scale was magnified to view the sitagliptin peak at the maximum because the peak high of sitagliptin is too low. |
| ii. | Documents for the procurement of impurity standards missing for sitagliptin phosphate monohydrate | Documents for impurity standard were provided |
| iii. | 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 phosphate monohydrate present in the same sample aliquot. | The specificity of UV method was performed during method development which shows that the both actives absorbs at different wavelength and do not interfere each other even placebo was also run during specificity |
| iv. | Innovator performs propyl gallate assay as propyl gallate is carcinogenic Justify the exemption of these test by API manufacturer and applicant. | The WHO has set an estimated acceptable daily limit of intake of propyl gallate at up to 1.4 mg/kg as per guideline the average 70 kg person can take 98 mg per day while we are using 1 mg per tablet in our product which is negligible to cause any carcinogenic effect. |

**Decision: Registration Board decided to approve registration of "Trapeze plus XR tablet 50/500 mg" by M/s Scotmann Pharmaceuticals Islamabad. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1257. | M/s Werrick Pharmaceuticals, Plot # 216, 217, I-10/3, Industrial Area, Islamabad. | Api-Tab tablet 5 mg<br>Each film coated tablet contains: Apixaban USP …….5mg<br>Antithrombotic agents | Form-5-D<br>Dy. No: 42913<br>Dated.6-6-2017<br>Rs.20,000/- (17-12-18)<br>10's ; Rs. 316/- | ELIQUIS (USFDA Approved)<br>GMP inspection report conducted on Last inspection was conducted on 7-2-2017 concluding very good compliance |

| STABILITY STUDY DATA | |
|---|---|
| Drug | Api-Tab tablet 5 mg |
| Name of Manufacturer | M/s Werrick Pharmaceuticals, Plot # 216, 217, I-10/3, Industrial Area, Islamabad. |

| | | | |
|---|---|---|---|
| Manufacturer of API | Apixaban: M/s Glenmark pharmaceuticals ltd. Plot # 3109 C, GIDC industrial estate Ankleshwar-393002, Gujrat India. | | |
| API Lot No. | Apixaban: | | |
| Description of Pack (Container closure system) | Alu / PVC Blister Pack | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months<br>Real Time: 06 Months | | |
| Frequency | Accelerated: 0, 1,2,3,4, 6 (Months)<br>Real Time : 0, 3 ,6 (Months) | | |
| Batch No. | Trail #1 | Trail #2 | Trail #3 |
| Batch Size | 1500 Tablets | 1500Tablets | 1500 Tablets |
| Manufacturing Date | 3-2018 | 3-2018 | 3-2018 |
| Date of Initiation | 4-2018 | 4-2018 | 4-2018 |
| No. of Batches | 03 | | |
| Date of Submission | 17-2-2018 (Dy. No. 4294) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | Apixaban: Firm has submitted copy of GMP Certificate of manufacturer "M/s Glenmark pharmaceuticals ltd. Plot # 3109 C, GIDC industrial estate Ankleshwar-393002, Gujrat India. |
| 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. | Copy of invoice provided. Not ADC (Islamabad) attested |
| 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**

- Dissolution is according to USFDA.

**Data for exemption from On-site investigation of submitted stability data**

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | • Last onsite inspection of werrick pharmaceuticals was conducted on 19-4-2017 for Cell tab tablets (Sofosbuvir tablet). Approved in 273meeting<br>o Date of Inspection: 19-4-2017<br>o The HPLC is 21CFR Compliant.<br>o Audit trail on the testing reports was available and |

<table>
<tr><td></td><td></td><td>confirmed. Panel reviewed chromatograms for testing of API and trial batches audit trail at 0, 3 and 6 months for real time and accelerated stability testing</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Apixaban: The firm has submitted photocopies of Commercial Invoice attestation by ADC islamabad<br>The firm has imported “Apixaban” Raw Material, Qty; 0.1 kg; Batch # 801704823 from same source via Invoice # 2006007416 dated: 29-9-2017.<br>Clearance certificate # 2960 is provided.<br>Form 7, form 3</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• The firm has submitted that the reference standard and impurity standards are procured along with the APIs’ consignment and not separately.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Apixaban: The Firm has submitted copy of GMP Certificate of manufacturer “M/s Glenmark pharmaceuticals Ltd. Plot # 3109 C, GIDC industrial estate Ankleshwar-393002, Gujrat India issued by food and drug control administration Gandhinagar Gujrat state India which is valid till 18/8/2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from APIs manufacturer.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Apixaban:<br>Photocopy of COA of Batch No. 801704823 issued by “M/s Glenmark pharmaceuticals ltd. Plot # 3109 C, GIDC industrial estate Ankleshwar-393002, Gujarat India is submitted.<br>• Reference standards and impurity standards:<br>The firm has submitted copy of COA of Working Standards and impurity standards provided by the API Manufacturer</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of commercial invoices for the excipients used in the applied formulation.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted copy of R&D staff list.10 persons present in there R &D 8 are pharmacist, 1 MPhil microbiology and 1 MPhil chemistry</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 copy of SOP with the title ‘Authorized Protocol For Development of Api-tab 5 mg.<br>Effective date 16-2-2018</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th></tr>
<tr><td>Trail#1</td><td>1500 Tabs</td><td>3-2018</td></tr>
<tr><td>Trail#2</td><td>1500 Tabs</td><td>3-2018</td></tr>
<tr><td>Trail#3</td><td>1500 Tabs</td><td>3-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Api-Tab 5 mg ;<br>Stability Pack Size : 1 x 10’s<br>• Trail #1: Batch Size : 1500 Tablets<br>Yield 1218 Tablets (121 Packs) ,<br>28 Packs used for testing<br>93 packs are remaining<br>• Trail #2: Batch Size : 1500 Tablets<br>Yield 1247 Tablets (124 Packs) ,<br>26 Packs used for testing<br>98 packs are remaining<br>• Trail #3: Batch Size : 1500 Tablets<br>Yield 1237 Tablets (123 Packs) ,<br>26 Packs used for testing</td></tr>
</table>

| | | |
|---|---|---|
| | | 97 packs are remaining |
| **QA/QC DATA** | | |
| 12. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | • **Previously Reported in panel inspection:**<br>The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability & for Accelerated Stability studies)<br>Now the firm has submitted copy of record of digital data logger for temperature and humidity monitoring of stability chambers. |
| 13. | Method used for analysis of API along with COA. | • The firm has submitted photocopy of method used for analysis of APIs (Apixaban) along with COA. |
| 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 Specifications and Testing Method of Api-tab 5 mg and its validation data.<br>• Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 months stability data (Accelerated & Real Time). |
| 15. | Reports of stability studies of API from manufacturer. | **Apixaban:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) & **long term, 24 Months** (30°C±2°C & 65±5%RH) stability study reports of 03 batches of Apixaban |
| 16. | Analysis reports for excipients used. | The firm has submitted copy of COAs for the excipients (titanium dioxide, polysorbate tween 80, SLS, HPMC, Mg stearate, Lactose tablettose, and Microcrystalline cellulose, cross carmilose, talcum, used in the applied formulation. |
| 17. | Drug-excipients compatibility studies. | The firm has not performed Drug-excipients compatibility studies and has referred to monographs of Hand-book of Pharmaceutical Excipients in this regard and claimed Stability studies are indicative of chemical and physical compatibility with the drug product |
| 18. | Record of comparative dissolution data. | • Firm has submitted Comparative dissolution study of their product (Api-tab 5 mg) with Innovator's Brand Eliquis 5 mg" conducted on following dates ;<br>The details are as follows:<br>Feature / Reference Product / Product Pharma<br>Brand name / Eliquis 5 mg Tablets / Api-tab 5 mg Apixaban<br>• Comparative dissolution studies have been performed in following media:<br>Apixaban:<br>iv. 0.01N Hydrochloric Acid Solution<br>v. pH 4.5 Acetate buffer solution.<br>vi. pH 6.8 phosphate buffer solution. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted copy of Audit Trail for Initial, 3rd and 6th Month Testing Intervals |

**Evaluation by PEC:**

Above observation were communicated to firm vide letter no. F.1-1/2019/PEC-DRAP (AD PEC-VII), to which firm has responded as under:

| Sr.# | Deficiency/Observation | Response by Pharma. |
|---|---|---|
| i. | Provide the complete inspection report of cell tab to show evidence of The 21CFR Compliant of HPLC and Audit trail on the testing reports of cell tab 400 mg tablets | Provided and verified that HPLC is 21 CFR compliant and audit trails are available |

| | | |
|---|---|---|
| ii. | On Commercial invoice ADC attestation is not readable and clear | Attested copy is provided |
| iii. | List of qualified staff involved in product development with relevant experience does not mentioned their qualifications | Provided |
| iv. | The particle size of the drug substance was identified as a critical factor based on its influence on the dissolution of the tablets. A study was conducted to establish the drug substance particle size requirement that would produce the required in-vitro drug release and appropriate limit has been se https://www.ema.europa.eu/documents/assessment-report/eliquis-epar-public-assessment-report_en.pdf | The particle size of API manufacture was determined by API manufacturer as mentioned in COA of API (Particle size is mentioned as D (90)= 82.4 um) |
| v. | Why there is additional peaks along with principle peaks in chromatograms of drug assay and dissolution area at different time points (e.g. accelerated study, 1 month vial 2, 4, 5 etc.) | There are no additional peaks in the assay chromatograms where as in the dissolution chromatograms the extra peaks are due to the dissolution medium |
| vi. | Why baseline is not stable and there are extra peaks in comparative dissolution chromatograms. | The baseline and extra peaks in comparative dissolution chromatograms are due to different dissolution mediums used |

**Decision: Registration Board decided to constitute panel for the Api-Tab tablet 5 mg for onsite investigation to confirm genuineness / authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc., along with following observations**

| Sr. # | Observation | Response of Pharma |
|---|---|---|
| a | Why there is additional peaks along with principle peaks in chromatograms of drug assay and dissolution area at different time points (e.g. accelerated study, 1 month vial 2, 4, 5 etc.) | There are no additional peaks in the assay chromatograms where as in the dissolution chromatograms the extra peaks are due to the dissolution medium |
| b | Why baseline is not stable and there are extra peaks in comparative dissolution chromatograms. | The baseline and extra peaks in comparative dissolution chromatograms are due to different dissolution mediums used |

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1258. | M/s Werrick Pharmaceuticals, Plot # 216, 217, I-10/3, Industrial Area, Islamabad. | Api-Tab tablet 2.5 mg<br>Each film coated tablet contains: Apixaban USP …….2.5 mg<br>Antithrombotic agents | Form-5-D<br>Dy. No: 42914<br>Dated.17-12-2018<br>Rs.20,000/- (17-12-18)<br>10's ; Rs. 316/- | ELIQUIS (USFDA Approved)<br>GMP inspection report conducted on Last inspection was conducted on 7-2-2017 concluding very good compliance |

| STABILITY STUDY DATA | |
|---|---|
| Drug | Api-Tab tablet 2.5 mg |
| Name of Manufacturer | M/s Werrick Pharmaceuticals, Plot # 216, 217, I-10/3, Industrial Area, Islamabad. |
| Manufacturer of API | Apixaban: M/s Glenmark pharmaceuticals ltd. Plot # 3109 C, GIDC industrial estate Ankleshwar-393002, Gujrat India. |
| API Lot No. | Apixaban: |

| | | | |
|---|---|---|---|
| Description of Pack (Container closure system) | Alu / PVC Blister Pack | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months<br>Real Time: 06 Months | | |
| Frequency | Accelerated: 0, 1,2,3,4, 6 (Months)<br>Real Time : 0, 3 ,6 (Months) | | |
| Batch No. | Trail #1 | Trail #2 | Trail #3 |
| Batch Size | 1500 Tablets | 1500Tablets | 1500 Tablets |
| Manufacturing Date | 3-2018 | 3-2018 | 3-2018 |
| Date of Initiation | 4-2018 | 4-2018 | 4-2018 |
| No. of Batches | 03 | | |
| Date of Submission | 17-12-2018 (Dy. No. 42910) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | Apixaban: Firm has submitted copy of GMP Certificate of manufacturer "M/s Glenmark pharmaceuticals Ltd. Plot# 3109 C, GIDC industrial estate Ankleshwar-393002, Gujrat India. License #: 1708289 |
| 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. | Copy of invoice provided. Not ADC (Islamabad) attested |
| 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**

- Dissolution is according to USFDA.

**Data for exemption from On-site investigation of submitted stability data**

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | • Last onsite inspection of werrick pharmaceuticals was conducted on 19-4-2017 for Cell tab tablets (Sofosbuvir tablet). Approved in 273meeting<br>o Date of Inspection: 19-4-2017<br>o The HPLC is 21CFR Compliant.<br>o Audit trail on the testing reports was available and confirmed. Panel reviewed chromatograms for testing of API and trial batches audit trail at 0, 3 and 6 months for real time and accelerated stability testing |

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<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Apixaban: The firm has submitted photocopies of Commercial Invoice attested by ADC Islamabad<br>The firm has imported “Apixaban” Raw Material, Qty; 0.1 kg; Batch # 801704823 from same source via Invoice # 2006007416 dated: 29-9-2017.<br>Clearance certificate # 2960 is provided.<br>Form 7, form 3</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• The firm has submitted that the reference standard and impurity standards are procured along with the APIs’ consignment and not separately.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Apixaban: The Firm has submitted copy of GMP Certificate of manufacturer “M/s Glenmark pharmaceuticals Ltd. Plot # 3109 C, GIDC industrial estate Ankleshwar-393002, Gujrat India issued by food and drug control administration Gandhinagar Gujrat state India which is valid till 18/8/2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from APIs manufacturer.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Apixaban:<br>Photocopy of COA of Batch No. 801704823 issued by “M/s Glenmark pharmaceuticals ltd. Plot # 3109 C, GIDC industrial estate Ankleshwar-393002, Gujarat India is submitted.<br>• Reference standards and impurity standards:<br>The firm has submitted copy of COA of Working Standards and impurity standards provided by the API Manufacturer</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of commercial invoices for the excipients used in the applied formulation.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted copy of R&D staff list.10 persons present in there R &D 8 are pharmacist, 1 MPhil microbiology and 1 MPhil chemistry</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 copy of SOP with the title ‘Authorized Protocol For Development of Api-tab 2.5 mg.<br>Effective date 16-2-2018</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
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<tr><td>Trail#1</td><td>1500 Tabs</td><td>3-2018</td></tr>
<tr><td>Trail#2</td><td>1500 Tabs</td><td>3-2018</td></tr>
<tr><td>Trail#3</td><td>1500 Tabs</td><td>3-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Api-Tab 2.5 mg ;<br>Stability Pack Size : 1 x 10’s<br>• Trail #1: Batch Size : 1500 Tablets<br>Yield 1253 Tablets (125 Packs) ,<br>28 Packs used for testing<br>97 packs are remaining<br>• Trail #2: Batch Size : 1500 Tablets<br>Yield 1248 Tablets (124 Packs) ,<br>26 Packs used for testing<br>71 packs are remaining<br>• Trail #3: Batch Size : 1500 Tablets<br>Yield 1254 Tablets (125 Packs) ,<br>70 Packs used for testing<br>97 packs are remaining</td></tr>
<tr><td colspan="3">QA/QC DATA</td></tr>
</table>

<table>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Previously Reported in panel inspection:<br>The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability & for Accelerated Stability studies)<br>Now the firm has submitted copy of record of digital data logger for temperature and humidity monitoring of stability chambers from April till oct 2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>• The firm has submitted photocopy of method used for analysis of APIs (Apixaban) along with COA.</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 Specifications and Testing Method of Api-tab 2.5 mg and its validation data.<br>• Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 months stability data (Accelerated & Real Time).</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Apixaban: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5 % RH) & long term, 24 Months (30°C±2°C & 65±5%RH) stability study reports of 03 batches of Apixaban</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients (titanium dioxide, polysorbate tween 80, SLS, HPMC, Mg stearate, Lactose tablettose, and Microcrystalline cellulose, cross carmilose, talcum, used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• Stability studies are indicative of chemical and physical compatibility with the drug product</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative dissolution study of their product (Api-tab 2.5 mg) with Innovator’s Brand Eliquis 2.5 mg” conducted on following dates ;<br>The details are as follows:
<table>
<tr><td>Feature</td><td>Reference Product</td><td>Product Pharma</td></tr>
<tr><td>Brand name</td><td>Eliquis 2.5 mg Tablets</td><td>Api-tab 2.5 mg Apixaban</td></tr>
</table>
• Comparative dissolution studies have been performed in following media:<br>Apixaban:<br>vii. 0.01N Hydrochloric Acid Solution<br>viii. pH 4.5 Acetate buffer solution.<br>ix. pH 6.8 phosphate buffer solution.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted copy of Audit Trail for Initial, 3rd and 6th Month Testing Intervals</td></tr>
</table>

**Evaluation by PEC:**

Above observation were communicated to firm vide letter no. F.1-1/2019/PEC-DRAP (AD PEC-VII), to which firm has responded as under:

| S # | Deficiency/Observation | Response by Pharma. |
|---|---|---|
| I. | Provide the complete inspection report of cell tab to show evidence of The 21CFR Compliant of HPLC and Audit trail on the testing reports of cell tab 400 mg tablets | Provided and verified that HPLC is 21 CFR compliant and audit trails are available |
| II. | On Commercial invoice ADC attestation is not readable and clear | Attested copy is provided |
| III. | List of qualified staff involved in product development with relevant experience does not mentioned their qualifications | Provided |
| IV. | The particle size of the drug substance was identified as a critical factor based on its influence on the dissolution of the tablets. A study was conducted to establish the drug substance particle size requirement that would produce the required in-vitro drug release and appropriate limit has been se https://www.ema.europa.eu/documents/assessment-report/eliquis-epar-public-assessment-report_en.pdf | The particle size of API manufacture was determined by API manufacturer as mentioned in COA of API (Particle size is mentioned as D (90)= 82.4 um) |
| V. | Why there is additional peaks along with principle peaks in chromatograms of drug assay and dissolution area at different time points (e.g. accelerated study, 1 month vial 2, 4, 5 etc.) | There are no additional peaks in the assay chromatograms where as in the dissolution chromatograms the extra peaks are due to the dissolution medium |
| VI. | Why baseline is not stable and there are extra peaks in comparative dissolution chromatograms. | The baseline and extra peaks in comparative dissolution chromatograms are due to different dissolution mediums used |

**Decision: Registration Board decided to constitute panel for the Api-Tab tablet 2.5 mg for onsite investigation to confirm genuineness / authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc., along with following observations**

| S# | Observation | Response of Pharma |
|---|---|---|
| a | Why there is additional peaks along with principle peaks in chromatograms of drug assay and dissolution area at different time points (e.g. accelerated study, 1 month vial 2, 4, 5 etc.) | There are no additional peaks in the assay chromatograms where as in the dissolution chromatograms the extra peaks are due to the dissolution medium |
| b | Why baseline is not stable and there are extra peaks in comparative dissolution chromatograms. | The baseline and extra peaks in comparative dissolution chromatograms are due to different dissolution mediums used |

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1259. | M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi | Experta Tablet 90 mg<br>Each film coated tablet contains:<br>Ticagrelor… 90 mg<br>(Anti-coagulant)<br>In-house Specifications | Form-5D<br>Dy. No.<br>09-04-2015<br>Rs. 50,000/-<br>Pack Size:<br>14's<br>178.57/- | BRILINTA of Astrazenica USFDA Approved.<br>Not applicable<br><br>GMP compliant dated 07/02/18<br>"On the basis of current inspection it was observed |

| | | | | |
|---|---|---|---|---|
| | | | | that the firm rectified all observations noted during last GMP Inspection." |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Experta Tablet 90 mg | | |
| Name of Manufacturer | M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi | | |
| Manufacturer of API | Ticagrelor:: Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china | | |
| API Lot No. | **Ticagrelor:** TGL-160301 | | |
| Description of Pack (Container closure system) | Alu / Alu Blister Pack | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time : 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months Real Time: 18 Months | | |
| Frequency | Accelerated: 0, 3 ,6 (Months)<br>Real Time : 0, 3 ,6 ,9, 12, 18 (Months) | | |
| Batch No. | TR001/EXP | TR002/EXP | TR003/EXP |
| Batch Size | 165 Tablets | 165 Tablets | 165 Tablets |
| Manufacturing Date | 2 - 2017 | 2– 2017 | 2– 2017 |
| Date of Initiation | 15-2-2017 | 15-2-2017 | 15- 2-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 23/10/2018 (Dy. No. 36409-B) | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr. No.** | **Documents To Be Provided** | **Status** |
| 1. | COA of API | Yes |
| 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. | Tecaglore: Firm has submitted copy of GMP Certificate of manufacturer Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china valid till 7/9/2020 |
| 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. | Copy of ADC (Karachi) attested invoice provided for 0.1 kg of Ticagrelor provided in which issuer is Changzhou pharmaceuticals factory no. 2 cailing road Changzhou Jiangsu china |
| 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 |

<table>
<tr><th colspan="3">REMARKS OF EVALUATOR</th></tr>
<tr><th colspan="3">Data for exemption from On-site investigation of submitted stability data</th></tr>
<tr><th colspan="3">Administrative Portion</th></tr>
<tr><td>1.</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>• Registration Board approved Nisita Tablets 60 mg and Vibrenta tablet 400/100 mg in its 279 Meeting.<br>o Date of Inspection: 19-02-2017.<br>o The HPLC is 21CFR Compliant.<br>o Audit trail on the testing were available.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Tecaglore: The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 05-12-2017, Commercial Invoice attestation on dated 22/2/18 for 0.1 kg of Tecaglore. Batch # TGL-160301 from Changzhou pharmaceuticals factory no. 2 cailing road Changzhou Jiangsu china</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• The firm has submitted analytical reports/COA of reference standard & impurity standards.<br>• The firm has clarified that the reference standard and impurity standards are provided free of cost along with the APIs' consignment and not separately by Nantong chanyoo.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The Firm has submitted copy of GMP Certificate of manufacturer "Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Tecaglore API:<br>Photocopy of COA of Batch No. TGL-160301 issued by "M/s Nantong Chanyoo Pharmaceutical Co., Ltd. China" is submitted.<br>• Reference standards and impurity standards:<br>The firm has submitted copy of Working Standards and impurity standards provided by the API Manufacturer</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of commercial invoices for the excipients used in the applied formulation.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted copy of R&D staff list.2 pharmacists and 2 BSC are present in there R &D</td></tr>
<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 copy of SOP with the title 'Product Development Protocols'.<br>Effective date 28-02-2017.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th colspan="3">Experta Tablet 90 mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th></tr>
<tr><td>TR001/EXP</td><td>165 Tabs</td><td>2-2017</td></tr>
<tr><td>TR002/EXP</td><td>165 Tabs</td><td>2-2017</td></tr>
<tr><td>TR003/EXP</td><td>165 Tabs</td><td>2-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>• TR001: Batch Size : 165 Tablets<br>Remaining: 28 tablets</td></tr>
</table>

| | | |
|---|---|---|
| | | • TR002: Batch Size : 165 Tablets<br>Remaining: 28 tablets<br>• TR003: Batch Size : 165 Tablets<br>Remaining: 28 tablets |
| **QA/QC DATA** | | |
| 12. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | The firm has submitted copy of record of digital data logger (Logit Chart, Technoman) for temperature and humidity monitoring of stability chambers. |
| 13. | Method used for analysis of API along with COA. | • The firm has submitted photocopy of method used for analysis of APIs along with COA. |
| 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 Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 months stability data (Accelerated) & Real Time. |
| 15. | Reports of stability studies of API from manufacturer. | **Tacagrelor:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) & **long term, 12 Months** (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches |
| 16. | Analysis reports for excipients used. | The firm has submitted copy of COAs for the excipients used in the applied formulation. |
| 17. | Drug-excipients compatibility studies. | • The firm has not submitted Drug-excipients compatibility studies and has referred to the Innovator Product (Brilinta). |
| 18. | Record of comparative dissolution data. | • Firm has submitted Comparative dissolution study of their product with Innovator's Brand " Brilinta" conducted on following dates ;<br>• The details are as follows: |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted copy of Audit Trail for march 2018 to august 208, but the data from Feb 2017-feb 2018 were un-retrievable from the system but firm claim to have hard copies of chromatograms |

| **Feature** | **Reference Product** | **Product of Tabross Pharma** |
|---|---|---|
| Brand name | Brilinta Tablets 90 mg | Experta Tablet 90 mg |
| Mfg. date | Not mentioned | 2-2017 |

**Evaluation by PEC:**

| **Sr.#** | **Deficiency/Observation** | **Response by Pharma.** |
|---|---|---|
| | On commercial invoice different manufacturer was mentioned. On commercial invoice Changzhou pharmaceutical is mentioned and GMP provided is of Nantong Jiangsu | Firm provided the statement by Changzhou pharmaceuticals factory declare that Nantong chanyoo pharmatech Co.Ltd located No 2 tonghai Sirod Yangkou chemicals industrial park, rudong coastal economic development zone, Nantong Jiangsu province 226407, PR China is our wholly owned subsidiary. |
| | Stability of API ticaglerol is at 25°C ± 2°C & 60±5%RH | Manufacturer has started stability study at zone IV-A conditions and completed 1 month stability data. And undertake to provide 12 month real time stability |
| | The GMP certificate of Nantong Jiangsu is valid till November 2018, provide valid GMP | Valid GMP is provided, valid up to 7/9/2020 |
| | Comparative dissolution is not performed according to recommended methods on 3 pH medium. | Dissolution is performed on 3 mediums at 4.5, 1.2 and 6.8 on fresh trail batch, dissolution was performed at 5, 10, 15, 20, 30, 45 and 60 minutes. |

| | | |
|---|---|---|
| | Exact polymorphic form could not be verified as no data of types of polymorphic forms available/provided by the firm and it's not possible to precisely identify the stable polymorphic form of Ticagrelor. | This is to provide exact info of polymorphic form of ticagrelor as per required by registration board. According to lit review and research patents it can be verified that crystalline form II is used in drug product formulation and we are using the same (COA is provided) |

**Decision: Registration Board deferred the case for submission of stability data of API as per Zone IV-A. As manufacturer has provided with only 1 month stability data of 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1260. | M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi | Experta Tablet 60 mg<br><br>Each film coated tablet contains:<br>Ticagrelor… 60 mg<br>(Anti-coagulant)<br>In-house Specifications | Form-5D<br>Dy. No.<br>31835<br>16-Nov-2015<br>Rs. 50,000/-<br>Pack Size:<br>14's<br>142.87/- | BRILINTA of Astrazenica USFDA Approved.<br>Not applicable<br><br>GMP compliant dated |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Experta Tablet 60 mg | | |
| Name of Manufacturer | M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi | | |
| Manufacturer of API | Ticagrelor:: Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china | | |
| API Lot No. | **Ticagrelor:** TGL-160301 | | |
| Description of Pack (Container closure system) | Alu / Alu Blister Pack | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time : 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months Real Time: 18 Months | | |
| Frequency | Accelerated: 0, 3 ,6 (Months)<br>Real Time : 0, 3 ,6 ,9, 12, 18 (Months) | | |
| Batch No. | TR001/EXP | TR002/EXP | TR003/EXP |
| Batch Size | 250 Tablets | 250 Tablets | 250 Tablets |
| Manufacturing Date | 2 - 2017 | 2– 2017 | 2– 2017 |
| Date of Initiation | 15-2-2017 | 15-2-2017 | 15- 2-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 23/10/2018 (Dy. No. 36409-B) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |

| | | |
|---|---|---|
| 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. | Tecaglore: Firm has submitted copy of GMP Certificate of manufacturer Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china valid till 3-nov-2018 |
| 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. | Copy of ADC (Karachi) attested invoice provided for 0.1 kg of Ticagrelor provided in which issuer is Changzhou pharmaceuticals factory no. 2 cailing road Changzhou Jiangsu chaina |
| 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**

**Data for exemption from On-site investigation of submitted stability data**

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | • Registration Board approved Nisita Tablets 60 mg and Vibrenta tablet 400/100 mg in its 279 Meeting.<br>○ Date of Inspection: 19-02-2017.<br>○ The HPLC is 21CFR Compliant.<br>○ Audit trail on the testing were available. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | **Tecaglore:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 05-12-2017, Commercial Invoice attestation on dated 22/2/18 for 0.1 kg of Tecaglore. Batch # TGL-160301 from Changzhou pharmaceuticals factory No. 2 cailing road Changzhou Jiangsu chaina |
| 3. | Documents for the procurement of reference standard and impurity standards. | • The firm has submitted analytical reports/COA of reference standard & impurity standards.<br>• The firm has clarified that the reference standard and impurity standards are provided free of cost along with the APIs' consignment and not separately by Nantong chanyoo. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | The Firm has submitted copy of GMP Certificate of manufacturer "Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china. |
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| 6. | Certificate of analysis of the API, reference standards and impurity standards | • **Tecaglore API:**<br>Photocopy of COA of Batch No. TGL-160301 issued by "M/s Nantong Chanyoo Pharmaceutical Co., Ltd. China" is submitted.<br>• **Reference standards and impurity standards:**<br>The firm has submitted copy of Working Standards and impurity standards provided by the API Manufacturer |
| 7. | Documents for the | Firm has submitted copy of commercial invoices for the excipients used in |

<table>
<tr><td></td><td>procurement of excipients used in product development?</td><td>the applied formulation.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted copy of R&D staff list.2 pharmacists and 2 BSC are present in there R &D</td></tr>
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<tr><td>TR003/EXP</td><td>250 Tabs</td><td>2-2017</td></tr>
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<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>• TR001: Batch Size : 250 Tablets<br>Remaining: 42 tablets<br>• TR002: Batch Size : 250 Tablets<br>Remaining: 42 tablets<br>• TR003: Batch Size : 250 Tablets<br>Remaining: 42 tablets</td></tr>
<tr><td colspan="3">QA/QC DATA</td></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>The firm has submitted copy of record of digital data logger (Logit Chart, Technoman) for temperature and humidity monitoring of stability chambers.</td></tr>
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<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Tacagrelor: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 12 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not submitted Drug-excipients compatibility studies and has referred to the Innovator Product (Brilinta).</td></tr>
</table>

<table>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>
<ul>
<li>Firm has submitted Comparative dissolution study of their product with Innovator's Brand " Brilinta" conducted on following dates ;</li>
<li>The details are as follows:</li>
</ul>
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Tabross Pharma</th></tr>
<tr><td>Brand name</td><td>Brilinta Tablets 90 mg</td><td>Experta Tablet 90 mg</td></tr>
<tr><td>Mfg. date</td><td>Not mentioned</td><td>2-2017</td></tr>
<tr><td>Medium</td><td colspan="2">0.2% w/v tween 80 in water</td></tr>
<tr><td>RPM</td><td colspan="2">75</td></tr>
</table>
</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted copy of Audit Trail for march 2018 to august 208, but the data from Feb 2017-feb 2018 were un-retrievable from the system but firm claim to have hard copies of chromatograms</td></tr>
</table>

**Evaluation by PEC:**

| Sr.# | Deficiency/Observation | Response by Pharma. |
|---|---|---|
| i. | On commercial invoice different manufacturer was mentioned. On commercial invoice Changzhou pharmaceutical is mentioned and GMP provided is of Nantong Jiangsu | Firm provided the statement by Changzhou pharmaceuticals factory declare that Nantong chanyoo pharmatech Co.Ltd located No 2 tonghai Sirod Yangkou chemicals industrial park, rudong coastal economic development zone, Nantong Jiangsu province 226407, PR China is our wholly owned subsidiary. |
| ii. | Stability of API ticaglerol is at 25˚C ± 2˚C & 60±5%RH | Manufacturer has started stability study at zone IV-A conditions and completed 1 month stability data. And undertake to provide 12 month real time stability |
| iii. | The GMP certificate of Nantong Jiangsu is valid till November 2018, provide valid GMP | Valid GMP is provided, valid up to 7/9/2020 |
| iv. | Comparative dissolution is not performed according to recommended methods on 3 pH medium. | Dissolution is performed on 3 mediums at 4.5, 1.2 and 6.8 on fresh trail batch, dissolution was performed at 5, 10, 15,20, 30, 45 and 60 minutes. |
| v. | Exact polymorphic form could not be verified as no data of types of polymorphic forms available/provided by the firm and it's not possible to precisely identify the stable polymorphic form of Ticagrelor. | This is to provide exact info of polymorphic form of ticagrelor as per required by registration board. According to lit review and research patents it can be verified that crystalline form II is used in drug product formulation and we are using the same (COA is provided) |

**Decision: Registration Board deferred the case for submission of stability data of API as per Zone IV-A. As manufacturer has provided with only 1 month stability data of API.**

| | | |
|---|---|---|
| 1261. | Name and address of manufacturer / Applicant | M/s. Atco Laboratories Limited, B-18, S.I.T.E, Karachi. |
| | Brand Name +Dosage Form + Strength | Advacort 0.1% Lotion |
| | Composition | Each ml contains:<br>Methyl prednisolone aceponate….1mg |
| | Diary No. Date of R& I & fee | Dy No. 127; 14-10-2010 |
| | Pharmacological Group | Alpha-adrenoreceptor antagonists/Muscarinic Antagonist. |
| | Type of Form | Form-5D |
| | Finished product Specifications | Manufacturer's specifications |
| | Pack size & Demanded Price | 30ml, 60ml : Rs. 225/-, Rs. 330/-, |
| | Approval status of product in Reference Regulatory Authorities | Approved in TGA |
| | Me-too status<br>(with strength and dosage form) | N/A |
| | GMP status | |
| | **Decision:** Deferred for the following:<br>1. Confirmation of manufacturing facility for steroids.<br>2. Stability studies as per ICH/ WHO guidelines.<br>3. Clinical trial data along with clinical justification. | |
| | Previous Decision: | Registration Board in its 246th meeting deferred the case for the following:<br>1. Confirmation of manufacturing facility for steroids.<br>2. Stability studies as per ICH/ WHO guidelines.<br>3. Clinical trial data along with clinical justification. |
| | Evaluation By PEC: | Now the firm has submitted the following:<br>• Stability studies data for the applied formulation & claimed Exemption from onsite investigation of stability studies.<br>• Applied drug Product is approved in TGA. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Advacort 0.1% Lotion | | |
| Name of Manufacturer | M/s. Atco Laboratories Limited, B-18, S.I.T.E, Karachi. | | |
| Manufacturer of API | **Methyl Prednisolone Aceponate:**<br>M/s SymbioticaSpeciality Ingredients SDN, BHD, Malaysia | | |
| API Lot No. | Methyl Prednisolone Aceponate: | | |
| Description of Pack<br>(Container closure system) | HDPE Bottles | | |
| Stability Storage Condition | Real Time: 30ºC ± 2ºC / 65% ± 5%RH<br>Accelerated:40ºC ±2ºC / 75% ± 5%RH<br>Conditions of zone Ivb | | |
| Time Period | Real Time: 06 Months<br>Accelerated:06Months | | |
| Frequency | Real Time: Initial,3,6 Months(on going)<br>Accelerated: Initial,1,2,3,4,6 Months | | |
| Batch No. | 152F17 | 153F17 | 154F17 |
| Batch Size | 800gm | 800gm | 800gm |
| Manufacturing Date | 20-06-2017 | 20-06-2017 | 21-06-2017 |
| Date of Initiation | 07-07-2017 | 07-07-2017 | 07-07-2017 |
| No. of Batches | 03 | | |
| Date of Submission | Dy No. 34108 : 15-10-18 | | |

| DOCUMENTS / DATA PROVIDED BY THE APPLICANT | | |
|---|---|---|
| **Sr. No.** | **Documents To Be Provided** | **Status** |
| 1. | COA of API | Yes |
| 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. | The firm has submitted photocopy of GMP certificate issued by National Pharmaceutical Regulatory Agency, Ministry Of Health Malaysia, valid till 19thApril 2019. |
| 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. | Yes |
| 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**

| | **Administrative Portion** | |
|---|---|---|
| 01 | Reference of last onsite panel inspection for instant dosageform conducted during last two years. | Drug Registration Board approved Nonit Lotion 0.5% (Ivermectin) in its 284th Meeting on the basis of inspection conducted on 26th of July, 2018 which confirms following:<br>• HPLC software is 21CFR Compliant as per record available with firm.<br>• Audit trail reports on testing are available & verifiable.<br>• Adequate monitoring & control are available for stability chambers.<br>*But same inspection does not confirm the existence of digital data logger with the firm, however; applicant has submitted temperature & humidity record of stability chambers recorded with digital data logger.* |
| 02 | Documents for the procurement of API with approval from DRAP (in case of import). | The firm has submitted photocopy of ADC (Karachi) attested dated 16-05-2017, Commercial Invoice dated 05-05-2017 for 1.0kg Methyl Prednisolone Aceponate.Commercial Invoice is issued by M/s SymbioticaSpeciality Ingredients SDN, BHD, Malaysia. |
| 03 | Documents for the procurement of reference standard and impurity standards | The firm has submitted photocopy of Invoice dated 14-5-2017 for 100mg Methyl Prednisolone Aceponate working standard.<br>The firm has submitted the photocopy of invoice dated 27.02.2018 for 10mg each of following impurity standards<br>• Methyl prednisolone<br>• Methyl prednisolone-21-acetate<br>• Methyl prednisolone-17-propionate<br>• Methyl prednisolone-21-propionate<br>• Methyl prednisolone-17-propionate-11, 21-diacetate |
| 04 | GMP/DML certificate of API manufacturer. | The firm has submitted photocopy of GMP certificate issued by National Pharmaceutical Regulatory agency, ministry of Health Malaysia, valid till 19th April 2019. |
| 05 | Mechanism for Vendor pre-qualification | The firm has submitted copy of API Management and Acceptance Policy |

<table>
<tr><td>06</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of methyl prednisolone aceponate, of the, reference standards and impurity standards issued by M/s SymbioticaSpeciality Ingredients SDN, BHD, Malaysia is submitted. Detail is as under
<table>
<tr><th>Particulars</th><th>Batch No.</th></tr>
<tr><td>Methyl prednisolon aceponate</td><td>19</td></tr>
<tr><td>Methyl prednisolne</td><td>WS/MBP/0217</td></tr>
<tr><td>Methyl prednisolone acetate</td><td>WS/methyl prednisolone/21/acetate/1116</td></tr>
<tr><td>Methyl prednisolone-17-propionate</td><td>WS/methyl prednisolone/17/propionate/1116</td></tr>
<tr><td>Methyl prednisolone-21-propionate</td><td>WS/methyl prednisolone/21/propionate/1116</td></tr>
<tr><td>Methyl prednisolone-17-propionate-11, 21-Diacetate</td><td>WS/methyl prednisolone/17/propionate-11, 21-Diacetate/0516</td></tr>
</table></td></tr>
<tr><td>07</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of commercial invoices for the excipients used in the applied formulation.</td></tr>
<tr><td>08</td><td>List of qualified staff involved in product development with relevant experience</td><td>The firm has submitted photocopy of List of qualified staff involved in product development/Scientific development & Analytical Services comprising of total 23 members.</td></tr>
<tr><td rowspan="2"></td><td colspan="2">Production Data</td></tr>
<tr><td>09</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Product Development Protocol(SOP referenceNo. PDD/PP/PD/001) filled for Advacort lotion 0.1%, dated 13-04-2017, which also includes stability protocol.</td></tr>
<tr><td>10</td><td>Complete batch manufacturing record of three stability batches</td><td>The firm has submitted photocopy of BatchManufacturing Record of the following 03 Batches of Advacort 0.1% lotion:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg date</th></tr>
<tr><td>152F17</td><td>800g</td><td>20.06.2017</td></tr>
<tr><td>153F17</td><td>800g</td><td>20.06.2017</td></tr>
<tr><td>154F17</td><td>800g</td><td>21.06.207</td></tr>
</table></td></tr>
<tr><td>11</td><td>Record of remaining quantities of stability batches.</td><td>The firm has reconciliation sheets mentioning details of all three trial batches of Advacort 0.1% Lotion.</td></tr>
<tr><td></td><td colspan="2">QC/ QA DATA</td></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>The firm has submitted digital temperature and humidity monitoring record for accelerated and long term conditions from July2017 to Jan 2018.</td></tr>
<tr><td>13</td><td>Method used for analysis of API along withCOA.</td><td>The firm has submitted photocopy of raw materialspecifications, raw material testing procedures along with COA for methyl prednisolone aceponate (Batch MPAP004/0816) from ATCO laboratories limited and M/s SymbioticaSpeciality Ingredients SDN, BHD, Malaysia.</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 Specifications and Testing Method for Advacort 0.1% Lotion.<br>Complete record of testing of stability batches 152F17, 153F17 and 154F17 (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with the stability data.</td></tr>
<tr><td>15</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 60 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Methyl Prednisolone Aceponate from M/s SymbioticaSpeciality Ingredients SDN. BDH, Malaysia.</td></tr>
<tr><td>16</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17</td><td>Drug-excipients compatibility studies</td><td>The firm has submitted the Drug excipients compatibility study report.</td></tr>
</table>

| | | |
|---|---|---|
| 18 | Record of comparative dissolution data. | Due to semisolid topical dosage form, its CDP is not required. |
| 19 | Compliance Record of HPLC software21CFR & audit trail reports on product testing. | The firm has submitted copy of Audit Trail for Initial, 1st3rd and 6th Month Testing Intervals of Advacort 0.1% Lotion. |

| Sr. No | Question By PEC | Response By Firm |
|---|---|---|
| 1 | Clarification is required whether stability studies of applied formulation are conducted in accordance with either zone IVa or IVb conditions, as conditions mentioned on stability summary sheets are of zone IVb. | We would like to inform that we are evaluating our products is astringent condition zone i.e.<br>Accelerated $40^0$ C $\pm$ $2^0$ C / 75% RH $\pm$5%RH<br>Long term $30^0$ C $\pm$ $2^0$ C / 75% RH $\pm$ 5%RH<br>As we are an exporting country and also export in ASEAN countries, which require stability studies of product in zone IVb so we are doing same for our local produts.<br>Stability studties of product for accelerated condition conducted at temperature 40 $\pm 2^0$C and RH 75$\pm$ 5% whereas long term stability studies are conducted at 30$\pm$ 2 % and RH 75$\pm$ 5% that has been submitted. Furthermore, it can also be verified by temperature monitering record of stability chambers already submitted. |
| 2 | Batch number of API is not mentioned on the commercial invoice. How did you come to know about the batch number of API. | Batch number of API in not mentioned on commercial invoice but mentioned in packing list. Packing list and invoice can be related with invoice number along with contract number and its date that is 117/0378 and 0071IRC007833 dated 05/04/2017 respectively. Related documents are being attached and stated information is highlighted for your convenience. Find in annexure 02. |
| 3 | Did you use analytical method of either supplier or your in house & have you performed method validation studies if yes, than submit the data. If No, than clarify/justify. | It is to inform that we are using our own developed method that is extracted from supplier's method for our product. Analytical method validation is performed and report is attached for review in annexure 03.<br>With this submission we hope to suffice your requirements and request you to include our subject products in the agenda of upcoming drug Registrant Board meeting for the grant of approval of registration. |
| 4 | COA of HPMC 2910 is not submitted. | It is to clarify that COA of HPMC 2910 has been submitted. However, COA is being submitted again for your review in Annexure 01. |

**Decision: Registration Board decided to approve registration of "Advacort 0.1% Lotion" by M/s Atco Laboratories Limited, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

**Evaluator PEC-XII**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1262. | M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot no. 2, M-2 Pharma Zone, 28-km Lahore Sharaqpur Road, District Sheikhupura. | **Dapajen 5mg Tablet**<br>Each film coated tablet contains:<br>Dapagliflozin propanediol monohydrate eq to dapagliflozin ……..…….5mg<br><br>Blood glucose lowering drugs, excl. insulins (Sodium-glucose co-transporter 2 (SGLT2) inhibitors)<br><br>Manufacturer's Specifications. | Form 5-D<br><br>Dairy No. 1270 dated 28-11-2016.<br>Rs.50,000/- dated 28-11-2016.(Challan#0565607)<br><br>As per SRO / 14's. | FARXIGA film coated tablets 5mg by M/s Astrazeneca AB (USFDA approved)<br><br>Last GMP inspection conducted on 06.11.2017 and the report concludes that overall the condition of firm is satisfactory. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Dapajen 5mg Tablet (Dapagliflozin propanediol monohydrate) | | |
| Name of Manufacturer | M/s Jenner Pharmaceuticals (Pvt) Ltd. | | |
| Manufacturer of API | M/s Fuxin Long Rui Pharmaceutical Co., Ltd.<br>Fluoride Industrial Park, Fuxin City, Liaoning Province – 123000, China. | | |
| API Lot No. | 160901 | | |
| Description of Pack (Container closure system) | Alu Alu Blister Pack in Unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 6 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,1,2,3,4,5,6 (months)<br>Real Time: 0,3,6 (months) | | |
| Batch No. | DAP-PB-008001 | DAP-PB-008002 | DAP-PB-008003 |
| Batch Size | 2000 Tablets | 2000 Tablets | 2000 Tablets |
| Manufacturing Date | 05-2018 | 05-2018 | 05-2018 |
| Date of Initiation | 15-05-2018 | 15-05-2018 | 15-05-2018 |
| No. of Batches | 03 | | |
| Date of Submission | 11-01-2019 (Dy. No. 1457) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents to Be Provided | Status |
|---|---|---|
| 1. | COA of API | • Method used for analysis of API along with copy of COA for dapagliflozin propanediol monohydrate from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. has been 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. | • Approval of DML of Fuxin Long Rui Pharmaceutical Co., Ltd. (Certificate number Liao 20150233) valid till 20-12-2022 confirmed.<br>• Weblink: http://app1.sfda.gov.cn/datasearcheng/face3/base.jsp?tableId=85&tableName=TABLE85&title=Database%20of%20approved%20Active%20Pharmaceutical%20Ingredients%20(APIs)%20and%20API%20manufacturers%20in%20China&bcId=136489131226659132460942000667<br>Accessed on 22-01-2019. |
| 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. | • Firm has submitted ADC attested copy dated **20-03-2017** confirming import of 175 grams of Dapagliflozin propanediol monohydrate.<br>Batch no. not mentioned on invoice<br>Invoice no. HK 1701121-B<br>• Firm has submitted copy of Form-3 confirming import of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd.<br>• Firm has submitted copy of Form-7 confirming batch no of API i.e. 160901. |
| 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 |
| **Data for exemption from On-site investigation of submitted stability data** | | |
| **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 "Lansodex Capsule 60mg and 30 mg, Sofopas Tablet 400/90 and 400 mg)", which was conducted on 10-12-2018 and was presented in 287th Meeting of Registration board. Registration Board decided to approve registration of Lansodex Capsule 60mg and 30 mg, Sofopas Tablet 400/90 and 400 mg of M/s Jenner Pharmaceuticals (Pvt) Ltd,. Sheikupura.<br>❖ According to the report generated following points were confirmed<br>a) The firm has complete record of qualification of equipment / instruments used for test and analysis of API and Sobovir Tablets 400mg.<br>b) The HPLC used for analysis of stability batches is Shimadzu 20 ATVP with auto sampler and gradient system and it was 21 CFR compliant.<br>c) The firm has demonstrated the audit trail reports for the data submitted for Sobovir Tablets 400mg.<br>d) The firm has valid calibration status for all the equipments/ instruments used in production and analysis of the Sobovir Tablets 400mg.<br>e) The firm has two separate Memmert (Germany) stability chambers for Real Time and Accelerated stability studies which are equipped with data loggers. For continuous power supply solar panels were |

<table>
<tr><td></td><td></td><td>installed Firm was advised to completely follow SOPs for continuous monitoring of stability chambers. Firm was also advised to use the installed alarm system more effectively.<br>f) Firm has dedicated area for product development, and all manufacturing area, equipment, personnel seemed to conform to a satisfactory level of cGMP compliance on the day of inspection.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>• Firm has submitted ADC attested copy dated 20-03-2017 confirming import of 175 grams of Dapagliflozin propanediol monohydrate.<br>Batch no. not mentioned on invoice<br>Invoice no. HK 1701121-B<br>• Firm has submitted copy of Form-3 confirming import of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd.<br>• Firm has submitted copy of Form-7 confirming batch no of API i.e. 160901.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• Firm has not submitted documents for procurement of reference and impurity standards.<br>• Quantity of working standard imported by the firm is not confirmed.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>• Approval of DML of Fuxin Long Rui Pharmaceutical Co., Ltd. (Certificate number Liao 20150233) valid till 20-12-2022 confirmed.<br>• Weblink:<br>http://app1.sfda.gov.cn/datasearcheng/face3/base.jsp?tableId=85&tableName=TABLE85&title=Database%20of%20approved%20Active%20Pharmaceutical%20Ingredients%20(APIs)%20and%20API%20manufacturers%20in%20China&bcId=136489131226659132460942000667<br>Accessed on 22-01-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• Firm has submitted vendor evaluation form which is filled by the applicant i.e. M/s Jenner Pharmaceuticals (Pvt) Ltd.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Certificate of analysis of the API, working standard and impurity standard submitted by the firm.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>• Firm has submitted documents for procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>• Firm has submitted list of 2 qualified person working in product development section.</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>• Firm has submitted SOP for product design and development protocol (document # PDP-STB-008) of Dapajen Tablet 5mg.<br>• Firm has submitted SOPs for stability study protocol. (document # JP/SSP/008) of Dapajen Tablet 5mg</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>• Firm has provided complete batch manufacturing record of all the three batches</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Batch No</th><th>Total no. of Tablets placed in stability chamber</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>DAP-PB-008001</td><td>854</td><td>336</td><td>520</td></tr>
<tr><td>DAP-PB-008002</td><td>854</td><td>336</td><td>520</td></tr>
<tr><td>DAP-PB-008003</td><td>854</td><td>336</td><td>520</td></tr>
</table>
</td></tr>
</table>

<table>
<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 record of digital data logger for temperature and humidity monitoring control for the complete stability period.<br>• For accelerated stability study the time period was from 25-04-2018 to 03-12-2018.<br>• For real time stability study the time period was from 25-04-2018 to 03-12-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>• Method used for analysis of API along with copy of COA for dapagliflozin propanediol monohydrate from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. has been submitted.<br>• Firm has submitted own analytical record i.e. method of analysis, lab report, raw data sheets, chromatograms for the analysis of Dapagliflozin propanediol monohydrate (batch# 160901).</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>• Firm has provided method used for analysis of FPP<br>Firm has submitted complete record of testing of stability batches including chromatograms, lab reports and raw data sheets</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>• Firm has submitted summary sheet of 3 batches of API conducted at 30˚C ± 2˚C / 65% ± 5%RH for long term for 36 months and 40˚C ± 2˚C / 75% ± 5%RH for accelerated studies for 6 months.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>• Firm has submitted COA and analysis reports of all excipients used in the study</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• Submitted by the firm.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative Dissolution studies report. The details of reference product & Sample product are as follows:
<table>
<tr><td>Feature</td><td>Reference product</td><td>Reference product Product of M/s Hilton</td></tr>
<tr><td>Brand name</td><td>Forxiga Tablets 5mg</td><td>Dapajen Tablets 5mg</td></tr>
<tr><td>Batch#</td><td>AAK 7311</td><td>DPA-PB-008001</td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:<br>• i. Acetate buffer pH 4.5</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
<tr><td colspan="3">Evaluation by PEC:</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “Dapajen tablet 5mg” by M/s Jenner Pharmaceuticals (Pvt) Ltd.,Sheikupura. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
</table>

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| 1263. | M/s Jenner Pharmaceuticals (Pvt) Ltd, Plot No. 2, M-2 Pharma Zone, 28-km Lahore Sharaqpur Road, District Sheikhupura. | **Dapajen 10mg Tablet**<br>Each film coated tablet contains:<br>Dapagliflozin propanediol monohydrate eq to dapagliflozin…….10mg<br><br>Blood glucose lowering drugs, excl. insulins (Sodium-glucose co-transporter 2 (SGLT2) inhibitors)<br><br>Manufacturer's Specifications. | Form 5-D<br><br>Dairy No. 1269 dated 28-11-2016.<br>Rs.50,000/- dated 28-11-2016.(Challan#0565606)<br><br>As per SRO / 14's. | FARXIGA film coated tablets 10mg by M/s Astrazeneca AB (USFDA approved)<br><br>Last GMP inspection conducted on 06.11.2017 and the report concludes that overall the condition of firm is satisfactory. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Dapajen 10mg Tablet (Dapagliflozin propanediol monohydrate) | | |
| Name of Manufacturer | M/s Jenner Pharmaceuticals (Pvt) Ltd. | | |
| Manufacturer of API | M/s Fuxin Long Rui Pharmaceutical Co., Ltd.<br>Fluoride Industrial Park, Fuxin City, Liaoning Province – 123000, China. | | |
| API Lot No. | 160901 | | |
| Description of Pack (Container closure system) | Alu Alu Blister Pack in Unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 6 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,1,2,3,4,5,6 (months)<br>Real Time: 0,3,6 (months) | | |
| Batch No. | DAP-PB-009001 | DAP-PB-009002 | DAP-PB-009003 |
| Batch Size | 2000 Tablets | 2000 Tablets | 2000 Tablets |
| Manufacturing Date | 05-2018 | 05-2018 | 05-2018 |
| Date of Initiation | 23-05-2018 | 23-05-2018 | 23-05-2018 |
| No. of Batches | 03 | | |
| Date of Submission | 11-01-2019 (Dy. No. 1458) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents to Be Provided | Status |
|---|---|---|
| 1. | COA of API | • Method used for analysis of API along with copy of COA for dapagliflozin propanediol monohydrate from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. has been 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. | • Approval of DML of Fuxin Long Rui Pharmaceutical Co., Ltd. (Certificate number Liao 20150233) valid till 20-12-2022 confirmed.<br>• Weblink: http://app1.sfda.gov.cn/datasearcheng/face3/base.jsp?tableId=85&tableName=TABLE85&title=Database%20of%20approved%20Active%20Pharmaceutical%20Ingredients%20(APIs)%20and%20API%20manufacturers%20in%20China&bcId=136489131226659132460942000667<br>Accessed on 22-01-2019. |
| 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. | • Firm has submitted ADC attested copy dated **20-03-2017** confirming import of 175 grams of Dapagliflozin propanediol monohydrate.<br>Batch no. not mentioned on invoice<br>Invoice no. HK 1701121-B<br>• Firm has submitted copy of Form-3 confirming import of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd.<br>• Firm has submitted copy of Form-7 confirming batch no of API i.e. 160901. |
| 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 |
| **Data for exemption from On-site investigation of submitted stability data** | | |
| **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 "Lansodex Capsule 60mg and 30 mg, Sofopas Tablet 400/90 and 400 mg)", which was conducted on 10-12-2018 and was presented in 287th Meeting of Registration board. Registration Board decided to approve registration of Lansodex Capsule 60mg and 30 mg, Sofopas Tablet 400/90 and 400 mg of M/s Jenner Pharmaceuticals (Pvt) Ltd,. Sheikupura.<br>❖ According to the report generated following points were confirmed<br>g) The firm has complete record of qualification of equipment / instruments used for test and analysis of API and Sobovir Tablets 400mg.<br>h) The HPLC used for analysis of stability batches is Shimadzu 20 ATVP with auto sampler and gradient system and it was 21 CFR compliant.<br>i) The firm has demonstrated the audit trail reports for the data submitted for Sobovir Tablets 400mg.<br>j) The firm has valid calibration status for all the equipments/ instruments used in production and analysis of the Sobovir Tablets 400mg. |

<table>
<tr><td></td><td></td><td>k) The firm has two separate Memmert (Germany) stability chambers for Real Time and Accelerated stability studies which are equipped with data loggers. For continuous power supply solar panels were installed Firm was advised to completely follow SOPs for continuous monitoring of stability chambers. Firm was also advised to use the installed alarm system more effectively.<br>l) Firm has dedicated area for product development, and all manufacturing area, equipment, personnel seemed to conform to a satisfactory level of cGMP compliance on the day of inspection.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>• Firm has submitted ADC attested copy dated 20-03-2017 confirming import of 175 grams of Dapagliflozin propanediol monohydrate.<br>Batch no. not mentioned on invoice<br>Invoice no. HK 1701121-B<br>• Firm has submitted copy of Form-3 confirming import of API from M/s Fuxin Long Rui Pharmaceutical Co., Ltd.<br>• Firm has submitted copy of Form-7 confirming batch no of API i.e. 160901.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• Firm has not submitted documents for procurement of reference and impurity standards.<br>• Quantity of working standard imported by the firm is not confirmed.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>• Approval of DML of Fuxin Long Rui Pharmaceutical Co., Ltd. (Certificate number Liao 20150233) valid till 20-12-2022 confirmed.<br>• Weblink:<br>http://app1.sfda.gov.cn/datasearcheng/face3/base.jsp?tableId=85&tableName=TABLE85&title=Database%20of%20approved%20Active%20Pharmaceutical%20Ingredients%20(APIs)%20and%20API%20manufacturers%20in%20China&bcId=136489131226659132460942000667<br>Accessed on 22-01-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• Firm has submitted vendor evaluation form which is filled by the applicant i.e. M/s Jenner Pharmaceuticals (Pvt) Ltd.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Certificate of analysis of the API, working standard and impurity standard submitted by the firm.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>• Firm has submitted documents for procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>• Firm has submitted list of 2 qualified person working in product development section.</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>• Firm has submitted SOP for product design and development protocol (document # PDP-STB-009) of Dapajen Tablet 5mg.<br>• Firm has submitted SOPs for stability study protocol. (document # JP/SSP/009) of Dapajen Tablet 5mg</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>• Firm has provided complete batch manufacturing record of all the three batches</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Batch No</th><th>Total no. of Tablets placed in stability chamber</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>DAP-PB-009001</td><td>854</td><td>336</td><td>518</td></tr>
</table>
</td></tr>
</table>

| | | | | | |
|---|---|---|---|---|---|
| | | DAP-PB-009002 | 854 | 336 | 518 |
| | | DAP-PB-009003 | 854 | 336 | 518 |
| **QA/QC DATA** | | | | | |
| 12. | Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated) | • Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period.<br>• For accelerated stability study the time period was from **25-04-2018** to **03-12-2018.**<br>• For real time stability study the time period was from **25-04-2018** to **03-12-2018.** | | | |
| 13. | Method used for analysis of API along with COA. | • Method used for analysis of API along with copy of COA for dapagliflozin propanediol monohydrate from M/s Fuxin Long Rui Pharmaceutical Co., Ltd. has been submitted.<br>• Firm has submitted own analytical record i.e. method of analysis, lab report, raw data sheets, chromatograms for the analysis of Dapagliflozin propanediol monohydrate (batch# 160901). | | | |
| 14. | Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) | • Firm has provided method used for analysis of FPP<br>Firm has submitted complete record of testing of stability batches including chromatograms, lab reports and raw data sheets | | | |
| 15. | Reports of stability studies of API from manufacturer. | • Firm has submitted summary sheet of 3 batches of API conducted at 30˚C ± 2˚C / 65% ± 5%RH for long term for 36 months and 40˚C ± 2˚C / 75% ± 5%RH for accelerated studies for 6 months. | | | |
| 16. | Analysis reports for excipients used. | • Firm has submitted COA and analysis reports of all excipients used in the study | | | |
| 17. | Drug-excipients compatibility studies. | • Submitted by the firm. | | | |
| 18. | Record of comparative dissolution data. | Firm has submitted comparative Dissolution studies report. The details of reference product & Sample product are as follows:<br>Feature / Reference product / Reference product Product of M/s Hilton<br>Brand name / Forxiga Tablets 10mg / Dapajen Tablets 10mg<br>Batch# / AAS 2301 / DPA-PB-009001<br><br>Comparative dissolution studies have been performed in following mediums:<br>• i. Acetate buffer pH 4.5 | | | |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Firm has submitted audit trail reports of stability studies of applied formulation | | | |
| **Evaluation by PEC:** | | | | | |
| **Decision: Registration Board decided to approve registration of "Dapajen tablet 10mg" by M/s Jenner Pharmaceuticals (Pvt) Ltd., Sheikupura. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.** | | | | | |

| 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<br><br>GMP Inspection Report Date<br>Remarks |
|---|---|---|---|---|
| 1264. | M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi | Vasac 24/26mg Tablets<br>Each film coated tablet contains<br>Sacubitril……..24mg<br>Valsartan.....….26mg<br><br>Neprilysin Inhibitor And Angiotensin II receptor blocker<br><br>Manufacturer's specification | Form 5<br><br>Dairy No.468 dated 17-09-2015<br><br>Rs.50,000/- dated 17-09-2015<br><br>10's, 30's, 60's; As per DPC<br>Alu-Alu Blister | Entresto Tablet of Novartis pharms, **USFDA**<br><br>Sacuvan tablets 24/26mg of GETZ pharma<br><br>Sovel Tablets of 24/26mg of pharmEvo.<br><br>GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Vasac 24/26mg Tablets | | |
| Name of Manufacturer | M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi | | |
| Manufacturer of API | M/s. Nantong Chanyoo Pharmatech Co., Ltd, China | | |
| API Lot No. | 201701001 | | |
| Description of Pack (Container closure system) | Alu Alu Blister Pack in Unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 6 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,3,6 (months)<br>Real Time: 0,3,6 (months) | | |
| Batch No. | VAS-250807-1 | VAS-250907-2 | VAS-251007-3 |
| Batch Size | 7000 tablets | 7000 tablets | 7000 tablets |
| Manufacturing Date | 07-2017 | 07-2017 | 07-2017 |
| Date of Initiation | 24-07-2017 | 24-07-2017 | 24-07-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 39548 (30-12-2018) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | Copy of COA (Batch #201701001) from M/s. Nantong Chanyoo Pharmatech 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. | Copy of GMP certificate (Certificate No. 2017006) issued by Nantong food and Drug Administration, China. It is valid until 07-09-2020. |

| | | |
|---|---|---|
| 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 Sacubitril+valsartan Trisodium Hemipentahydrate (LCZ696) 4.0 kg attested by ADC, DRAP, Karachi dated 09-01-2017. |
| 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: 30-12-2018 vide diary no. 39548

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Firm has referred to last onsite inspection of their product HILVEL Tablets (Sofosbuvir / Velpatasvir) which was considered and approved by Registration Board in its 277th Meeting with following details:<br>• **Date of Inspection:** 14-12-2017.<br>• The HPLC is 21CFR Compliant.<br>• Audit trail on the testing reports were available. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | The firm has submitted copy of commercial invoice for the procurement of Sacubitril+valsartan Trisodium Hemipentahydrate (LCZ696) 4.0 kg attested by ADC, DRAP, Karachi dated 09-01-2017. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copies of invoices from M/s Neon Chemicals working standards and impurity standards. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate (Certificate No. 2017006) issued by Nantong food and Drug Administration, China. It is valid until 07-09-2020. |
| 5. | Mechanism for Vendor pre-qualification | The firm has submitted Mechanism for Vendor pre-qualification. |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | • Copy of COA (Batch #201701001) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.<br>• Copy of COA of reference standard has been submitted<br>• COAs of impurity standards have 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 |

<table>
<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 VASAC 24/26mg film coated tablets”.</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>VAS-250807-1</td><td>7000 tablets</td><td>06-07-2017</td></tr>
<tr><td>VAS-250907-2</td><td>7000 tablets</td><td>06-07-2017</td></tr>
<tr><td>VAS-251007-3</td><td>7000 tablets</td><td>06-07-2017</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>Remaining Quantities of tablets</th></tr>
<tr><td>VAS-250807-1</td><td>7000 tablets</td><td>80 tablets</td></tr>
<tr><td>VAS-250907-2</td><td>7000 tablets</td><td>80 tablets</td></tr>
<tr><td>VAS-251007-3</td><td>7000 tablets</td><td>80 tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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 digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 01-07-2017 to 27-01-2018.</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 Sacubitril/Valsartan trisodium hemipentahydrate.</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 “Vasac 24/26mg tablets” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated and 12 Months Real Time Stability Study Data of 03 Batches of Sacubitril/Valsartan Complex (LCZ696) from M/s Nantong Chanyoo, China.</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>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that<br>“We are using the same qualitative formulation as innovator is using. Our stability studies also have not shown any incompatibility or significant degradation.”</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Entresto Tablets 24/26mg manufactured by M/s. Novartis Pharmaceuticals, Canada with Batch TK818. The firm‘s product results are comparable with Entresto 24/26mg Tablet.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted audit trail reports of Vasac 24/26mg tablet for the testing time points.</td></tr>
<tr><td colspan="3">Testing frequency of accelerated stability study data is not as per 278th meeting of Registration. Clarification is required.</td></tr>
</table>

**Decision: Registration Board decided to approve registration of "Vasac 24/26mg Tablets" by M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date |
|---|---|---|---|---|
| 1265. | M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi | Vasac 49/51mg Tablets<br>Each film coated tablet contains<br>Sacubitril……49mg<br>Valsartan.....51mg<br><br>Neprilysin Inhibitor And Angiotensin II receptor blocker<br><br>Manufacturer's specification | Form 5<br><br>Dairy No.466 dated 17-09-2015<br><br>Rs.50,000/- dated 17-09-2015<br><br>10's, 30's, 60's; As per DPC<br>Alu-Alu Blister | Entresto Tablet of Novartis pharms, **USFDA**<br><br>Sacuvan tablets 49/51mg of GETZ pharma<br><br>Sovel Tablets of 49/51mg of pharmEvo<br><br>GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Vasac 49/51mg Tablets | | |
| Name of Manufacturer | M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi | | |
| Manufacturer of API | M/s. Nantong Chanyoo Pharmatech Co., Ltd, China | | |
| API Lot No. | 201701001 | | |
| Description of Pack (Container closure system) | Alu Alu Blister Pack in Unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 6 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,3,6 (months)<br>Real Time: 0,3,6 (months) | | |
| Batch No. | VAS-249706-3 | VAS-249806-4 | VAS-249906-5 |
| Batch Size | 3500 tablets | 3500 tablets | 3500 tablets |
| Manufacturing Date | 06-2017 | 06-2017 | 06-2017 |
| Date of Initiation | 24-07-2017 | 24-07-2017 | 24-07-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 39548 (30-12-2018) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | Copy of COA (Batch #201701001) from M/s. Nantong Chanyoo Pharmatech 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. | Copy of GMP certificate (Certificate No. 2017006) issued by Nantong food and Drug Administration, China. It is valid until 07-09-2020. |
| 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 Sacubitril+valsartan Trisodium Hemipentahydrate (LCZ696) 4.0 kg attested by ADC, DRAP, Karachi dated 09-01-2017. |
| 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: 30-12-2018 vide diary no. 39548

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Firm has referred to last onsite inspection of their product HILVEL Tablets (Sofosbuvir / Velpatasvir) which was considered and approved by Registration Board in its 277th Meeting with following details:<br>• **Date of Inspection:** 14-12-2017.<br>• The HPLC is 21CFR Compliant.<br>• Audit trail on the testing reports were available. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | The firm has submitted copy of commercial invoice for the procurement of Sacubitril+valsartan Trisodium Hemipentahydrate (LCZ696) 4.0 kg attested by ADC, DRAP, Karachi dated 09-01-2017. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copies of invoices from M/s Neon Chemicals working standards and impurity standards. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate (Certificate No. 2017006) issued by Nantong food and Drug Administration, China. It is valid until 07-09-2020. |
| 5. | Mechanism for Vendor pre-qualification | The firm has submitted Mechanism for Vendor pre-qualification. |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | • Copy of COA (Batch #201701001) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.<br>• Copy of COA of reference standard has been submitted |

<table>
<tr><td></td><td></td><td>• COAs of impurity standards have 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 VASAC 49/51mg film coated tablets”.</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>VAS-249706-3</td><td>3500 tablets</td><td>06-07-2017</td></tr>
<tr><td>VAS-249806-4</td><td>3500 tablets</td><td>06-07-2017</td></tr>
<tr><td>VAS-249906-5</td><td>3500 tablets</td><td>06-07-2017</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>Remaining Quantities of tablets</th></tr>
<tr><td>VAS-249706-3</td><td>3500</td><td>80</td></tr>
<tr><td>VAS-249806-4</td><td>3500</td><td>80</td></tr>
<tr><td>VAS-249906-5</td><td>3500</td><td>80</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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 digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 01-07-2017 to 27-01-2018.</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 Sacubitril/Valsartan trisodium hemipentahydrate.</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 “Vasac 49/51mg tablets” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated and 12 Months Real Time Stability Study Data of 03 Batches of Sacubitril/Valsartan Complex (LCZ696) from M/s Nantong Chanyoo, China.</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>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that<br>“We are using the same qualitative formulation as innovator is using. Our stability studies also have not shown any incompatibility or significant degradation.”</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Entresto Tablets 49/51mg manufactured by M/s. Novartis Pharmaceuticals, Canada with Batch TK818. The firm‘s product results are comparable with Entresto 24/26mg Tablet.</td></tr>
</table>

| | | |
|---|---|---|
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted audit trail reports of Vasac 49/51mg tablet for the testing time points. |

Testing frequency of accelerated stability study data is not as per 278th meeting of Registration. Clarification is required.

**Decision: Registration Board decided to approve registration of "Vasac 49/51mg Tablets" by M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date Remarks |
|---|---|---|---|---|
| 1266. | M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi | Vasac 97/103mg Tablets<br>Each film coated tablet contains<br>Sacubitril……97mg<br>Valsartan.....…103mg<br><br>Neprilysin Inhibitor And Angiotensin II receptor blocker<br><br>Manufacturer's specification | Form 5<br><br>Dairy No.467 dated 17-09-2015<br><br>Rs.50,000/- dated 17-09-2015<br><br>10's, 30's, 60's; As per DPC<br>Alu-Alu Blister | Entresto Tablet of Novartis pharms, **USFDA**<br><br>Sacuvan tablets 97/103mg of GETZ pharma<br><br>Sovel Tablets of 97/103mg of pharmEvo<br><br>GMP Inspection conducted on 24-01-2018 concluded that the firm was operating at a very good level of GMP compliance at the time of inspection. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Vasac 97/103mg Tablets | | |
| Name of Manufacturer | M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi | | |
| Manufacturer of API | M/s. Nantong Chanyoo Pharmatech Co., Ltd, China | | |
| API Lot No. | 201701001 | | |
| Description of Pack (Container closure system) | Alu Alu Blister Pack in Unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 6 months<br>Real Time: 6 months | | |
| Frequency | Accelerated: 0,3,6 (months)<br>Real Time: 0,3,6 (months) | | |
| Batch No. | VAS-249006-5 | VAS-249206-6 | VAS-249306-7 |
| Batch Size | 2000 tablets | 2000 tablets | 2000 tablets |
| Manufacturing Date | 06-2017 | 06-2017 | 06-2017 |
| Date of Initiation | 14-07-2017 | 14-07-2017 | 14-07-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 39548 (30-12-2018) | | |

| DOCUMENTS / DATA PROVIDED BY THE APPLICANT | | |
|---|---|---|
| **Sr. No.** | **Documents To Be Provided** | **Status** |
| 1. | COA of API. | Copy of COA (Batch #201701001) from M/s. Nantong Chanyoo Pharmatech 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. | Copy of GMP certificate (Certificate No. 2017006) issued by Nantong food and Drug Administration, China. It is valid until 07-09-2020. |
| 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 Sacubitril+valsartan Trisodium Hemipentahydrate (LCZ696) 4.0 kg attested by ADC, DRAP, Karachi dated 09-01-2017. |
| 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: 30-12-2018 vide diary no. 39548

| Administrative Portion | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Firm has referred to last onsite inspection of their product HILVEL Tablets (Sofosbuvir / Velpatasvir) which was considered and approved by Registration Board in its 277th Meeting with following details:<br>• **Date of Inspection:** 14-12-2017.<br>• The HPLC is 21CFR Compliant.<br>• Audit trail on the testing reports were available. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | The firm has submitted copy of commercial invoice for the procurement of Sacubitril+valsartan Trisodium Hemipentahydrate (LCZ696) 4.0 kg attested by ADC, DRAP, Karachi dated 09-01-2017. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copies of invoices from M/s Neon Chemicals working standards and impurity standards. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate (Certificate No. 2017006) issued by Nantong food and Drug Administration, China. It is valid until 07-09-2020. |

<table>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Mechanism for Vendor pre-qualification.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA (Batch #201701001) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.<br>• Copy of COA of reference standard has been submitted<br>• COAs of impurity standards have 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 VASAC 97/103mg film coated tablets”.</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>VAS-249006-5</td><td>2000 tablets</td><td>06-07-2017</td></tr>
<tr><td>VAS-249206-6</td><td>2000 tablets</td><td>06-07-2017</td></tr>
<tr><td>VAS-249306-7</td><td>2000 tablets</td><td>06-07-2017</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>Remaining Quantities of tablets</th></tr>
<tr><td>VAS-249006-5</td><td>2000</td><td>80</td></tr>
<tr><td>VAS-249206-6</td><td>2000</td><td>80</td></tr>
<tr><td>VAS-249306-7</td><td>2000</td><td>80</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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 digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 01-07-2017 to 27-01-2018.</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 Sacubitril/Valsartan trisodium hemipentahydrate.</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 “Vasac 97/103mg tablets” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated and 12 Months Real Time Stability Study Data of 03 Batches of Sacubitril/Valsartan Complex (LCZ696) from M/s Nantong Chanyoo, China.</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>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that<br>“We are using the same qualitative formulation as innovator is using. Our stability studies also have not shown any incompatibility or significant degradation.”</td></tr>
</table>

| | | |
|---|---|---|
| 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 Entresto Tablets 24/26mg manufactured by M/s. Novartis Pharmaceuticals, Canada with Batch TK818. The firm's product results are comparable with Entresto 97/103mg Tablet. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted audit trail reports of Vasac 97/103mg tablet for the testing time points. |

Testing frequency of accelerated stability study data is not as per 278th meeting of Registration. Clarification is required.

**Decision: Registration Board decided to approve registration of "Vasac 97/103mg Tablets" by M/s. Hilton Pharma (Pvt.) Ltd. Plot 13/14, Sector 15, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date<br><br>Remarks |
|---|---|---|---|---|
| 1267. | M/s Barrett Hodgson Pakistan (Pvt) Ltd. F/423,S.I.T.E. Karachi. | HEPGARD-V TABLETS 400MG + 100 MG<br>Each film coated tablet contains:<br>Sofosbuvir….400mg<br>Velpatasvir…100mg<br>Direct Acting Antiviral agents against Hepatitis C virus<br>Manufacturer's Specifications. | Form 5<br><br>Dairy No.1758 dated 01-09-2016<br><br>Rs.50,000/- dated 01-09-2016<br><br>Pack of 10's Rs. 28,000/-,<br>Pack of 14's Rs. 39,200/-,<br>Pack of 20's Rs. 56,000/-<br>Pack of 28's Rs. 78,400/-<br>Pack of 30's Rs. 84,000/-<br>Alu-Alu Blister | Epclusa of Gilead Sciences, USA<br>**(USFDA approved)**<br><br>**N/A**<br><br>Last GMP inspection Dated 16th-28th August 2018 concluded that overall firm was found satisfactory and progressive towards good level of GMP compliance. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Hepgard-V Tablets 400mg + 100mg | | |
| Name of Manufacturer | M/s Barrett Hodgson Pakistan (Pvt) Ltd., F/423,S.I.T.E., Karachi. | | |
| Manufacturer of API | **Sofosbuvir:** M/s Nantong Chanyoo Pharmatech Co., Ltd, China<br>**Velpatasvir-Co-Povidone:** M/s Nantong Chanyoo Pharmatech Co., Ltd, China | | |
| API Lot No. | **Sofosbuvir:** RD-SFB (Form-VI)-201701201<br>**Velpatasvir-Co-Povidone:** 201703001 | | |
| Description of Pack (Container closure system) | High Density Polyethylene (HDPE) bottles | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 0, 4, 12, 26 weeks Real Time: 0, 12, 26 weeks | | |
| Frequency | Accelerated: 26 (weeks) Real Time: 26 (weeks) | | |
| Batch No. | PLT-T-075 | EXP-T-917 | PLT-T-076 |
| Batch Size | 800 tablets | 400 tablets | 800 tablets |
| Manufacturing Date | 04-2018 | 02-2018 | 04-2018 |
| Date of Initiation | 05-2018 | 04-2018 | 05-2018 |

| | |
|---|---|
| No. of Batches | 03 |
| Date of Submission | 43735 (24-12-2018) |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | **Sofosbuvir:** Copy of COA (Batch# RD-SFB (Form-VI)-201701201) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.<br>**Velpatasvir Copovidone:** Copy of COA (Batch# 201703001) from M/s. Nantong Chanyoo Pharmatech 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. | **Sofosbuvir:** Copy of GMP certificate issued by Jiangsu Nantong Pharmaceutical Association, China has been submitted. It is valid until 07/09/2020.<br>**Velpatasvir Copovidone:** Copy of GMP certificate issued by Nantong Chemical & Medical Industry Association, China has been submitted. It is valid until Dec. 05, 2019. |
| 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. | **Sofosbuvir:** The firm has submitted copy of commercial invoice for the import of 880g of Sofosbuvir (Form-VI) (Invoice#CY116386) attested by ADC DRAP, Karachi dated 27-03-2017.<br>**Velpatasvir Copovidone:** The firm has submitted copy of commercial invoice for the import of 440g Velpatasvir Copovidone (Invoice#CY116386) attested by ADC DRAP, Karachi dated 27-03-2017. |
| 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 26 weeks Accelerated and 26 weeks 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: 24-12-2018 vide diary no. 43735

**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 "Hepgard Tablets 400mg (sofosbuvir)", which was conducted on 9th August, 2017 and was presented in 273rd meeting of Registration board. Registration Board decided to approve registration of Hepgard Tablets 400mg (sofosbuvir) by M/s. M/s Barrett Hodgsons Pakistan (Private) Ltd. Karachi. |

| | | |
|---|---|---|
| | | ❖ According to the report generated on 18th April, 2017 following points were confirmed<br>a) The firm has used two separate HPLCs one for testing for API while the other for testing of their finished drug. The first HPLC software is not 21CFR compliant, whereas the second HPLC software is 21CFR compliant.<br>b) Audit trail on the testing reports cannot be made as the HPLC used is not 21CFR compliant, however, the HPLC used for testing of stability batches of the finished product is 21CFR compliant hence audit trail on this HPLC can be made.<br>c) The firm possesses stability chambers with continuous power supply and digital data loggers.<br>❖ While on Re-inspection for verification of Authenticity of stability data dated 09th August, 2017 following points were confirmed<br>d) Redesigning of HVAC in the tablet manufacturing area has been done.<br>Staff is adequately trained and training record is available. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | **Sofosbuvir:** The firm has submitted copy of commercial invoice for the import of 0.88Kg & 750mg of Sofosbuvir (Form-VI) (Invoice#CY116386) attested by ADC DRAP, Karachi dated 27-03-2017.<br>**Velpatasvir Copovidone:** The firm has submitted copy of commercial invoice for the import of 0.44Kg Velpatasvir Copovidone (Invoice#CY116386) attested by ADC DRAP, Karachi dated 27-03-2017. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copy of commercial invoice for the procurement of working standards. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | **Sofosbuvir:** Copy of GMP certificate issued by Jiangsu Nantong Pharmaceutical Association, China has been submitted. It is valid until 07/09/2020.<br>**Velpatasvir Copovidone:** Copy of GMP certificate issued by Nantong Chemical & Medical Industry Association, China has been submitted. It is valid until Dec. 05, 2019. |
| 5. | Mechanism for Vendor pre-qualification | The firm has submitted Mechanism for Vendor pre-qualification. |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | • **Sofosbuvir:** Copy of COA (Batch# RD-SFB (Form-VI)-201701201) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.<br>• **Velpatasvir Copovidone:** Copy of COA (Batch# 201703001) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.<br>• Copies of COAs of working standards have been submitted<br>• COAs of impurity standards have 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. |
| **Production Data** | | |
| 9. | Authorized Protocols/SOP for the | The firm has submitted photocopy of "Protocols/SOP |

<table>
<tr><td></td><td>development & stability testing of trial batches.</td><td>for the Development of Hepgard-V Tablet 400mg +100mg".</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>EXP-T-917</td><td>400 tablets</td><td>26-02-2018</td></tr>
<tr><td>PLT-T-075</td><td>800 tablets</td><td>28-04-2018</td></tr>
<tr><td>PLT-T-076</td><td>800 tablets</td><td>28-04-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>28 Tablets / pack
<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>EXP-T-917</td><td>12 Packs</td><td>9 Packs</td><td>3 Packs</td></tr>
<tr><td>PLT-T-075</td><td>20 Packs</td><td>18 packs</td><td>2 Packs</td></tr>
<tr><td>PLT-T-076</td><td>20 Packs</td><td>18 packs</td><td>2 Packs</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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 digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 22-02-2018 to 28-11-2018.</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 Sofosbuvir Form-VI and Velpatasvir Co-povidone.</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 "Vasac 97/103mg tablets" along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated and 12 Months Real Time Stability Study Data of 03 Batches for Sofosbuvir Form-VI and Velpatasvir Co-povidone from M/s Nantong Chanyoo Pharmatech Co., Ltd, China.</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>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted details of Drug-excipient compatibility studies by designing combinations of APIs and excipients.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with MyHepAll Tablets 400mg/100mg manufactured by M/s. Mylan, India with Batch # 3081910. The firm's product results are comparable with MyHepAll 400/100mg Tablet.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted audit trail reports of Hepgard-V tablet for the testing time points.</td></tr>
<tr><td colspan="3">The firm was communicated to provide clarification about testing frequency of accelerated stability study data which is not as per 278th meeting of Registration Board. In response, the firm requested to accept the submitted stability studies data for aforementioned product and for future they informed that we will follow the test frequency as per decision made in 278th meeting.</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of "HEPGARD-V TABLETS 400MG + 100 MG" by M/s Barrett Hodgson Pakistan (Pvt) Ltd.F/423, S.I.T.E. Karachi.. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
</table>

| 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<br><br>GMP Inspection Report Date<br><br>Remarks |
|---|---|---|---|---|
| 1268. | M/s Wilson's Pharmaceuticals, I-9, Industrial Area, Islamabad | Excel Tablets 40mg<br>Each uncoated tablet contains:<br>Azilsartan Medoxomil (as Potassium)…...40mg<br><br>Anti-hypertensive<br><br>Manufacturer's specifications | Form 5-D<br><br>Dairy No. Nil dated 18-03-2011,<br>Rs.15,000/-,<br>18-03-2011,<br>35,000/-<br>29-10-2018,<br>10's, 20's, 30's & 60's: 28.0 / Tablet | Edarbi Tablet of Takeda Pharma **(USFDA approved)**<br><br>**N/A**<br><br>Last GMP inspection conducted on 24-01-2018 concluding good level of cGMP compliance at the time of inspection. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Excel Tablets 40mg | | |
| Name of Manufacturer | M/s Wilson's Pharmaceuticals, I-9, Industrial Area, Islamabad | | |
| Manufacturer of API | M/s Ami Lifesciences Pvt. Ltd, Gujarat , India | | |
| API Lot No. | AZP/50310517 | | |
| Description of Pack (Container closure system) | Alu Alu Blister pack | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 0,1,2,3,4,6 months<br>Real Time: 0, 3, 6 months | | |
| Frequency | Accelerated: 06 (months)<br>Real Time: 06 (months) | | |
| Batch No. | Trial # 01 | Trial # 02 | Trial # 03 |
| Batch Size | 1500 tablets | 1500 tablets | 1500 tablets |
| Manufacturing Date | 12-2017 | 12-2017 | 12-2017 |
| Date of Initiation | December, 2017 | December, 2017 | December, 2017 |
| No. of Batches | 03 | | |
| Date of Submission | 35870 (29-10-2018) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | Copy of COA (Batch# AZP/50310517) from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India 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. | Copy of GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India has been submitted. It is valid until 26-04-2019. |
| 3. | Protocols followed for conduction of stability study and details of tests. | Yes |
| 4. | Data of 03 batches will be supported by | Yes |

| | | |
|---|---|---|
| | attested respective documents like chromatograms, laboratory reports, data sheets etc. | |
| 5. | Documents confirming import of API etc. | The firm has submitted copy of commercial invoice for the import of 960.30g of Azilsartan Medoxomil potassium salt (Invoice#EXP/A/138/2017-18) attested by ADC DRAP, Islamabad dated 16-08-2017. |
| 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: 39582 vide diary no. 03-12-2018

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | Firm has referred to onsite inspection reports of their product "Saferon tablets (Sofosbuvir 400 mg)", which was presented in 278th meeting of Registration Board held on 29-31st Jan, 2018.<br>**Observations:** Software of HPLC present in the firm is 21 CFR compliant and audit trail on the testing reports was available and confirmed. Panel reviewed chromatograms for testing of API and trial batches at 0, 3 and 6 months for real time and accelerated stability testing.<br>**Decision:** Registration Board decided to approve registration of "Saferon (Sofosbuvir 400mg)" by M/s Wilson Pharmaceuticals, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | The firm has submitted copy of commercial invoice for the import of 960.30g of Azilsartan Medoxomil potassium salt (Invoice#EXP/A/138/2017-18) attested by ADC DRAP, Islamabad dated 16-08-2017. |
| 3. | Documents for the procurement of reference standard and impurity standards. | The firm has submitted copy of commercial invoice for the procurement of working standards and impurity standards. |
| 4. | Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin. | Copy of GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India has been submitted. It is valid until 26-04-2019. |
| 5. | Mechanism for Vendor pre-qualification | The firm has submitted Mechanism for Vendor pre-qualification. |
| 6. | Certificate of analysis of the API, reference standards and impurity standards | • Copy of COA (Batch# AZP/50310517) from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India is submitted. |

<table>
<tr><td></td><td></td><td>• Copy of COA of working standards have been submitted<br>• COAs of impurity standards have been submitted.<br>Impurity A<br>Impurity B<br>Impurity C</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 “Excel Tablets 40mg”.</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>12-2017</td></tr>
<tr><td>Trial # 02</td><td>1500 Tablets</td><td>12-2017</td></tr>
<tr><td>Trial # 03</td><td>1500 Tablets</td><td>12-2017</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>570 Tabs (3×10’s, 19 Packs)</td><td>256</td><td>314</td></tr>
<tr><td>Trial # 02</td><td>570 Tabs (3×10’s, 19 Packs)</td><td>256</td><td>314</td></tr>
<tr><td>Trial # 03</td><td>570 Tabs (3×10’s, 19 Packs)</td><td>256</td><td>314</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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 digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 11-11-2017 to 01-06-2018.</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 Azilsartan Medoxomil Potassium Salt.</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 “Excel Tablets 40mg” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated (5ºC±3ºC) and 24 Months Real Time 25ºC±2ºC/60%±5%RH Stability Study Data of 03 Batches for Azilsartan Medoxomil potassium salt from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India.</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 submitted that ingredients of Excel Tablets 40mg and Edarbi Tablets (innovator brand) are same. |
| 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 and pH 7.8 buffers with Edarbi Tablets 40mg manufactured by M/s. Takeda, Osaka, Japan with Batch # EB-TL40-04. The firm's product (Excel Tablets 40mg) results are comparable with Edarbi Tablets 40mg. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted audit trail reports of Excel tablet 40mg from 14-12-2017 to 21-06-2018. |

**Decision: Registration Board deferred the case for submission of stability data of API conducted at Zone IV-A.**

| 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<br><br>GMP Inspection Report Date<br><br>Remarks |
|---|---|---|---|---|
| 1269. | M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi | Tikanox-60 Tablets<br><br>Each Film coated tablet contains:<br>Ticagrelor…...60mg<br><br>Platelet activation inhibitor<br><br>Manufacturer's specifications | Form 5-D<br><br>Dairy No.1984 dated 25-05-2016,<br>Rs.50,000/-,<br>24-05-2016,<br>Not mentioned | Brilinta Tablet of Astrazeneca Pharms<br>**(USFDA approved)**<br><br>**N/A**<br>Last GMP inspection was conducted on 14-12-2017 The company is found complying CGMP as of today and panel unanimously agreed to issue CGMP certificate for export along with COPP, The management was advised to continue the process of up gradation. |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Tikanox-60 Tablets | | |
| Name of Manufacturer | M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi | | |
| Manufacturer of API | M/s Glenmark Pharmaceuticals Ltd. Gujarat, India | | |
| API Lot No. | 82160137 | | |
| Description of Pack (Container closure system) | PVC Blister of 1×10's pack | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/75%±5% RH<br>Real Time: 30˚C ± 2˚C/65%±5% RH | | |
| Time Period | Accelerated: 0,1,2,3,4,6,8,12,16,20,24,26 weeks<br>Real Time: 0,1,2,3,4,6,8,12,16,20,24,26 weeks | | |
| Frequency | Accelerated: 26 (weeks) Real Time: 26 (weeks) | | |
| Batch No. | T-001 | T-002 | T-003 |
| Batch Size | 1000 tablets | 1000 tablets | 1000 tablets |
| Manufacturing Date | 07-2017 | 07-2017 | 07-2017 |

| | | | |
|---|---|---|---|
| Date of Initiation | 28-07-2017 | 30-07-2017 | 30-07-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 1213 (10-01-2019) | | |

| DOCUMENTS / DATA PROVIDED BY THE APPLICANT | | |
|---|---|---|
| **Sr.#** | **Documents To Be Provided** | **Status** |
| 1. | COA of API. | Copy of COA (Batch# 82160137) from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India 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. | Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019. |
| 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 import of 600g of Ticagrelor (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016. |
| 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 26 weeks Accelerated and 26 weeks 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: 1213 vide diary no. 10-01-2019

| Administrative Portion | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | The firm has submitted reference of already approved product in 285th meeting the decision as:<br>Registration Board decided to approve registration of Vebuvir Tablets 400 mg (Sofosbuvir) of M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 km, Adyala road, post office Dahgal, Rawalpindi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.<br>**Date of inspection**: 8th August, 2018<br>The HPLC software of the firm is 21 CRF compliant.<br>The firm has provided USB data loggers, which are set for recording temperature and humidity after each hour. |
| 2. | Documents for the procurement of API with approval from DRAP (in case of import). | The firm has submitted copy of commercial invoice for the import of 600g of Ticagrelor |

<table>
<tr><td></td><td></td><td>(Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of commercial invoice for the procurement of working standards.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Mechanism for Vendor pre-qualification.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA (Batch# 82160137) from M/s. Glenmark Pharmaceuticals Ltd. Gujarat, India is submitted.<br>• Copy of COA of working standards have been submitted<br>• COAs of impurity standards have been submitted.<br>Impurity A<br>Impurity B<br>Impurity C</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>
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<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 “Excel Tablets 40mg”.</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>T-001</td><td>1000 Tablets</td><td>07-2017</td></tr>
<tr><td>T-002</td><td>1000 Tablets</td><td>07-2017</td></tr>
<tr><td>T-003</td><td>1000 Tablets</td><td>07-2017</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>T-001</td><td>866</td><td rowspan="3">634</td><td>232</td></tr>
<tr><td>T-002</td><td>881</td><td>247</td></tr>
<tr><td>T-003</td><td>871</td><td>237</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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 digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 18-07-2017 to 06-02-2018.</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 COA for Ticagrelor.</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 “Tikanox-60 Tablets” along with Stability Study Reports.</td></tr>
</table>

| | | |
|---|---|---|
| 15. | Reports of stability studies of API from manufacturer. | The firm has submitted photocopy of 06 Months Accelerated (40ºC±2ºC/75%±5%RH) and 36 Months Real Time (25ºC±2ºC/60%±5%RH) Stability Study Data of 03 Batches for Ticagrelor from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India |
| 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 submitted that ingredients of Tikanox-60 Tablets and Brilinta 60mg Tablet (innovator brand) are same. |
| 18. | Record of comparative dissolution data. | The firm has performed comparative dissolution studies with Brilinta 60mg Tablets manufactured by M/s. Astrazeneca Pharms, USA (Batch#JP0010, EXP 02/20). The firm's product (Tikanox-60 Tablets) results are comparable with BRILINTA 60mg Tablets. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted audit trail reports of Tikanox-60 Tablets from 11-08-2017 to 26-01-2018. |

The storage conditions under which real time stability studies of API were conducted are not as per Zone IVA. The firm has not performed comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8.

**Decision: Registration Board deferred the case for submission of stability data of API conducted at Zone IV-A and submission of comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8.**

| 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<br><br>GMP Inspection Report Date<br><br>Remarks |
|---|---|---|---|---|
| 1270. | M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi | Tikanox-90 Tablets<br><br>Each Film coated tablet contains: Ticagrelor…...90mg<br><br>Platelet activation inhibitor<br><br>Manufacturer's specifications | Form 5-D<br><br>Dairy No.1985 dated 25-05-2016, Rs.50,000/-, 24-05-2016, Not mentioned | Brilinta Tablet of Astrazeneca Pharms<br>**(USFDA approved)**<br><br>**N/A**<br>Last GMP inspection was conducted on 14-12-2017 The company is found complying CGMP as of today and panel unanimously agreed to issue CGMP certificate for export along with COPP, The management was advised to continue the process of up gradation. |

| **STABILITY STUDY DATA** | |
|---|---|
| Drug | Tikanox-90 Tablets |
| Name of Manufacturer | M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi |
| Manufacturer of API | M/s Glenmark Pharmaceuticals Ltd. Gujarat, India |
| API Lot No. | 82160137 |
| Description of Pack (Container closure system) | PVC Blister of 1×10's pack |
| Stability Storage Condition | **Accelerated:** 40˚C ± 2˚C/75%±5% RH **Real Time:** 30˚C ± 2˚C/65%±5% RH |

| | | | |
|---|---|---|---|
| Time Period | Accelerated: 0,1,2,3,4,6,8,12,16,20,24,26 weeks<br>Real Time: 0,1,2,3,4,6,8,12,16,20,24,26 weeks | | |
| Frequency | Accelerated: 26 (weeks) Real Time: 26 (weeks) | | |
| Batch No. | T-001 | T-002 | T-003 |
| Batch Size | 1000 tablets | 1000 tablets | 1000 tablets |
| Manufacturing Date | 07-2017 | 07-2017 | 07-2017 |
| Date of Initiation | 23-07-2017 | 24-07-2017 | 25-07-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 121 (10-01-2019) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API. | Copy of COA (Batch# 82160137) from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India 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. | Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019. |
| 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 import of 600g of Ticagrelor (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016. |
| 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 26 weeks Accelerated and 26 weeks 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: 1213 vide diary no. 10-01-2019

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | The firm has submitted reference of already approved product in 285th meeting the decision as:<br>Registration Board decided to approve registration of Vebuvir Tablets 400 mg (Sofosbuvir) of M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 km, Adyala road, post office Dahgal, Rawalpindi. Manufacturer will place first three production batches of both products on long |

<table>
<tr><td></td><td></td><td>term stability studies throughout proposed shelf life and on accelerated studies for six months.<br>Date of inspection: 8th August, 2018<br>The HPLC software of the firm is 21 CRF compliant.<br>The firm has provided USB data loggers, which are set for recording temperature and humidity after each hour.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of commercial invoice for the import of 600g of Ticagrelor (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of commercial invoice for the procurement of working standards.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Mechanism for Vendor pre-qualification.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA (Batch# 82160137) from M/s. Glenmark Pharmaceuticals Ltd. Gujarat, India is submitted.<br>• Copy of COA of working standards have been submitted<br>• COAs of impurity standards have been submitted.<br>Impurity A<br>Impurity B<br>Impurity C</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>
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<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 “Tikanox-90 Tablets”.</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>T-001</td><td>1000 Tablets</td><td>07-2017</td></tr>
<tr><td>T-002</td><td>1000 Tablets</td><td>07-2017</td></tr>
<tr><td>T-003</td><td>1000 Tablets</td><td>07-2017</td></tr>
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<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>T-001</td><td>874</td><td rowspan="3">634</td><td>240</td></tr>
<tr><td>T-002</td><td>878</td><td>244</td></tr>
<tr><td>T-003</td><td>870</td><td>236</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers</td><td>Firm has submitted photocopies of digital data logger record for Accelerated stability chamber and Real</td></tr>
</table>

| | | |
|---|---|---|
| | (real time and accelerated) | Time stability chamber starting from 18-07-2017 to 06-02-2018. |
| 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 COA for Ticagrelor. |
| 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 "Tikanox-90 Tablets" along with Stability Study Reports. |
| 15. | Reports of stability studies of API from manufacturer. | The firm has submitted photocopy of 06 Months Accelerated (40ºC±2ºC/75%±5%RH) and 36 Months Real Time (25ºC±2ºC/60%±5%RH) Stability Study Data of 03 Batches for Ticagrelor from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India |
| 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 submitted that ingredients of Tikanox-90 Tablets and Brilinta 90mg Tablet (innovator brand) are same. |
| 18. | Record of comparative dissolution data. | The firm has performed comparative dissolution studies with Brilinta 90mg Tablets manufactured by M/s. Astrazeneca Pharms, USA (Batch#JP0010, EXP 02/20). The firm's product (Tikanox-90 Tablets) results are comparable with BRILINTA 90mg Tablets. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | The firm has submitted audit trail reports of Tikanox-60 Tablets from 11-08-2017 to 26-01-2018. |

The storage conditions under which real time stability studies of API were conducted are not as per Zone IVA. The firm has not performed comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8.

**Decision: Registration Board deferred the case for submission of stability data of API from supplier conducted at Zone IV-A. conditions**

| 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<br><br>GMP Inspection Report Date & Remarks | Previous DRB Decision / Remarks (if any) |
|---|---|---|---|---|---|
| 1271. | M/s Dyson Research Laboratories (Pvt.) Ltd. 28th KM Ferozpur Road, Lahore. | ROFIN TABLETS 500 mcg<br><br>Each film coated tablet contains: Roflumilast ……..500mcg<br><br>Phosphodiesterase 4 inhibitor<br><br>Manufacturer's specifications | Form-5D Diary No.1259 dated 27-10-2015, Rs. 50,000/- dated 15-10-2015 | DALIRESP Tablet of Astrazeneca (USFDA approved)<br><br>Last inspection report 01-8-2017 with conclusion that panel Recommended issuance of GMP certificate to the firm. | |

**STABILITY STUDY DATA**

| | |
|---|---|
| Drug | ROFIN TABLETS 500 mcg |
| Name of Manufacturer | M/s Dyson Research Laboratories (Pvt.) Ltd. 28th KM Ferozpur Road, Lahore. |
| Manufacturer of API | M/s Glenmark Pharmaceuticals Ltd., Maharashtra, India |
| API Lot No. | 83160055 |
| Description of Pack | Alu/Alu Blister in outer unit carton |

| | | | |
|---|---|---|---|
| (Container closure system) | | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months Real Time: 09 Months | | |
| Frequency | Accelerated: 0,1,2,3,6 (Months) Real Time: 0,1,2,3,6,9 (Months) | | |
| Batch No. | T02 | T03 | T04 |
| Batch Size | 1000 Tabs | 1000 Tabs | 1000 Tabs |
| Manufacturing Date | 09-2017 | 09-2017 | 09-2017 |
| Date of Initiation | 20-09-2017 | 20-09-2017 | 20-09-2017 |
| No. of Batches | 3 | | |
| Date of Submission | 29-10-2018 (Dy. No. 35703) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s Glenmark Pharmaceuticals Ltd India has been 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. | The firm has submitted copy of GMP certificate of M/s Glenmark Pharmaceuticals Ltd, India (Certificate No.6081505) issued by Food and Drug Administration, Maharashtra State India. |
| 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. | Copy of ADC (Lahore) attested commercial Invoice Dated 25-10-2016 issued by M/s Glenmark Pharmaceuticals (Pvt.) Ltd, India (invoice No: 2007500913) is submitted. |
| 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 provided 06 Months Accelerated and 09 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: 29-10-2018 (Dy. No. 35703)

**Administrative Portion**

| | | |
|---|---|---|
| 1. | Reference of last onsite panel inspection for instant dosage form conducted during last two years. | • Registration Board decided to approve registration of "Sovir 400mg tablets (Sofosbuvir) by M/s. Dyson Research Laboratories Pvt, 28-km, Ferozepur Road, Lahore." Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.<br>• **Date of inspection:** 17th January, 2018<br>• The HPLC software of the firm is 21 CFR compliant.<br>• Firm has demonstrated audit trail reports (assay analysis on HPLC) for the submitted stability batches. |

<table>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of ADC (Lahore) attested commercial Invoice Dated 25-10-2016 issued by M/s Glenmark Pharmaceuticals (Pvt.) Ltd, India (invoice No: 2007500913) is submitted.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted that required Reference standard for the product applied for Registration ‘Rofin 500mcg’ (Roflumilast 500mcg), was delivered by indentor “Morgan Chemicals” in person at our plant.<br>The firm undertakes that M/s Glenmark pharmaceutical claims no impurity in their COA, so physical unavalabilityof impurity is justified.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>The firm has submitted copy of GMP certificate of M/s Glenmark Pharmaceuticals Ltd, India (Certificate No.6081505) issued by Food and Drug Administration, Maharashtra State India.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted document stating rationale for selection of Manufacturer of the API ‘Roflumilast’.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA of API (Roflumilast) from M/s Glenmark Pharmaceuticals Ltd India has been submitted.<br>• COAs of reference standards bearing Batch No. 83170223 from M/s Glenmark Pharmaceuticals Ltd India 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 R&D 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 Rofin 500mcg Tablets”.</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>T02</td><td>1000 tablets</td><td>09-2017</td></tr>
<tr><td>T03</td><td>1000 tablets</td><td>09-2017</td></tr>
<tr><td>T04</td><td>1000 tablets</td><td>09-2017</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>Tablets for Blistering</th><th>Tablets used for stability testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>T02</td><td>590 Tabs</td><td>460 Tabs</td><td>130 Tabs</td></tr>
<tr><td>T03</td><td>590 Tabs</td><td>460 Tabs</td><td>130 Tabs</td></tr>
<tr><td>T04</td><td>590 Tabs</td><td>460 Tabs</td><td>130 Tabs</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></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 Accelerated stability chamber starting from 18-09-2017 to 17-07-2018 and real time stability chamber from 19-07-2017 to 01-12-2018.</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 COA for API Roflumilast.</td></tr>
</table>

| | | |
|---|---|---|
| 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 Procedures for Rofin Tablet 500mcg along with Stability Study Reports. |
| 15. | Reports of stability studies of API from manufacturer. | The firm has submitted accelerated stability study data ($40^oC \pm 2^oC$/ 75% ± 5% RH) of 6 months and real time stability data ($25^oC \pm 2^oC$/ 75% ± 5% RH) of 60 months for three batches of Roflumilast. |
| 16. | Analysis reports for excipients used. | The firm has submitted analysis reports of excipients used in formulation. |
| 17. | Drug-excipients compatibility studies. | The firm has submitted that as the formulation of Tablet Rofin 500mcg is qualitatively same to that of innovator brand "Daliresp 500mcg" that provides reason to exclude any drug-excipients incompatibility but the quality is further ensured by the literature review. |
| 18. | Record of comparative dissolution data. | The firm has performed comparative dissolution studies at pH 1.2, pH 4.5 and pH 6.8 with Daliresp 500mcg Tablets manufactured by M/s. Astrazeneca pharms. The firm's product (Rofin 500mcg Tablets) results are comparable with Daliresp 500mcg Tablets. |
| 19. | Compliance Record of HPLC software 21CFR & audit trail reports on product testing. | Audit trails on testing reports of 1st month, 2nd month, 3rd month and 6th month were submitted by the firm. |

Firm has not performed comparative dissolution profile at three dissolution media i.e., pH 1.2, pH 4.5, pH 6.8. Clarification is required.

**Previous Decision:** Deferred for submission of comparative dissolution profile at three dissolution media i.e., pH 1.2, pH 4.5, pH 6.8 **(M-287).**

**Evaluation by PEC:** The firm has submitted comparative dissolution profile at pH 1.2, pH 4.5 and pH 6.8.

**Decision: Registration Board decided to approve registration of ROFIN TABLETS 500 mcg by M/s Dyson Research Laboratories (Pvt.) Ltd. 28th KM Ferozpur Road, Lahore. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months**

**Case No. 09: Miscellaneous Cases.**

**a. Cases Referred by Appellate Board:**

1272. **Sovel 400/100mg Tablet (Sofosbuvir/Velpatasvir) of M/s Indus Pharmaceuticals, Karachi**

The following case was forwarded by Deputy Director (Appellate Board) through letter No. F.1-3/2018-AB(M-151) dated 4th February 2019 containing decision of the Appellate Board which was taken in its 151st meeting held on 16-01-2019 as per Appeal No. 07/2018 of M/s Indus Pharmaceuticals, Karachi for their product "Sovel 400/100mg Tablet" which was rejected by Registration Board in 277th meeting. The letter further provided the decision which is as:

*"**The Board agreed with the submission made by the firm and allowed the appeal. The Secretary, Registration Board is directed to place the product "Sovel 400/100mg Tablet (Sofosbuvir/Velpatasvir) on the agenda of the forthcoming meeting of Registartion Board for issuance of the registration of product accordingly"***

Accordingly the agenda of the same product (as already rejected in 277th meeting) is placed before the Board for its consideration.

| 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<br><br>GMP Inspection Report Date & Remarks | Previous DRB Decision / Remarks (if any) |
|---|---|---|---|---|---|
| 1273. | M/s Indus Pharma (Pvt.) Ltd.<br><br>26-27 & 63-67, Sector 27, Korangi Industrial Area 74900.<br><br>Karachi. | SOVEL Tablet 400mg / 100mg<br><br>Each film coated tablet contains:-<br>Sofosbuvir…400mg<br>Velpatasvir…100mg<br><br>(Anti-Viral) | Form 5-D<br>Dairy No. 1426 dated 5-10-2016<br>Rs.50,000/-<br>Rs. 5,855/- per pack of 28 tablets.<br>Rs.209.12/- per tablet. | EPCLUSA by M/s Gilead Sciences Inc. USA.<br><br>Not applicable.<br><br>GMP compliant dated 16-8-2017. | The Firm has claimed Manufacturer's Specifications. |

| STABILITY STUDY DATA | | | |
|---|---|---|---|
| Drug | SOVEL Tablet 400mg / 100mg (Sofosbuvir + Velpatasvir) | | |
| Name of Manufacturer | M/s Indus Pharma (Pvt.) Ltd. Karachi. | | |
| Manufacturer of API | Sofosbuvir: M/s Beijing Huikang Boyuan Chemical Tech Co., Ltd. China. | | |
| | Velpatasvir: M/s Xian Reyphon Pharmaceutical Co., Ltd. China. | | |
| API Lot No. | Sofosbuvir: 151218 | | |
| | Velpatasvir: 161202 | | |
| Description of Pack (Container closure system) | HDPE Plastic Bottle. | | |
| Stability Storage Condition | Accelerated: 40°C ± 2°C & 75±5%RH<br>Real Time: 30°C ± 2°C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months Real Time: 06 Months | | |
| Frequency | Accelerated: 0,1,3,6 (Month) Real Time: 0,3,6 (Month) | | |
| Batch No. | P-1/SVL-400/100mg | P-2/SVL-400/100mg | P-3/SVL-400/100mg |
| Batch Size | 2,500 Tablets | 2,500 Tablets | 2,500 Tablets |
| Manufacturing Date | 01-2017 | 01-2017 | 01-2017 |
| Date of Initiation | 25-01-2017 | 31-01-2017 | 31-01-2017 |
| No. of Batches | 03 | | |

| Date of Submission | 18-08-2017 (Dy. No. 12428) |
|---|---|

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr.# | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | M/s Beijing Huikang Boyuan Chemical Tech Co., Ltd. China:<br>Copy of GMP Certificate for Pharmaceutical Products issued by Liaoning Food and Drug Administration, China is submitted. |
| | | M/s Xi'an Reyphon Pharmaceutical Co., Ltd. China:<br>Copy of GMP Certificate for Pharmaceutical Products issued by Xi'an Food and Drug Administration, China is submitted. |
| 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. | Sofosbuvir:<br>Copy of ADC (Karachi) attested invoice is submitted. |
| | | Velpatasvir:<br>Copy of ADC (Karachi) attested invoice is submitted. |
| 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 |

**PREVIOUS REMARKS OF EVALUATOR[1]**

- The firm has clarified that at the time of application a tentative test method was submitted specifying the dissolution 75% in 45min, but during formulation development, lab scale and pilot scale batches were manufactured and the dissolution specifications now meet the USP criteria i.e. 75% in 30min and complies FDA's proposed specifications for this formulation and has submitted revised test methods and specifications.
- The firm also clarified that at the time of initial submission of dossier, a tentative formulation with powdered form of Velpatasvir was submitted in Master Formulation as well as in Method of Manufacturing, but during formulation development, lab scale and pilot scale batches were manufactured with Velpatasvir Co-Povidone (1:1 dried dispersion form) and the same material will be used in commercial manufacturing. A copy of COA of Velpatasvir Co-Povidone (1:1 dried dispersion form) from M/s Reyphon China, along with revised Master Formulation and Method of Manufacturing has been submitted.
- The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Pilot Scale Batches.

During the proceedings of the Registration Board a case of personal hearing of M/s AGP Limited, Karachi was discussed. The firms' representative apprised Registration Board that M/s Beijing Huikang Boyuan Chemical Tech Co. Ltd. (Supplier) is not a licensed pharmaceutical unit rather it is an R&D plant therefore they are unable to provide GMP certificate from concerned province / state drug administration.

**Decision:** Registration Board deferred the case for the following:

- Clarification of above since the API (Sofosbuvir) is of the same source (M/s Beijing Huikang Boyuan Chemical Tech Co. Ltd); while the firm has submitted GMP Certificate for Pharmaceutical Products issued by Liaoning Food and Drug Administration, China.

- Moreover the firm was directed to submit Legalized GMP Certificate for Pharmaceutical Products issued by Liaoning Food and Drug Administration, China.

Now the firm vide letters dated 20-11-2017 (Dy. No. 21537) and 19-12-2017 (Dy. No. 25206) has submitted the following clarification:

1. Company Profile of M/s Beijing Huikang stating that the headquarters and R&D Centre are located at Fengtai District of Beijing whereas the plant is based in Fluoride Industrial Park, Fuxin City, Liaoning Province.
2. Acknowledgement receipt from FDA of the following Drug Master File Submission:
   DMF Number Assigned:28919
   Date of Submission: December 24, 2014
   DMF Type: II
   Subject (Title): SOFOSBUVIR as manufactured in Beijing, China.
   Holder: Beijing Huikang Bouyuan Chemical Co., Ltd.
   Submitted By: Beijing Huikang Bouyuan Chemical Co., Ltd.
   Agent: None
   The status of DMF is marked "A".
   "A" = Active. This means that the DMF was found acceptable for filing, administratively, and has not been closed.
3. Drug Master File (Module 3, Applicant's Part) for Sofosbuvir depicting following information:
   Head Office: Beijing Huikang Bouyuan Chemical Co., Ltd. No.5 Haiying Road, Fengtai District, Beijing-100070, China.
   Manufacturing Site: Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China.
   *Note: Fuxin Long Rui Pharmaceutical Co., Ltd. and Beijing Huikang Bouyuan Chemical Co., Ltd. belongs to same owner*.
   Batch Analyses: COAs of 03 consecutive batches illustrating the actual results that have been obtained from routine quality control by Beijing Huikang Bouyuan Chemical Co., Ltd. Add: No.7 Haiying Road, Science City, Fengtai District, Beijing, China.
4. Legalized photocopy of GMP Certificate for Pharmaceutical Products of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. issued by Fuxin Food and Drug Administration, China.

**Proceedings:** Mr. Mirza Danish Hussain Barlas (Manager Regulatory Affaiirs) appeared before the Board to present the case. Mr. Danish agreed to the statement of M/s AGP Limited, Karachi (as discussed in previous meeting) that M/s Bejing Huikang Boyuan Chemical Co., Ltd is an R&D unit and apprised the Board that since in 2014, China forbid any sort of manufacturing in Capital City (Beijing) therefore their principal manufacturer i.e. M/s Bejing Huikang Boyuan Chemical Co., Ltd, shifted their commercial manufacturing facility to Liaoning Province under the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd.

Mr. Danish hence requested the Board to consider the GMP certificate of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. since their imported API i.e Sofosbuvir was manufactured by M/s Fuxin Long Rui Pharmaceutical Co., Ltd.

Upon inquiring Mr. Danish could not submit any legal document, issued by relevant authority confirming the relationship between M/s Bejing Huikang Boyuan Chemical Co., Ltd & M/s Fuxin Long Rui Pharmaceutical Co., Ltd.

**Decision of 277th meeting** of Registration Board: Registration Board upon consideration of submission made by representative of firm decided to reject the case since the firm could not satisfy the Board regarding GMP status of their supplier of Sofosbuvir i.e. M/s Bejing Huikang Boyuan Chemical Co., Ltd.

**Decision: As per directions of Appellate Board, Registration Board decided to approve the product with as Innovator's specifications. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

1274. **Omera (Omeprazole) & Esomega (Esomeprazole) Injections by M/s BF Biosciences Ltd., 5-Km, Sundar Raiwind Road, Raiwind.**

Following cases were presented in 277th meeting of Registration Board, submitted on Form 5 along with enclosures on CTD format. The details of cases & decisions of Board are reproduced as under:

| | | |
|---|---|---|
| **1.** | Name and address of manufacturer / Applicant | M/s BF Biosciences Ltd., 5-Km, Sundar Raiwind Road, Raiwind. |
| | Brand Name +Dosage Form + Strength | Omera 40mg Infusion<br>(Lyophilized Powder For Solution For Intravenous Injection) |
| | Composition | Each vial contains:<br>Omeprazole (as sodium) …40mg |
| | Diary No. Date of R& I & fee | Dy. No.16942; 04-10-2017; Rs.20,000/- (03-10-2017) |
| | Pharmacological Group | Proton pump inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 1's;As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Risek Injection 40mg of M/s Getz Pharma (Reg.#024170) |
| | GMP status | Last inspection report 08-09-2017 Panel concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | • Firm has section approval for Biological parenteral only whereas applied formulation does not fall in this category.<br>• Firm has submitted Enclosures along with form 5 as per CTD format approved in 264th meeting of registration Board.<br>• Firm has submitted reports of accelerated & real time stability studies for three batches. |
| | **Decision: Registration Board deferred the case for personal hearing for clarification of firm's request to manufacture applied formulation in Biological parenteral section.** | |
| **2.** | Name and address of manufacturer / Applicant | M/s BF Biosciences Ltd., 5-Km, Sundar Raiwind Road, Raiwind. |
| | Brand Name +Dosage Form + Strength | Esomega 40mg Infusion<br>(Lyophilized Powder For Solution For Intravenous Injection) |
| | Composition | Each vial contains:<br>Esomeprazole (as sodium) …40mg |
| | Diary No. Date of R& I & fee | Dy. No.16941; 04-10-2017; Rs.20,000/- (03-10-2017) |
| | Pharmacological Group | Proton pump inhibitors |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | X-Prazole 40mg Infusion of M/s Mediate Pharmaceuticals, Karachi (Reg.#057925) |
| | GMP status | Last inspection report 08-09-2017 Panel concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | • Firm has section approval for Biological parenteral only whereas applied formulation does not fall in this category.<br>• Firm has submitted Enclosures along with form 5 as per CTD format approved in 264th meeting of registration Board. |

| | | |
|---|---|---|
| | | • Firm has submitted reports of accelerated & real time stability studies for three batches. |
| | **Decision: Registration Board deferred the case for personal hearing for clarification of firm's request to manufacture applied formulation in Biological parenteral section.** | |

**Following details have been submitted of Module 3 (Quality / CMC) for both above cited applications:**

**Contents of Module: 3 (Quality / CMC)**

| Module | Section | Sub-section | Contents | Data submitted |
|---|---|---|---|---|
| **3** | **3.2.S** | | **DRUG SUBSTANCE** | |
| | | 3.2.S.1 | **General Information** | Detail submitted for<br>i. Nomenclature<br>ii. Structure<br>iii. General properties |
| | | 3.2.S.2 | **Manufacture** | Detail submitted for<br>i. Manufacturer(s)<br>ii. Description of Manufacturing Process and Process Controls |
| | | 3.2.S.3 | **Characterization** | Detail submitted for<br>i. Elucidation of Structure and other Characteristics<br>ii. Impurities |
| | | 3.2.S.4 | **Control of Drug Substance** | Detail submitted for<br>i. Control of Drug Substance<br>ii. Specification<br>iii. Analytical Procedures<br>iv. Validation of Analytical Procedures<br>v. Batch Analyses<br>vi. Justification of Specification |
| | | 3.2.S.5 | **Reference Standards or Materials** | Detail submitted for Reference Standards |
| | | 3.2.S.6 | **Container Closure System** | Detail submitted for Container Closure System |
| | | 3.2.S.7 | **Stability** | Detail submitted for Stability. (Protocol & reports have been submitted) |
| | **3.2.P** | | **DRUG PRODUCT** | |
| | | 3.2.P.1 | **Description and Composition of Drug Product** | Detail submitted for Composition of Drug Product |
| | | 3.2.P.2 | **Pharmaceutical Development** | Detail submitted for Components of the Drug Product. |
| | | 3.2.P.3 | **Manufacture** | Detail submitted for<br>i. Manufacturer(s)<br>ii. Batch Formula<br>iii. Description of Manufacturing Process and Process Controls<br>iv. Controls of Critical Steps and Intermediates<br>Undertaking has been submitted for Process validation |
| | | 3.2.P.4 | **Control of Excipient** | Detail submitted for<br>i. Specifications<br>ii. Analytical Procedures<br>All excipients used are of Pharmacopoeal grades |
| | | 3.2.P.5 | **Control of Drug Product** | Detail submitted for<br>i. Specification(s)<br>ii. Analytical Procedures<br>iii. Validation of Analytical Procedures |

| | | | | |
|---|---|---|---|---|
| | | | | (Protocol & report have been submitted) |
| | | 3.2.P.6 | **Reference Standards or Materials** | Detail submitted for Reference Standards or Materials |
| | | 3.2.P.7 | **Container Closure System** | Detail submitted for Container Closure System |
| | | 3.2.P.8 | **Stability** | Following have been submitted:<br>i. Stability Summary and Conclusions<br>ii. Post-approval Stability Protocol and Stability Commitment<br>iii. Stability Data (Only reports have been submitted.) |

- Now, the firm has requested for personal hearing before the Honourable Drug Registration Board to enable to them to present their case. The representatives of the firm now have been called upon for personal hearing.

**Proceedings:** Dr. Ajmal Nasir (Director Technical) appeared before the Board and briefed regarding justification for the manufacturing of non- biologicals along with bio-pharmaceuticals at BF Biosciences Ltd as under:

"BF Biosciences is manufacturing six products i.e. Interferon Alpha 2a, Interferon Alpha 2b, Pegylated interferon alpha 2a, Erythropoietin, Filgrastim and Terlipressin acetate injections.

Drug Substances manufactured using a Biological system using living organisms/cell lines through culturing or Recombinant DNA are termed as BIOLOGICALS, whereas Drug Products manufactured using already produced Biological Drug Substances (which no longer contain living organisms) are termed as Bio-Pharmaceuticals. Dedicated facility is required for the manufacturing of BIOLOGICAL SUBSTANCES and certain other highly sensitizing compounds etc., but not for biopharmaceuticals

All above-mentioned products manufactured at BF Biosciences are ***Bio-Pharmaceuticals***. These bio-pharmaceutical formulations are peptides that are easily denatured by temperature as well as pH changes, and thus can be eliminated from the facility through cleaning validation between production batches. These do not therefore bear contamination risks carried by penicillin-based antibiotics and other products requiring dedicated manufacturing facilities.

Bio-Pharmaceuticals formulation and filling / Lyophilization (if required) is allowed as per WHO [1], Eudralex [2] and FDA [3] guidelines along with non-Biopharmaceuticals on Campaign basis.

At BF Biosciences we intend to avail this allowance to manufacture non-Biologicals along with Bio-Pharmaceuticals on Campaign basis.

All required controls and systems are in place and are compliant to requirements for campaign-based manufacturing of bio- pharmaceuticals and non- biologicals."

REFERENCES


1) **Annex 3 WHO good manufacturing practices for biological products** Replacement of Annex 1 of WHO Technical Report Series, No. 822 Section 9 , 13 GMP OF BIOLOGICAL PRODUCTS WHO s22400en.pdf
2) EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 EU guidelines forGood Manufacturing Practice for Medicinal Products for Human and Veterinary Us e Annex 2 Manufacture of Biological active substances and Medicinal Products for Human Use Section 8 g and 9
3) **FDA approves BioMarin's manufacturing facility in Cork, Ireland** he FDA has approved BioMarin Pharmaceutical's bulk biologics manufacturing plant, located in Cork, Ireland for production of the formulated bulk substance. Niamh Marriott (European Pharmaceutical Review)

- It is pertinent to mention that M/s BF Biosciences Ltd. Lahore was previously granted registration for Omega injection (Omeprazole), Reg. No. 067967, in same manufacturing facility vide letter no. F.15-7/2010-Reg-V (M-228) dated 10-12-2010.
  Later Central Licensing Board in 235th meeting while discussing the case of renewal of DML of M/s BF Bio Sciences, Lahore passed following orders in respect of Omega injection (Omeprazole) , Reg. No. 067967:-
  "The Board was apprised by licensing division that the firm in its renewal application has mentioned that they have registration of omeprazole at biotech facility where as panel in the inspection report has mentioned that the firm has dedicated biotech manufacturing facility only. The Board in this regard advised to refer the case of registration of Omega injection (Omeprazole), Reg. No. 067967 to Drug Registration Board for its consideration and further necessary action accordingly".

  Registration Board in its 245th meeting held on 29th & 30th September, 2014 decided to issue show cause for cancellation of registration of Omega injection (Omeprazole), Reg. No. 067967, registered in the name of M/s BF Biosciences Ltd. Lahore.

Subsequently Omega injection (Omeprazole), Reg. No. 067967 of M/s BF Biosciences Ltd. Lahore, was de-registered vide letter no. F.15-2/2015-Reg-V (M-247)

**Decision of 278th meeting:** Registration Board deliberated the matter in detail and decided to refer the case to Central Licensing Board for their comments on firm's request as CLB has granted for Biological parenteral section only.

Subsequently the firm appealed before the Appellate Board, wherein the case was presented in 151st meeting of the Appellate Board. The proceedings and order of the Appellate Board are reproduced as under:

**BEFORE THE APPELLATE BOARD IN ITS 151ST SITTING HELD ON 16TH JANUARY, 2019**

**ORDER**

| | |
|---|---|
| **Appeal No.** | **32/2018** |
| **Appellant:** | **M/s BF Biosciences, Lahore** |
| **Appeal preferred against the decision of:** | **Central Licensing Board** |
| **Decision Appealed Against:** | **Appeal against rejection of application for manufacturing of non-biological parental preparations at the facility of biological preparations.** |
| **Date of the issuance of the decision:** | **07-08-2018** |
| **Date of the Appeal received:** | **04-10-2018** |

**Present:**

| | |
|---|---|
| 1. Dr. Dr. Shaikh Akhter Hussain | Chairman |
| 2. Dr. Jamil Anwar | Member |
| 3. Mr. Qaiser Muhammad | Member |
| 4. Mr. Salim Khan | Member |
| 5. Dr. Farzana Chaudhary | Member (Expert) |
| 6. Brig. Dr. Akbar Waheed | Member (Expert) |
| 7. Prof. Dr. Maqsood Ahmad | Member (Expert) |
| 8. Mr. Shahid Nasir | Member (Expert) |

**Appellant represented by:**

1. Mr. Omar Waheed, General Manager, M/s BF Biosciences, Lahore.
2. Mr. Baqar Hasan, Director (Reg. & Legal), M/s BF Biosciences, Lahore.
3. Dr. Ajmal Nasir, Director (Technical), M/s BF Biosciences, Lahore.

**Proceedings:**

The appellant challenged the decision passed by the Central Licensing Board in its 264th meeting held on 09-07-2018 whereby the Central Licensing Board in its 264th meeting held on 9th July, 2018 has considered their request for campaign manufacturing of non-biological products in biological manufacturing facility under DML No. 000655 and decided as under:

> "The Central Licensing Board considered the report of the Technical Evaluation Committee and decided to regret the permission for manufacture of non-biological parental preparations at the facility of biological preparations at M/s BF Biosciences Limited, Lahore under Drug Manufacturing License no. 000655 (formulation) on campaign manufacture basis as no such circumstances /exceptional case of emergency exists as required under the rules. The same may be conveyed to Drug Registration Board as the case was referred by the said Board for comments. The Central Licensing Board however, considered the recommendations at Serial No. 2 of the Committee and also decided to forward the same to Drug Registration Board for consideration."

2. Furthermore, the Central Licensing Board approved the recommendations of Technical Evaluation Committee at Serial No. 2 that BF Biosciences may be facilitated by processing pending applications for biological drugs on priority to overcome underutilization of the facility as country needs biological products as well.

3. The representative of the firm delivered a comprehensive presentation. The main thrust of argument of the appellant was that the firm is not producing biological but bio-pharmaceuticals. He further submitted that the terms "biological" and "biopharmaceutical" are defined as follows:-

> **BIOLOGICAL PRODUCT:--** A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
> REFERENCE: 42 U.S. Codex. 262(a) FDA
>
> Since all the products filled by BF Biosciences are peptides and proteins in nature they did not fall in the definition of Biologics as described above and hence are not Biologics. Peptides and proteins are considered a s Biopharmaceuticals due to the use of Living organism in the manufacture of the final product. However, the finished product does not contain any live organism as given in definition below.
>
> **BIO PHARMACEUTICALS:--** A therapeutic product made through the genetic manipulation of living things or their cells, including (but not limited) *proteins and monoclonal antibodies, peptide, and other molecules that are not chemically synthesized,* along with gene therapies, cell therapies and engineered tissues. Biopharmaceuticals ethical pharmaceutical drugs derived through bioprocessing.
> REFERENCE: Glossary, International Society of Pharmaceutical Engineers (ISPE)

4. The representative of the firm added that there is no reference in any guideline requirement for separate formulation and filling sections for biopharmaceutical and pharmaceutical products. However extra care is advised vide:-

(i) EudraLex The Rules Governing Medical Product in the European Union (Vol. 4).
(ii) EU Guideline for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.

5. Following examples of permissions to manufacture biopharmaceutical & non biopharmaceutical on campaign basis were quoted by the firm:-

(i) FDA has approved BioMarin Pharmaceuticals's bulk biologics manufacturing plant, located in Cork, Ireland for production of the formulated bulk substance. (Elsufase alfa (trade name Vimizim) is a drug for the treatment of Morquio syndrome which is caused by deficiency in the enzyme N-acetylagalcatosamine-6-sulfatase. Elosulfase alfa is synthetic version of the enzyme (non Biological product). This facility is for the manufacturing of Bulk biologics and allowed to manufacture bulk for their product Vimizim ( Elosulfase alfa) is a non-biological product on campaign based manufacturing by following The above mentioned guidelines for change over and campaign based manufacturing and use facility as multiproduct facility.

(ii) Baxter's facility at Halle Germany. Based on "Risk Assessment" combined with State of the Art Organizational Procedures & Technical Standards in accordance with Industry Standards Baxter was allowed to manufacture:

- Small Molecules (cytotoxic & non Cytotoxic)
- Liposomal & NOano particle Formulation
- Monoclonal antibodies
- ADCs (Antibody Drug Conjugates)
- Nocleic Acid Products e.g. Gene Therapeutics.

Baxter was allowed to manufacture small molecules (non biopharmaceuticals) along with biopharmaceuticals including Liposomal and Nano particle formulation, MABS, DCs etc based on guidelines on campaign based manufacturing and risk assessment and mitigation.

| **Bio Pharmaceuticals** | **Non Biopharmaceuticals** |
|---|---|
| Liposome's | Oxiplatin |
| Enoxaparin Sodium | Lidocaine |
| Heparin Sodium | Gentamicin |
| MABs (Monoclonal Anti Bodies) | |
| ADCs (antibody Drug Conjugates | |

6. Responding to a query raised by the Chairman regarding campaign manufacturing timetable, the firm proposed to change over on quarterly basis due to shelf life requirement in tender business. Following checklist will be strictly observed on change over from biopharmaceutical to non-biopharmaceuticals (and *vice versa*) which will be verified by DRAP:

| **CHANGE OVER CHECKLIST** | | | |
|---|---|---|---|
| **Sr.** | **Activity** | **Date:** | |
| 1 | Last Production campaign was for | | |
| | | **Yes** | **No** |
| 2 | All manufacturing/Formulation Equipment for last manufacturing campaign removed from area and kept segregated. | | |
| 3(a) | Dispensing area is cleaned, sanitized as per SOP after last campaign and logged in. | | |
| 3(b) | Formulation Area is cleaned, sanitized as per SOP after last campaign and logged in. | | |
| 3(c) | Filling Area is cleaned, sanitized as per SOP after last campaign and logged in. | | |
| 4 | Changeover of Machine and filling machine as per change over SOP and logged in. | | |
| 5 | Freeze dryer is cleaned and sterilized through CIP & SIP procedure and logged in after last campaign. | | |
| 6 | New change parts are installed after cleaning as per approved SOP and Sterilization. | | |

| | | | |
|---|---|---|---|
| 7 | All Manufacturing equipment & filling parts are product specific / dedicated and logged in. | | |

7. Prof. Dr. Maqsood Ahmad stated the protocols are different for both products i.e. biological and pharmaceutical. Patients cannot be put to risk by allowing campaign manufacturing. The firm clarified that they are manufacturing bio-pharmaceuticals and not biological products. As per international guidelines, manufacturing of bio-pharmaceuticals with pharmaceuticals on campaign basis is allowed.

8. The Board noted that the firm has very stringent quality assurance mechanism with state of the art manufacturing and quality control facility in line with the international regulations.

9. The Board allowed the appeal and permitted M/s BF Biosciences, Lahore for manufacturing of proton-pump inhibitors (Omeprazole & Esomeprazole) in already approved section for biological drugs on campaign manufacturing basis. The Secretary, Registration Board is directed to place the following products of the appellant before the Registration Board in its forthcoming meeting and issue registrations within 30 days thereof:-

(i) Omera (Omeprazole) 40mg injection.
(ii) Esomega (Esomeprazole) 40mg injection.

10. The appellant may be allowed to manufacture other proton-pump inhibitors, including Lansoprazole and Dexlansoprazole, if it fulfills the requirement of CTD dossier. However, the campaign manufacturing is allowed on the basis of change over checklist mentioned in paragraph 6 (above) subject to verification by the panel comprising the following, before each interval of production:-

(i) Mr. Shahid Nasir (Member, Appellate Board); and
(ii) Mt. Asim Rauf, Additional Director (E&M), DRAP, Lahore.

**Decision: Registration Board deferred above products for the submission of following as required by the CTD:**

**i. Stability data of three batches as per Zone-IVA conditions according to directions of Registration board in oits 278th meeting.**
**ii. Process validation data.**

**b. New submission of the firm against already rejected product:**

M/s Vision Pharmaceuticals Islamabad has applied for transfer of their already registered product Artilide Tablet 100mg (Reg No. 033768) from contract manufacturing to their own facility. The case was considered and Rejected by Registration Board in its 252nd meeting due to non-availability of the approval status of this formulation in reference regulatory authorities. Registration Board in its 269th meeting decided to approve the formulation of nimesulide 100mg Tablet after reviewing the formulation and keeping in view its approval by EMA.

The firm has submitted a fresh application dated 21-01-2019 with same brand name requesting to consider their case on priority since their application was rejected earlier.

The details of the case are as follows:

| | | |
|---|---|---|
| 1275. | Name and address of manufacturer / Applicant | M/s Vision Pharmaceuticals (Pvt.) Ltd., Plot No. 22 - 23, Industrial Estate, Kahuta road, Model Town, Islamabad. |
| | Brand Name +Dosage Form + Strength | Artilide 100mg Tablet |
| | Composition | Each tablet Contains:<br>Nimesulide……100mg |
| | Diary No. Date of R& I & fee | Dy.No 2694 dated 21-01-2019 Rs. 20,000/- 21-01-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished Product Specification | Firm has claimed in house specification |
| | Pack size & demanded price | 15's: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by EMA |
| | Me-too status | Nims tablet by M/s Sami |
| | GMP status | Vision Pharmaceuticals was issued GMP certificate based on inspection dated 26-01-2018 |
| | Remarks of the Evaluator[3]. | • |
| | **Decision: Approved with Innovator's specifications and with a pack size for 15 days as per recommendations of EMA only for the following clinical indications as a second-line choice.**<br>**a) Treatment of acute pain**<br>**b) Primary dysmenorrhea** | |

**c.**

| | | |
|---|---|---|
| 1. | Name and address of Manufacturer / Applicant | CCL Pharmaceuticals (Pvt.) Ltd. 62- Industrial Estate, KotLakhpat Lahore. |
| | Brand Name + Dosage Form + Strength | Talam tablet 5/80mg |
| | Composition | Each film coated tablet contains:<br>Amlodipine(as besylate)…..5 mg<br>Telmisartan…. 80mg |
| | Diary No. Date of R&I & fee | Dy No.9692; 21-07-2017; Rs.20,000/- |
| | Pharmacological Group | Antihypertensive |
| | Type of Form | Form-5 |
| | Finished Product Specification | Innovator's Specifications |
| | Pack Size & Demanded Price | 7×2's, 1×10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Ezitab-AM Tablet 5/80mg of M/s. Werrick Pharmaceuticals |
| | GMP status | GMP inspection conducted on 20-04-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance. |
| | Remarks Of Evaluator | |
| | Previous Decision | Registration Board in its 283rd meeting deferred the case for the following:<br>For clarification of applied dosage form since reference product is available as uncoated tablet whereas firm has applied for film coated tablet. |
| | Evaluation by PEC | There is a typographical error in the Strength of one of the APIs of above stated formulation, It was erroneously written Amlodipine (as besylate )…5mg at that time, but in real it is Amlodipine (as besylate …10mg. so correction is required to be made in the strength of Amlodipine(as besylate), & than |

| | | |
|---|---|---|
| | | composition will become as Follow:<br>Each tablet contains:<br>Amlodipine(as besylate)…..10 mg<br>Telmisartan…. 80mg<br>Me too: Available<br>Approval status in RRA: Approved in US-FDA |
| | **Decision: Approved with innovator's specification.** | |

2. R-V vides its letter No. F.8-6/2013-Reg-V dated 24th October, 2018 forwarded a duplicate dossier of below mentioned product of CCL Pharmaceutical for Evaluation having following information on the letter.

| Sr. N. | Name of firm | Name of drug(s) with composition | Date of submission of fee |
|---|---|---|---|
| 1. | M/s. CCL Pharma, Lahore. | Talam tablet 5/80mg<br>Each film coated tablet contains:<br>Amlodipine(as besylate)…..5 mg<br>Telmisartan…. 80mg | Dy. No. 9695<br>Dated 21-07-2017<br>(Duplicate Dossier) |

| | |
|---|---|
| Name and address of Manufacturer / Applicant | CCL Pharmaceuticals (Pvt.) Ltd. 62- Industrial Estate, KotLakhpat Lahore. |
| Brand Name+DosageForm+Strength | Talam tablet 5/80mg |
| Composition | Each film coated tablet contains:<br>Amlodipine(as besylate)…..5 mg<br>Telmisartan…. 80mg |
| Diary No. Date of R&I & fee | Dy No.9695; 21-07-2017; Rs.20,000/-<br>(duplicate fee challan & duplicate dossier) |
| Pharmacological Group | Antihypertensive |
| Type of Form | Form-5 |
| Finished Product Specification | Innovator's Specifications |
| Pack Size & Demanded Price | 7×2's, 1×10's; As per SRO |
| Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| Me-too status | Ezitab-AM Tablet 5/80mg of M/s. Werrick Pharmaceuticals |
| GMP status | GMP inspection conducted on 20-04-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance. |
| Remarks Of Evaluator | |
| **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |

**Case No.01: Standardization of Label Claim of Sacubitril and Valsartan Containing Tablets:**

Registration Board in its various meetings approved the grant of registration for following products containing valsartan and sacubitril as per below mentioned details:

| Sr. No. | Reference of Reg. Board Meeting | Name of Manufacturer | Name of Drug and Composition | Standardized Label Claim as per USFDA |
|---|---|---|---|---|
| I | II | III | IV | V |
| 1. | M-285 | M/s Atco Laboratories Limited, B-18, S.I.T.E., Karachi. | Valsac tablet 24mg/26mg<br>Each film coated tablet contains:<br>Sacubitril…24.3mg<br>Valsartan…25.7mg<br>(as Sacubitril valsartan sodium salt complex) | Valsac tablet 24mg/26mg<br><br>Each film coated tablet contains:<br>Sacubitril…24mg<br>Valsartan…26mg |
| 2. | M-285 | M/s Atco Laboratories Limited, B-18, S.I.T.E., Karachi. | Valsac tablet 49mg/51mg<br>Each film coated tablet contains:<br>Sacubitril…48.6mg<br>Valsartan…51.4mg<br>(as Sacubitril valsartan sodium salt complex) | Valsac tablet 49mg/51mg<br><br>Each film coated tablet contains:<br>Sacubitril…49mg<br>Valsartan…51mg |
| 3. | M-285 | M/s Atco Laboratories Limited, B-18, S.I.T.E., Karachi. | Valsac tablet 97mg/103mg<br>Each film coated tablet contains:<br>Sacubitril…97.2mg<br>Valsartan…102.8mg<br>(as Sacubitril valsartan sodium salt complex) | Valsac tablet 97mg/103mg<br><br>Each film coated tablet contains:<br>Sacubitril…97mg<br>Valsartan…103mg |
| 4. | M-283 | M/s Sami Pharmaceuticals (Pvt.) Ltd. F-95, Off. Hub River Road, S.I.T.E., Karachi | Valsatril 97mg/103mg Tablet<br>Each film coated tablet contains:<br>Sacubitril …… 97.2 mg<br>Valsartan ……. 102.8 mg | Valsatril 97mg/103mg Tablet<br>Each film coated tablet contains:<br>Sacubitril …… 97mg<br>Valsartan ……103 mg |
| 5. | M-283 | M/s Sami Pharmaceuticals (Pvt.) Ltd. F-95, Off. Hub River Road, S.I.T.E., Karachi | Valsatril 49mg/51mg Tablet<br>Each film coated tablet contains:<br>Sacubitril …….48.6 mg<br>Valsartan ……51.4 mg | Valsatril 49mg/51mg Tablet<br>Each film coated tablet contains:<br>Sacubitril …….49 mg<br>Valsartan ……51 mg |
| 6. | M-284 | M/s Sami Pharmaceuticals (Pvt.) Ltd. F-95, Off. Hub River Road, S.I.T.E., Karachi | Valsatril 24mg/26mg Tablet<br>Each Tablet contains:<br>Sacubitril …….. 24.3mg<br>Valsrtan ……25.7mg | Valsatril 24mg/26mg Tablet<br>Each Tablet contains:<br>Sacubitril …….. 24mg<br>Valsrtan ……26mg |

In order to harmonize the label claim of all above mentioned formulations, it was standardized in accordance with that approved by USFDA (as mentioned vide column V of above table) and Registration certificates have been issued accordingly.

**Decision: Registration Board noted the information and endorsed the above mentioned standardization of label claim (Column V) for being in line with that approved by Reference Regulatory Authority.**

**Case No.02: Approved Products of M/s Noa Hemis, Karachi**

Registration Board in its 284th meeting, held on 31st July- 1st August, 2018, approved the grant of registration for following products of M/s Noa Hemis, Karachi as per below mentioned details:

**TABLE-I**

| S.No. | Brand Name & Composition | GMP Status mentioned in minutes of M-284 | Decision taken vide M-284 |
|---|---|---|---|
| 1. | Symenda 5mg Tablet<br>Each film coated tablet contains:<br>Memantine Hydrochloride….5mg<br>USP | Last GMP Inspection conducted on 20-03-2018 and report concludes that firm is considerd to be operating at an acceptable level of GMP compliance | Approved |
| 2. | Symenda 10mg Tablet<br>Each film coated tablet contains:<br>Memantine Hydrochloride….10mg<br>USP | -do- | Approved |
| 3. | Opamac 25mg Tablet<br>Each film coated tablet contains:<br>Topiramate…….25mg<br>USP | -do- | Approved |
| 4. | Opamac 50mg Tablet<br>Each film coated tablet contains:<br>Topiramate……50mg<br>USP | -do- | Approved. |
| 5. | Maxi-Luma Cream<br>Each gram of cream contains:<br>Fluocinolone Acetonide …….0.1mg<br>Hydroquinone….40mg<br>Tretinoin…….0.5mg<br>Manufacturer's specification | -do- | Approved with innovator's specification. |
| 6. | Osmolat Rice Powder Sachet<br>(Banana flavour)<br>Each sachet contains:<br>Rice Powder (Pre cooked)…….6g<br>Sodium Citrate……0.58<br>Sodium Chloride…..0.35g<br>Potassium Chloride..0.30g Manufacturer's specification | -do- | Approved with innovator's specification. |
| 7. | Osmolat Rice Powder Sachet<br>(Orange flavour)<br>Each sachet contains:<br>Rice Powder (Pre cooked)…….6g<br>Sodium Citrate……0.58<br>Sodium Chloride…..0.35g<br>Potassium Chloride..0.30g Mfg. Specification | -do- | Approved with innovator's specification. |

However, in the same meeting following 05 cases of M/s Noa Hemis, Karachi were deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm (dated 20-3-2018) does not conclude GMP compliant status. Details are as under:

**TABLE-II**

| S# | Brand Name & Composition | GMP Status mentioned in minutes of M-284 | Decision taken vide M-284 |
|---|---|---|---|
| 1. | Rinip Tablet 1mg<br>Each film coated tablet contains:<br>Ropinirole (as HCl)…..1mg<br>USP | The FID conducted inspection of the firm on 20-3-2018 and noticed some observations. | Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. |

| | | | |
|---|---|---|---|
| | | Accordingly, letter was sent to the firm to rectify the observations. Firm did not submit compliance report. | |
| 2. | Rinip Tablet 0.25mg<br>Each film coated tablet contains:<br>Ropinirole (as HCl)…..0.25mg<br>USP | -do- | Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. |
| 3. | Tusofyl Syrup<br>Each 5ml syrup contains:<br>Acefylline Piperazine…..125mg<br>Manufacturer's | -do- | Deferred for following:<br>• Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.<br>• Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting. |
| 4. | Tusofyl Cough Syrup<br>Each 5ml syrup contains:<br>Acefylline Piperazine…..45mg<br>Diphenhydramine as HCl……8mg<br>Manufacturer's | -do- | Deferred for following:<br>• Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.<br>• Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting. |
| 5. | Robotin Syrup<br>Each 5ml syrup contains:<br>Carbocysteine……250mg<br>Manufacturer's | -do- | Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. |

Accordingly, registration letters of products approved in 284th meeting were with held for clarification regarding GMP status. Later on, in 285th meeting of Registration Board, the firm was again granted registration of following products considering same inspection report i.e., dated 20-03-2018, as per below mentioned details:

**TABLE-III**

| S.No. | Brand Name & Composition | GMP Status mentioned in minutes of M-284 | Decision taken vide M-285 |
|---|---|---|---|
| 1. | DIFLUCORT CREAM<br>Each gram cream contains:<br>Diflucortolone valerate……..1mg<br>Isoconazole nitrate……...10mg<br>In-house | Last GMP Inspection conducted on 20-03-2018 and report concludes that firm is considered to be operating at an acceptable level of GMP compliance. | Approved with innovator's specification. |
| 2. | ZiQuil Syrup<br>Each 5ml of syrup contains:<br>Paracetamol…….250mg<br>Promethazine HCl…..5mg<br>Dextromethorphan HBr…….3.75mg<br>In-house specification | Last GMP Inspection conducted on 20-03-2018 and report concludes that firm is considered to be operating at an acceptable level of GMP compliance. | Approved with innovator's specification. |

The firm has now provided subsequent inspection report dated 09-08-2018, indicating "Good compliance" and requested for issuance of registration letter for products approved in M-284.

**Decision: Registration Board acceded to the grant of registration for above mentioned products (at S.No.1-7 of Table-I).**

**Case No.03: Request for Change in Registration Status of Products from M/s. AGP (Pvt) Ltd, B-23, S.I.T.E, Karachi To M/s. GlaxoSmithKline Pakistan Ltd, Karachi.**

M/s. GlaxoSmithKline Pakistan Ltd, Plot#5, Sector 21, Korangi Industrial Area, Karachi (DML#000248) has requested to change registration status of following product from M/s. AGP (Private) Limited B-23, S.I.T.E, Karachi to their name of the firm:-

| Sr. No. | Reg. No. | Name of Drug (s) | Initial letter of registration with renewal status. |
|---|---|---|---|
| 1. | 006952 | Nootropil Injection<br>Each 5ml contains:-<br>Piracetam… 1gm | Initial registration date 30-01-1984 in the name of M/s. PDH Labs; Lahore<br>1st transfer of reg. approval dated 31-12-1995<br>2nd transfer of reg. approval dated 27-02-2006<br>Renewal of application granted on 28-06-2011 for 5 years<br>Renewal applied on 22-01-2016 |

They have provided following documents:-

i. Application on From-5 along with fee of Rs. 20,000/-
ii. Copies of initial letter of registration and its renewal status.
iii. NOC for CRF.
iv. Manufacturing facility (Liquid Injection Ampoule Section) of the applicant firm verified from panel inspection report dated 31-10-2017 and section approval letter dated 26-02-2018.
v. Copy of GMP inspection report of M/s GSK dated 26-10-2018 indicating "Good level".
vi. NOC from existing registration holder dated 02-05-2017.

***Decision of M-284:***

*Registration Board deferred the case for fresh NOC from registration holder and for renewal status from RRR Section.*

The firm has now submitted fresh NOC from M/s. AGP Limited B-23, S.I.T.E, Karachi dated 26-12-2018. Furthermore, RRR section has communicated the renewal status as "Renewal application of year 2016 by M/s AGP (Pvt) Ltd. Karachi received within time, under Rule 27 of Drug Licensing, Registering & Advertising Rules, 1976."

**Decision: Registration Board decided as follows:**

**i. Cancellation of registration of Nootropil Injection (R#006952) from the name of M/s. AGP (Private) Limited B-23, S.I.T.E, Karachi.**
**ii. Approved registration of Nootropil Injection in the name of M/s. GlaxoSmithKline Pakistan Ltd, Plot#5, Sector 21, Korangi Industrial Area, Karachi (DML#000248).**
**iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.04: Approved Product of M/s Sante (Pvt) Limited, Karachi**

Registration Board, in its 281st meeting, approved the grant of registration for following product of M/s Sante (Pvt) Limited, Karachi

| | |
|---|---|
| Name and address of manufacturer / Applicant | M/s Sante (Pvt) limited Pharmaceuticals, 245/2-Z, Block 6, PECHS, Karachi |
| Brand Name +Dosage Form + Strength | Ilashes Ophthalmic Solution 0.03% |
| Diary No. Date of R& I & fee | Dy.No. , 18-4-2016, Rs.50,000/- (Duplicate) |
| Composition | Each ml contains:<br>Bimatoprost……0.3 mg |
| Pharmacological Group | Prostaglandin Analog |
| Type of Form | Form-5 |
| Finished product Specification | Manufacturer's specifications |
| Pack size & Demanded Price | 1's; As Per SRO |

| | |
|---|---|
| Approval status of product in Reference Regulatory Authorities. | Bimatoprost of Apotex Inc (**USFDA**) |
| Me-too status | Lumigan eye drops of Barret Hodgson (Reg # 033177) |
| GMP status | Last inspection report dated 20-11-17 confirms good compliance to GMP |
| Previous remarks of the Evaluator. | Section of sterile ophthalmic drops present. |
| Previous decision(s) | Deferred in 277th meeting for confirmation of Diary number date of submission of dossier from R & I Section. |
| Evaluation by PEC | ● The firm has submitted Diary No. 10809 from R&I section dated 19-06-2014.<br>● Photocopy of fee challan Rs. 50,000/- dated 20-05-2014 has been provided. |
| **Decision: Approved with innovator's specifications. Reference will be sent to Budget & Accounts Division for verification of challan and Board authorized its Chairman for the issuance of registration letter.** | |

Before issuance of registration letter, the firm was asked to provide alternate brand names. In response, the firm has provided alternate names and informed that they initially applied for above mentioned product on Form 5D with prescribed fee of Rs.50,000/-because their product, having same formulation as of Lumigan Eye Drops of M/s Barrett Hodgson (R#033177), however, with a new indication i.e., "to treat hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness." In this regard, the firm has also provided copy of application on Form-5 along with detail of correspondence with Pharmaceutical Evaluation Cell supporting their aforementioned claim.

It is submitted that the instant formulation containing Bimatprost (A prostaglandin analogue) has been approved by USFDA for following indications:

i. **Reduction of elevated intraocular pressure** in patients with open angle glaucoma or ocular hypertension (i.e., USFDA approved Lumigan by Allergan, supplied in sterile opaque white low density polyethylene ophthalmic dispenser bottles and tips with turquoise polystyrene caps in the following sizes:
    - 1mL fill in a 5 mL container
    - 2.5mL fill in a 5 mL container
    - 5mL fill in a 10 mL container
    - 7.5mL fill in a 10 mL container

ii. **Treatment of hypotrichosis** of the eyelashes by increasing their growth including length, thickness and darkness (i.e., USFDA approved Latisse by Allergan), supplied in sterile opaque white low density polyethylene dispenser bottles and tips with turquoise polystyrene caps accompanied by sterile, disposable applicators:
    - 3 mL in a 5 mL bottle with 70 applicators
    - 5 mL in a 5 mL bottle with 140 applicators

**WARNING AND PRECAUTIONS (AS PER USFDA)**

**Effects of Latisse on Intraocular Pressure**

In patients using LUMIGAN or other prostaglandin analogs for the treatment of elevated intraocular pressure, the concomitant use of LATISSE may interfere with the desired reduction in intraocular pressure. Patients using prostaglandin analogs for intraocular pressure reduction should only use LATISSE after consulting with their physician.

In this regard, it is also submitted that M/s Schazoo Pharmaceuticals, Lahore, has already been granted approval for registration of same formulation with above mentioned 2 different indications under different brand names vide 276th meeting of Registration Board.

Furthermore, as per copy of form-5, provided by the firm, they have applied pack size of 3ml in a 5ml Bottle with applicators. However, the firm has now requested to issue registration letter with following pack sizes:

- 3ml with 70 applicators
- 5ml with 140 applicators

**Decision: Registration Board deliberated the case and decided the firm will submit its choice to get the registration with applicator or without applicator. However, in either case, no MRP increase will be granted.**

**Case No.05: Approved Product of M/s GaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi.**

Following product of M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi was approved by the Registration Board in its 243rd meeting, held on 08-09 May, 2014, as per following details:-

| S# | Name & Address of Manufacture/ Applicant | 1. Brand Name<br>2. Dosage Form<br>3. Composition<br>4. Pharmacological Group | 1. Type of form<br>2. Type of application<br>3. Demanded Price/ Pack size<br>4. Initial date, diary<br>5. Date on which fee becomes complete according to type of application/ or Form (Total Fee) | 1. Me-too Status<br>2. GMP status | Decision |
|---|---|---|---|---|---|
| 1 | M/s GaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi | Panadol Joint Tablet<br>Each modified release tablet contains:<br>Paracetamol Ph Eur 665mg modified release<br>(Non narcotic Analgesic)<br>Finished product specifications are Manufacturer | 1. Form 5 A<br>2. 20's Rs. 200/-<br>3. 22-06-12<br>4. 18-04-13<br>Rs.150,000/- | 1. Paracetamol-Osteo 665mg modified release tablets approved by TGA<br>2. New Drug<br>3. Firm was inspected on 20-01-2011 and GMP compliance was good. | Approved with change in brand name. |

The Cost & Pricing Division has now fixed the price of above mentioned formulation. However, while possessing for issuance of registration letter, it was informed by the firm that the above mentioned application was made for bulk import and local repacking. In this regard the firm has now provided revised Form- 5D (for being a new molecule) along with fee of Rs.5000/- as per following details:

| | |
|---|---|
| Name and address of Applicant | M/s GaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi-74000 |
| Name and address of manufacturer | **Manufacturing Site:**<br>M/s GaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia.<br>**Packaging Site:**<br>M/s GaxoSmithKline Pakistan Limited, F-268 S.I.T.E., Karachi (DML 000233) |
| Name of exporting country | Australia |
| Type of Form | Form 5-D |
| Diary No. & Date of R& I | Dy. No.4343 Dated 30/01/2019 |
| Fee including differential fee | Rs. 5,000/- Dated 30/01/2019 |
| Brand Name +Dosage Form + Strength | Panadol Joint Tablet |

| | |
|---|---|
| Composition | Each modified release tablet contains:<br>Paracetamol…….665mg |
| Pharmacological Group | NSAID |
| Proposed Shelf life | 48 months |
| Demanded Pack size & Price | Rs. 200/- per 20's |
| International availability | TGA Approved Panadol Back and Neck Long Lasting Paracetamol 665mg Modified Release film coated Tablets |
| Me-too status | N/A |
| Detail of certificates attached | Notarized copy of CoPP<br>Certificate No. 11/0084<br>The facilities and operations conform to GMP as recommended WHO.<br>Free sale: Confirms the free sale of the product in exporting country.<br>GMP: Notarized copy of GMP Certificate based on inspection conducted on 04-03-2011. |
| GMP Status of Packaging site. | Last GMP Inspection Report dated 11-09-2018.<br>"The firm is found to complying at good level of GMP requirements at the time of inspection" |
| DML of Packaging site. | DML was issued/ renewed dated 10-07-2010. The firm has applied for renewal of DML vide application dated 22-06-2015. |
| **Details of Import, Packing & Batch Release:**<br>M/s GaxoSmithKline Pakistan Limited, F-268 S.I.T.E., Karachi (DML 000233) will be responsible for Complete testing and QC release of the product.<br>The firm has elaborated complete details of import, packing & batch release of finished product **Step # 1**: Bulk labeled tablets of Pandaol Joint will be imported from M/s GaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia. **Step # 2:** Complete testing will be performed as per requirement of tableting mentioned in QC release. **Step # 3:** Bulk tablets will be packed in blisters, unit cartons and finally in master cartons. This packing activity will be performed in GMP compliant facility located at GSK Pakistan Limited F-268 SITE, Karachi. **Step # 4:** QC release & batch release of the final dosage form will be done by the GSK Pakistan limited. | |

The Board was further informed that original dossier of above mentioned case has been traced along with Original & Legalized CoPP (Certificate No. 11/0084). However, requirement of stability data needs deliberation.

**Decision:** **Registration Board deferred the case for submission of stability data and associated documents. The Board further advised that the panel shall be constituted for onsite investigation to confirm genuineness/ authenticity of submitted data/documents without waiting for confirmation/ finalization of minutes of 288th meeting.**

**Case No.06: Request for Change in Registration Status of Products From M/s Cirin Pharmaceuticals, Hattar To M/s. ICI Pakistan Ltd. Karachi.**

M/s. ICI Pakistan Ltd., S-33, Hawkes Bay Road, Karachi has requested for change in registration status of following products from M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase III, Industrial Estate, Hattar to their name. The details are given as under:

| S.No. | Name of Drug(s) | Reg.No. | Date of Registration & Approved Pack/MRP | Remarks |
|---|---|---|---|---|
| I | II | III | IV | V |
| 1 | Misoclear Tablet<br>Each tablet contains:-<br>Misoprostol…….... 200mcg<br>( Int. Ph. Specification) | 084191 | 28-04-2017<br>Rs.100/10's | Dy.1737 (14.01.2019)<br>Rs.20,000/- |

The management of the firm has provided following documents:-

i. Application on Form-5 with Original Fee challan of Rs. 20,000/-.
ii. Copies of initial letter of registration as stated in column IV above.
iii. Panel Inspection Report of M/s ICI Pakistan Ltd., S-33, Hawkes Bay Road, Karachi for renewal of DML as evidence of approved section (Tablet General) dated 02-03-2018.
iv. Copy of last GMP inspection of M/s ICI Pakistan Ltd., S-33, Hawkes Bay Road, Karachi, dated 22-01-2018, indicating "Good" level of GMP compliance.
v. NOC from M/s Cirin Pharmaceuticals, 32/2A, Phase III, Industrial Estate, Hattar dated 11-01-2019.

**Decision: Registration Board decided as follows:**

**i. Cancellation of registration of Misoclear Tablet (R#084191) from the name of M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase III, Industrial Estate, Hattar.**

**ii. Approved registration of Misoclear Tablets in the name of M/s. ICI Pakistan Ltd., S-33, Hawkes Bay Road, Karachi.**

**iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.07: Request of M/s. Delta Pharma Pvt Ltd, Nowshera For Grant of Afresh Registration.**

Registration Board in 276th meeting held on 22nd 25th November, 2017, declared registration of all drugs of M/s. Delta Pharma Pvt Ltd, Nowshera invalid due to non renewal of DML. The firm has now been granted approval of Oral Liquid (general) Section and Dry Suspension (General) Section vide Licensing Division's Letter No. F.3-2/96-Lic pt dated 03-12-2018. Management of the firm has now applied for registration of following products on form-5 with fee of Rs.20,000/- each as per details mentioned below:

| S# | Brand Name, Composition and (Reg.No) | Dy.No./Date & Demanded Pack / Price | Evidence of Availability in RRAs and Me-too Status Provided by Firm | Last Inspection Report & DML | Remarks |
|---|---|---|---|---|---|
| 1. | M.B.Ron Syrup<br>Each 5ml contains:<br>Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron…..50mg<br>(Reg.No.040607) | Dy.No.1174<br>06-12-18<br>20,000/-<br>26-12-2018<br>120ml<br>As per SRO | N/A<br>Ironal Syrup by M/s. Helix Pharma (Pvt) Ltd,. Karachi | Last inspection report 12-10-2018 for grant of additional sections.<br>DML 18-12-2017 | - |
| 2. | Delmol Suspension<br>Each 5ml contains:<br>Paracetamol……120mg<br>(Reg.No.022294) | Dy.No.1173<br>26-12-18<br>20,000/-<br>04-12-18<br>60ml<br>As per SRO | UK MHRA approved.<br>Paracetamol Suspension by M/s. British Pharma, Lahore. | -do- | USP Monograph is available for applied formulation |
| 3. | Delmol Forte Suspension<br>Each 5ml contains:<br>Paracetamol……250mg<br>(Reg.No.022295) | Dy.No.1176<br>26-12-18<br>20,000/-<br>04-12-18<br>60ml<br>As per SRO | UK MHRA approved.<br>Panadol Forte Suspension by M/s. GlaxoSmithKline Pakistan Limited | -do- | USP Monograph is available for applied formulation |
| 4. | Deltafen Suspension<br>Each 5ml contains:<br>Ibuprofen……100mg<br>(Reg.No.020915) | Dy.No.1175<br>26-12-18<br>20,000/-<br>04-12-18<br>90ml<br>As per SRO | UK MHRA approved.<br>Ibudol Suspension by M/s. Mediways International Lahore | -do- | USP Monograph is available for applied formulation. |

**Decision:** **Registration Board approved the grant of registration with "As per Innovator's Specifications" for product at S.No.1 and "USP Specifications" for products at S.No.2-4 of above table.**

**Case No.08: Approved Product of M/s City Pharmaceuticals Laboratories, Karachi**.

Registration Board, in its 237th meeting held on 26th February, 2013, approved the following product of M/s City Pharmaceuticals Laboratories, Karachi as per following details:

| S# | Name of drug(s) & Composition | Proposed Pack size | Demanded Price | Remarks |
|---|---|---|---|---|
| 1 | Vitamin B12 1000 mcg Injection<br>Each ml contains:<br>Vitamin B12 ……....1000 mcg | As per PRC | As per PRC | Deferred for provision of information regarding calibration of machines, validation of processes & appointment of sufficient technical staff |

***Decision of M-237:***

*The request of the firm was acceded by the Board subject to submission of differential fee.*

Pricing Division has fixed the MRP of above mentioned formulation, vide SRO 906 dated 07-9-2017 and the firm has now requested for issuance of registration letter and submitted following documents:

i. Copy of balance fee challan of Rs.12,000/-
ii. Last GMP Inspection Report Dated 26-09-2018(Satisfactory).
iii. Copy of Section Approval (Liquid Injection) dated 11-06-2011.

**Decision:** **Registration Board approved the grant of registration with "As per Innovator's Specifications" for product at S.No.1 of above table. Furthermore, for verification of fee challan, procedure shall be adopted as adopted by the Board in 285th meetings.**

**Case No.9: Request for Change in Registration Status of Products From M/s OBS Pakistan (Pvt.) Ltd, Karachi To M/s. Aspin Pharma, Karachi.**

M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 has requested for change of registration status of following products from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name through contract manufacturing by M/s. OBS Pakistan (Pvt.) Ltd; C-14, S.I.T.E, Karachi. The details are given as under:

| S.#. | Reg.# | Name of Drug(s) | Approved Pack/MRP | Registration History | Dy.No, Date & Fees/Remarks |
|---|---|---|---|---|---|
| I | II | III | IV | V | VI |
| 1 | 093005 | Gabolest Capsule 25mg<br>Each capsule contains:<br>Pregabalin .... 25mg<br>(As per Innovator's Specifications) | Rs.121.00/<br>14's | Initial date of Reg.<br>31-12-2018 | Dy.No.3393<br>08-02-2019<br>Rs.70,000/- |
| 2 | 093006 | Gabolest Capsule 50mg<br>Each capsule contains:<br>Pregabalin ... 50mg<br>(As per Innovator's Specifications) | Rs.202.00/<br>14's | Initial date of Reg.<br>31-12-2018 | Dy.No.3392<br>08-02-2019<br>Rs.70,000/- |
| 3 | 093007 | Gabolest Capsule 100mg<br>Each capsule contains:<br>Pregabalin .... 100mg<br>(As per Innovator's Specifications) | Rs.281.00/<br>14's | Initial date of Reg.<br>31-12-2018 | Dy.No.3390<br>08-02-2019<br>Rs.70,000/- |
| 4 | 093008 | Gabolest Capsule 200mg<br>Each capsule contains:<br>Pregabalin .... 200mg<br>(As per Innovator's Specifications) | Rs.468.00/<br>14's | Initial date of Reg.<br>31-12-2018 | Dy.No.3388<br>08-02-2019<br>Rs.70,000/- |
| 5 | 093009 | Gabolest Capsule 225mg<br>Each capsule contains: | Rs.526.00/<br>14's | Initial date of Reg. | Dy.No.3387<br>08-02-2019 |

| | | | | | |
|---|---|---|---|---|---|
| | | Pregabalin .... 225mg<br>(As per Innovator's Specifications) | | 31-12-2018 | Rs.70,000/- |
| 6 | 076661 | Gabolest Capsule 150mg<br>Each capsule contains:<br>Pregabalin ..... 150mg<br>(As per Innovator's Specifications) | Rs.815.00/<br>14's | Initial date of Reg.<br>23-01-2015 | Dy.No.3389<br>08-02-2019<br>Rs.70,000/- |
| 7 | 076662 | Gabolest Capsule 300mg<br>Each capsule contains:<br>Pregabalin ..... 300mg<br>(As per Innovator's Specifications) | Rs.1358.00/<br>14's | Initial date of Reg.<br>23-01-2015 | Dy.No.3386<br>08-02-2019<br>Rs.70,000/- |
| 8 | 076663 | Gabolest Capsule 75mg<br>Each capsule contains:<br>Pregabalin .... 75mg<br>(As per Innovator's Specifications) | Rs.490.00/<br>14's | Initial date of Reg.<br>23-01-2015 | Dy.No.3391<br>08-02-2019<br>Rs.70,000/- |
| 9 | 089147 | Kapdex 30mg Capsule<br>Each capsule contains:<br>Dexlansoprazole dual delayed release pellets eq. to Dexlansoprazole…30mg<br>(As per Innovator's Specification) | Rs.451.00/<br>30's | Initial date of Reg.<br>31-05-2018 | Dy.No.3383<br>08-02-2019<br>Rs.70,000/-<br>Pellets registered source: M/s Vision Pharmaceuticals, Islamabad |
| 10 | 089148 | Kapdex 60mg Capsule<br>Each capsule contains:<br>Dexlansoprazole dual delayed release pellets eq. to Dexlansoprazole..60mg<br>(As per Innovator's Specification) | Rs.696.00/<br>30's | Initial date of Reg.<br>31-05-2018 | Dy.No.3382<br>08-02-2019<br>Rs.70,000/-<br>Pellets registered source: M/s Vision Pharmaceuticals, Islamabad |
| 11 | 075821 | Virunix-B 1mg Tablet<br>Each film coated tablet contains:<br>Entecavir as monohydrate ...1mg<br>(Manufacturer Specifications ) | Rs. 17000.00/<br>30's | Initial date of Reg.<br>03-04-2013<br>Renewal<br>18-01-2018 | Dy.No.3384<br>08-02-2019<br>Rs.70,000/-<br>USP Monograph is available for applied formulation |
| 12 | 075822 | Virunix-B 0.5mg Tablet<br>Each film coated tablet contains:<br>Entecavir as monohydrate...0.5mg<br>(Manufacturer Specifications ) | Rs. 9000.00/<br>30's | Initial date of Reg.<br>03-04-2013<br>Renewal<br>18-01-2018 | Dy.No.3385<br>08-02-2019<br>Rs.70,000/-<br>USP Monograph is available for applied formulation |

The management of the firm has provided following documents:-

i. Application on Form-5 with original fee challan of Rs. 70,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column V above table.
iii. Tablet (General) Section approval of M/s. OBS Pakistan (Pvt.) Ltd; Karachi verified from Licensing Division's letter for renewal of DML (dated 08th July, 2015) & Capsule (General) vide licensing Division letter no.F-2-1/2000-Lic(Vol-I) dated 13-04-2018.
iv. Copy of last GMP inspection report of M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 06th November, 2018 indicating "Good" level.
v. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 28th January, 2019.
vi. Consent/NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 28th January, 2019 for Contract manufacturing of above mentioned products.
vii. DML of M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 31st March, 2015.
viii. DML of M/s Aspin dated 31st May, 2015
ix. Undertakings in the light of SOPs approved vide M-283.
x. Copy of Contract Agreement of M/s. OBS Pakistan (Pvt.) Ltd; Karachi. and M/s Aspin

The Board was further informed that M/s Aspin Pharma, Karachi has 04 sections, therefore, entitled for contract manufacturing of 20 products as per policy of 5 products per section while the firm has already been granted registration of 04 products.

**Decision: Registration Board decided as follows:**

i. **Cancellation of registration of products at S.No. 1-12 from the name of M/s. OBS Pakistan (Pvt.) Ltd; C-14, S.I.T.E, Karachi.**
ii. **Approved registration of products at S.No. 1-12 in the name of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 through contract manufacturing by M/s. OBS Pakistan (Pvt.) Ltd; C-14, S.I.T.E, Karachi.**
iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.10: Request for Change in Registration Status of Products from M/s OBS Pakistan (Pvt.) Ltd, Karachi to M/s. Aspin Pharma, Karachi.**

M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 has requested for change of registration status of following products from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name through contract manufacturing by M/s. AGP Limited, D-109, S.I.T.E, Karachi (Contract Manufacturer remain the same). The details are given as under:

| S.No. | Reg.No. | Name of Drug(s) | Approved Pack/MRP | Registration History | Remarks |
|---|---|---|---|---|---|
| I | II | III | IV | V | VI |
| 1 | 057942 | M-Span 100mg/5ml Dry Suspension<br>Each 5ml contains:<br>Cefixime as trihydrate...100mg<br>(USP Specifications) | Rs.180.00/ 30ml | Initial date of Reg. 30-07-2009 via contract Manufacturing from M/s Mediate Pharma Ltd<br>Change of Contract Manufacturing to M/s Macter International 07-02-2011<br>Change of Contract Manufacturing to M/s AGP Ltd 14-12-2015<br>Permission is valid up to 30-06-2020 | Dy.No.3414 11-02-2019 Rs.20,000/- |
| 2 | 057943 | M-Span 200mg/5ml Dry Suspension<br>Each 5ml contains:<br>Cefixime as trihydrate...200mg<br>(USP Specifications) | Rs.300.00/ 30ml | | Dy.No.3416 11-02-2019 Rs.20,000/- |
| 3 | 057944 | M-Span 400mg Capsules<br>Each capsule contains:<br>Cefixime as trihydrate...400mg<br>(USP Specifications) | Rs.325.00/ 5's | | Dy.No.3415 11-02-2019 Rs.20,000/- |

The management of the firm has provided following documents:-

i. Application on Form-5 with original fee challan of Rs. 20,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column V above.
iii. Section approval of M/s. AGP Limited, D-109, S.I.T.E, Karachi.
iv. Copy of last GMP inspection report of M/s. AGP Limited, D-109, S.I.T.E, Karachi dated 0$^{9th}$ August, 2018 indicating "Good" level (Sections: Capsule (Ceph), Tablet (Ceph), Dry suspension (Ceph).
v. NOC from M/s. AGP Pakistan (Pvt.) Ltd; Karachi dated 29$^{th}$ January, 2019.
vi. Consent/NOC from M/s. AGP Limited, D-109, S.I.T.E, Karachi dated 29$^{th}$ January, 2019 for Contract manufacturing of above mentioned products.
vii. DML of M/s Aspin dated 31$^{st}$ May, 2015
viii. DML of M/s AGP, Karachi dated 15-07-2014.
ix. Undertakings in the light of SOPs approved vide M-283.
x. Contract Agreement of M/s. AGP Limited, D-109, S.I.T.E, Karachi and M/s Aspin

**Decision: Registration Board deferred the request for submission of requisite fee for grant of contract manufacturing permission.**

**Case No.11: Request for Change in Registration Status of Products From M/s AGP Ltd, Karachi To M/s. Aspin Pharma, Karachi.**

M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 has requested for change of registration status of following products from M/s. AGP Ltd; Karachi to their name through contract manufacturing by M/s. AGP Ltd; B-23, S.I.T.E, Karachi. The details are given as under:

| S.No. | Reg.No. | Name of Drug(s) | Approved Pack/MRP | Registration History | Remarks |
|---|---|---|---|---|---|
| I | II | III | IV | V | VI |
| 1 | 055121 | Xovat 5mg Tablet<br>Each tablet contains:<br>Rosuvastatin as calcium ….5mg<br>(Manufacturer Specifications) | Rs. 120.00/<br>10's | Initial date of Reg.<br>02-03-2009<br>Last Renewal<br>02-03-2014 | Dy.No.3395<br>11-02-2019<br>Rs.70,000/-<br>Standard Formulation approved by RRAs is film coated. |
| 2 | 055122 | Xovat 10mg Tablet<br>Each tablet contains:<br>Rosuvastatin as calcium<br>….10mg<br>(Manufacturer Specifications) | Rs. 200.00/<br>10's | Initial date of Reg.<br>02-03-2009<br>Last Renewal<br>02-03-2014 | Dy.No.3396<br>11-02-2019<br>Rs.70,000/-<br>Standard Formulation approved by RRAs is film coated. |
| 3 | 055123 | Xovat 20mg Tablet<br>Each tablet contains:<br>Rosuvastatin as calcium<br>….20mg<br>(Manufacturer Specifications) | Rs. 400.00/<br>10's | Initial date of Reg.<br>02-03-2009<br>Last Renewal<br>02-03-2014 | Dy.No.3397<br>11-02-2019<br>Rs.70,000/-<br>Standard Formulation approved by RRAs is film coated. |
| 4 | 082244 | Xovat 40mg Tablet<br>Each tablet contains:<br>Rosuvastatin as calcium<br>….20mg<br>(As per Innovators Specifications) | Rs. 800.00/<br>10's | Initial date of Reg.<br>26-09-2017 | Dy.No.3398<br>11-02-2019<br>Rs.70,000/-<br>Standard Formulation approved by RRAs is film coated. |

The management of the firm has provided following documents:-

i. Application on Form-5 with original fee challan of Rs. 70,000/- for each product.
ii. Copies of initial letters of registration as stated in column V above table.
iii. Section (Tablet General) approval of M/s AGP from Licensing Division dated 28-4-2016.
iv. Copy of last GMP inspection of M/s AGP, dated 16-10-2018, indicating "Good" level.
v. NOC from M/s. AGP Ltd; Karachi 29-01-2019.
vi. DML of M/s Aspin dated 31st May, 2015
vii. DML of M/s AGP, Karachi dated 06-02-2015.
viii. Undertakings in the light of SOPs approved vide M-283.
ix. Contract Agreement of M/s. AGP Limited, Karachi and M/s Aspin, Karachi.

**Decision: Registration Board decided as follows:**

**i. Cancellation of registration of products at S.No. 1-4 from the name of M/s. AGP Ltd; B-23, S.I.T.E, Karachi.**

**ii. Approved registration of products at S.No. 1-4 in the name of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 through contract manufacturing by M/s. AGP Ltd; B-23, S.I.T.E, Karachi. Furthermore, formulations shall be standardized in accordance with that approved by Reference Regulatory Authorities.**

**iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.12: Request For Change in Registration Status of Products From M/s OBS Pakistan (Pvt.) Ltd, Karachi To M/s. Aspin Pharma, Karachi.**

M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 has requested for change of registration status of following products from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name through contract manufacturing by M/s. Global Pharmaceuticals Pvt. Ltd; Islamabad (Contract Manufacturer remain the same). The details are given as under:

| S.No. | Reg.No. | Name of Drug(s) | Approved Pack/MRP | Registration History | Remarks |
|---|---|---|---|---|---|
| I | II | III | IV | V | VI |
| 1 | 089308 | Onem IV Injection<br>Each vial contains:<br>Imipenem Monohydrate eq. to Imipenem ….500mg<br>Cilastatin Sodium eq. to Cilastatin …. 500mg<br>(USP Specifications) | Rs.776.55/1's | Date of Reg. in the name of M/s OBS Pakistan (Pvt) Ltd, Karachi via contract Manufacturing from M/s Global Pharmaceuticals Pvt. Ltd: 29-12-2018 | Dy.No.3399<br>11-02-2019<br>Rs.20,000/- |

The management of the firm has provided following documents:-

i. Application on Form-5 with original fee challan of Rs. 20,000/- for each product.
ii. Copies of initial letters of registration as stated in column V above.
iii. Section (Dry Powder Injection Penem) approval verified from panel inspection of M/s Global for renewal of DML dated 26-12-2018.
iv. Copy of last GMP inspection of M/s Global, dated 26-12-2018.
v. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi 29-01-2019.
vi. DML of M/s Aspin dated 31st May, 2015.
vii. DML of M/s Global, Islamabad dated 26-02-2013 and renewal applied on 11-12-2017.
viii. Consent/NOC from M/s. Global for contract manufacturing dated 29-01-2019.
ix. Undertakings in the light of SOPs approved vide M-283.
x. Contract Agreement of M/s. Global, Islamabad and M/s Aspin, Karachi.

**Decision: Registration Board deferred the request for submission of requisite fee for grant of contract manufacturing permission.**

**Case No.13: Request for Change in Registration Status of Products From M/s. Spencer & Company, Karachi to M/s. Zafa Pharmaceutical Laboratories (Private) Ltd., Karachi.**

M/s. Zafa Pharmaceutical Laboratories (Private) Ltd., Karachi (DML# 000516) has requested for change of registration status of following products from M/s. Spencer & Company, D-105, SITE, Karachi to their name through contract manufacturing by M/s Reign Pharmaceuticals TBIC PCSIR (Pvt) Ltd., Karachi. The details are given as under:

| Sr. No. | Reg. No. | Name of Drug(s) | Approved Pack/MRP | Registration History | Remarks |
|---|---|---|---|---|---|
| I | II | III | IV | V | VI |
| 1 | 067695 | Moxilox 400mg Tablet<br>Each tablet contains:<br>Moxifloxacin ….400 mg<br>(BP Specification) | Rs.475/5's | Initial date of Reg.<br>16-04-2011<br>Last Renewal<br>06-04-2016 | Dy.No.3419<br>11-02-2019<br>Rs.50,000/-<br>Standard Formulation approved by RRAs is film coated. |

| | | | | | |
|---|---|---|---|---|---|
| 2 | 053035 | Levos 500mg Tablets<br>Each tablet contains:<br>Levofloxacin (as hemihydrate)…..500mg<br>(USP Specification) | Rs.416.00/<br>10's | Initial date of Reg.<br>29-10-2008<br>Transfer of registration letter dated 08-07-2010 from M/s Spencer Pharma (Pvt) Ltd. Karachi to M/s Spencer & Co. Pakistan Ltd. D-105, SITE, Karachi<br>Last Renewal:<br>29-06-2015 | Dy.No.3420<br>11-02-2019<br>Rs.50,000/-<br>Standard Formulation approved by RRAs is film coated. |
| 3 | 036902 | Levos 250mg Tablets<br>Each tablets contains:<br>Levofloxacin (as Hemihydrate)…..250mg | Rs.250/<br>1x10's | Initial date of Reg.<br>31-01-2005<br>Renewal of registration letter issued on 27-4-2010, stating date of renewal:<br>31-01-2015<br>Last Renewal<br>23-01-2015 | Dy.No.3421<br>11-02-2019<br>Rs.50,000/-<br>Standard Formulation approved by RRAs is film coated. |
| 4 | 014283 | Polygard Tablets<br>Each tablet contains:-<br>Ciprofloxacin HCl Monohydrate 250mg (equivalent to Ciprofloxacin 250mg base) | As per SRO 471(I)/93/<br>10's | Initial date of Reg.<br>05-08-1993<br>Renewal of registration letter issued on 29-08-2008, stating date of renewal:<br>05-08-2008<br>Last Renewal<br>26-07-2013 | Dy.No.05<br>12-02-2019<br>Rs.20,000/-<br>Standard Formulation approved by RRAs is film coated. |
| 5 | 053036 | Polygard 500mg Tablets<br>Each tablet contains:-<br>Ciprofloxacin.....500mg (as Hydrochloride)<br>(USP Specification) | Rs.260/<br>10's | Initial date of Reg.<br>29-10-2008<br>Transfer of registration letter dated 08-07-2010 from M/s Spencer Pharma (pvt) Ltd. Karachi to M/s Spencer & Co. Pakistan Ltd.D-105, site, Karachi<br>Last Renewal<br>07-07-2015 | Dy.No.04<br>12-02-2019<br>Rs.20,000/-<br>Standard Formulation approved by RRAs is film coated. |

The management of the firm has provided following documents:-

i. Application on Form-5 with original fee challan of Rs.50,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column V above.
iii. Section approval (Tablet) of M/s. Reign, Pharmaceuticals TBIC PCSIR (Pvt) Ltd., Karachi verified from panel inspection report dated 28-11-2013.
iv. Copy of last GMP inspection report of M/s. Reign, Karachi dated 08th November, 2017 indicating "Good" level.
v. NOC from M/s. Spencer & company (Pvt) Ltd, Karachi dated 04h February, 2019.
vi. Consent/NOC from M/s Reign, Karachi for contract manufacturing.
vii. Copy of Contract Agreement between M/s. Zafa, Karachi & M/s Reign, Karachi.
viii. DML of M/s. Reign, Karachi dated 28th November, 2012 with renewal applied on 26-09-2017.
ix. Licensing Division's Letter F.No.2-3/88-Lic (Vol-III) as evidence for validity of DML of M/s Spencer & Company till 18-07-2015 with renewal applied on 22-07-2015.
x. DML of M/s. Zafa, Pharmaceutical Laboratories (Private) Ltd., Karachi (DML# 000516).
xi. Undertakings in the light of SOPs approved vide M-283.

**Decision: Registration Board decided as follows:**

i. **Cancellation of registration of products at S.No. 1-5 from the name of M/s. Spencer & Company, D-105, SITE, Karachi.**

ii. **Approved registration of products at S.No. 1-5 in the name of M/s. Zafa Pharmaceutical Laboratories (Private) Ltd., Plot No. A-79, S.I.T.E, Superhighway, Karachi (DML# 000516) through contract manufacturing by M/s Reign Pharmaceuticals TBIC PCSIR (Pvt) Ltd., Karachi. Furthermore, formulations shall be standardized in accordance with that approved by Reference Regulatory Authorities.**

iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.14: Request for Change in Registration Status of Products From M/s. Spencer & Company, Karachi to M/s Reign Pharmaceuticals (Pvt) Ltd., Karachi.**

M/s Reign Pharmaceuticals (Pvt) Ltd., Karachi (DML# 000757) has requested for change of registration status of following products from M/s. Spencer & Company, D-105, SITE, Karachi (DML # 000272) to their name. The details are given as under:

| S.No. | Reg.No. | Name of Drug(s) | Approved Pack/MRP | Registration History | Remarks |
|---|---|---|---|---|---|
| I | II | III | IV | V | VI |
| 1 | 032559 | Avofen Tablets<br>Each tablet contains:-<br>Ketotifen (as Hydrogen fumarate)……..1mg | Rs.70.00/<br>3x10's | Initial date of Reg.<br>17-04-2004<br>Renewal of registration letter issued on 25-05-2009, stating renewal valid upto: 17-04-2014<br>Last Renewal<br>14-04-2014 | Dy.No.3413<br>11-02-2019<br>Rs.20,000/-<br><br>UK MHRA approved. |
| 2 | 032560 | Avofen Syrup<br>Each 5ml contains:-<br>Ketotifen (as Hydrogen fumarate)……..1mg | Rs.45.00/<br>60ml | Initial date of Reg.<br>17-04-2004<br>Renewal of registration letter issued on 25-05-2009, stating renewal valid upto: 17-04-2014<br>Last Renewal<br>14-04-2014 | Dy.No.3412<br>11-02-2019<br>Rs.20,000/-<br><br>ANSM approved. |
| 3 | 039382 | Eron Plus Drops<br>Each ml contains:-<br>Iron Polymaltose Complex .50mg | Rs.65.00/<br>15ml | Initial date of Reg.<br>12-07-2005<br>Transfer of registration letter dated 08-07-2010 from M/s Spencer Pharma (pvt) Ltd. Karachi to M/s Spencer & Co. Pakistan Ltd.D-105, site, Karachi<br>Last Renewal<br>29-06-2015 | Dy.No.3407<br>11-02-2019<br>Rs.20,000/-<br>Standard Formulation contains" Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron…50mg/ml" |
| 4 | 039383 | Eron Plus Syrup<br>Each 5ml contains:-<br>Iron Polymaltose Complex 50mg | Rs.70.00/<br>60ml | Initial date of Reg.<br>12-07-2005<br>Transfer of registration letter dated 08-07-2010 from M/s Spencer Pharma (pvt) Ltd. Karachi to M/s Spencer & Co. Pakistan Ltd.D-105, site, Karachi | Dy.No.3408<br>11-02-2019<br>Rs.20,000/-<br><br>Standard Formulation contains" Iron (III) Hydroxide Polymaltose Complex eq. to |

| | | | | | |
|---|---|---|---|---|---|
| | | | | Last Renewal 29-06-2015 | Elemental Iron…50mg/5ml" and the firm has applied the same. |
| 5 | 039384 | Eron Plus Tablets<br>Each tablet contains:-<br>Iron Polymaltose Complex 100mg<br>Folic Acid ……0.35mg | Rs.70.00/ 10's | Initial date of Reg. 29-10-2005<br>Last Renewal 29-06-2015 | Dy.No.3409 11-02-2019 Rs.20,000/- Standard Formulation contains" Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron…100mg" and the firm has applied the same. |
| 6 | 053030 | IRI Syrup<br>Each 5ml contains:-<br>Lactulose ……...3.35gm<br>(USP Specification) | Rs.109.00/ 120ml | Initial date of Reg. 29-10-2008<br>Last Renewal 16-10-2018<br>With fee of **Rs 10,000/-** | Dy.No.3400 11-02-2019 Rs.20,000/- **Registered Source:** Import in bulk from M/s. Inalco S.P.A VIA Calabiana, Milano, Italy and local repacking at M/s. Spencer Pharmaceuticals, Karachi. Documents related to source have not been provided for instant application. |
| 7 | 053031 | Nalcam 7.5mg tablets<br>Each tablet contains:-<br>Meloxicam ……7.5mg<br>(USP Specifications) | Rs.55.00/ 10's | Initial date of Reg. 29-10-2008<br>Last Renewal 16-10-2018 | Dy.No.3410 11-02-2019 Rs.20,000/- |
| 8 | 053032 | Nalcam 15 mg tablets<br>Each tablet contains:-<br>Meloxicam ……15mg<br>(USP Specifications) | Rs.96.00/ 10's | Initial date of Reg. 29-10-2008<br>Last Renewal 16-10-2018 | Dy.No.3411 11-02-2019 Rs.20,000/- |
| 9 | 053034 | Nortic Tablets<br>Each tablet contains:-<br>Norfloxacin……400mg<br>(USP – Specification) | Rs.90.00/ 10's | Initial date of Reg. 29-10-2008<br>Last Renewal 16-10-2018 | Dy.No.3401 11-02-2019 Rs.20,000/- Standard formulation approved by RRAs is "film coated" |
| 10 | 053037 | Andin Tablets<br>Each tablet contains:-<br>Loratadine…….10mg<br>(USP Specification) | Rs.45.00/ 10's | Initial date of Reg. 29-10-2008<br>Last Renewal 16-10-2018 | Dy.No.3403 11-02-2019 Rs.20,000/- Standard formulation approved by RRAs is "film coated" |
| 11 | 053038 | Andin Syrup<br>Each 5ml contains:-<br>Loratadine…….5mg<br>(USP Specification) | Rs.48.00/ 60ml | Initial date of Reg. 29-10-2008<br>Last Renewal 16-10-2018 | Dy.No.3402 11-02-2019 Rs.20,000/- |
| 12 | 067696 | Peficin 400mg Tablet<br>Each tablet contains:<br>Pefloxacin ……400 mg | Rs.222/ 10's | Initial date of Reg. 16-04-2011<br>Last Renewal | Dy.No.3404 11-02-2019 Rs.20,000/- |

| | | | | | |
|---|---|---|---|---|---|
| | | (Manufacturer's Specification) | | 06-04-2016 | |
| 13 | 067697 | Nimovas 30mg Tablet<br>Each tablet contains:<br>Nimodipine …….30 mg<br>(Manufacturer's Specification) | Rs.150/ 10's<br>Rs.300/ 20's<br>Rs.450/ 30's | Initial date of Reg.<br>16-04-2011<br>Last Renewal<br>07-04-2016 | Dy.No.3405<br>11-02-2019<br>Rs.20,000/- |
| 14 | 061991 | Speny Syrup<br>Each 15ml contains:-<br>Iron Protein succinylate 800mg eq. to elemental Iron……..40 mg<br>(Manufacturer's Specification) | Rs.95/60ml | Initial date of Reg.<br>17-09-2010<br>Last Renewal<br>11-09-2015 | Dy.No.3406<br>11-02-2019<br>Rs.20,000/- |
| 15 | 013791 | Glamet Tablet 150mg<br>Each film coated tablet contains:<br>Ranitidine (as Hydrochloride)…150mg | Rs.49.25/ 10's | Initial date of Reg.<br>17-11-1992<br>Renewal of registration letter issued on 22-12-2008, stating date of renewal: 17-11-2007<br>Last Renewal<br>25-10-2017 | Dy.No.06<br>12-02-2019<br>Rs.20,000/- |

The management of the firm has provided following documents:-

i. Application on Form-5 with original fee challan of Rs. 20,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column V above.
iii. Section approval (Tablet & Liquid Syrup) of M/s. Reign, Pharmaceuticals TBIC PCSIR (Pvt) Ltd., Karachi verified from panel inspection report dated 28-11-2013.
iv. Copy of last GMP inspection report of M/s. Reign, Karachi dated 08th November, 2017 indicating "Good" level.
v. NOC from M/s. Spencer & company (Pvt) Ltd, Karachi dated 04h February, 2019.
vi. DML of M/s. Reign, Karachi dated 28th November, 2012 with renewal applied on 26-09-2017.
vii. Licensing Division's Letter F.No.2-3/88-Lic (Vol-III) as evidence for validity of DML of M/s Spencer & Company till 18-07-2015 with renewal applied on 22-07-2015.
viii. Undertakings in the light of SOPs approved vide M-283.

**Decision: Registration Board decided as follows:**

**i. Cancellation of registration of products at S.No. 1-5 & 7-15 from the name of M/s. Spencer & Company, D-105, SITE, Karachi.**

**ii. Approved registration of products at S.No. 1-5 & 7-15 in the name of M/s Reign Pharmaceuticals TBIC PCSIR (Pvt) Ltd., Karachi. Furthermore, formulations shall be standardized in accordance with that approved by Reference Regulatory Authorities.**

**iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**iv. Deferred the product at S.No.6 for submission of information/documents regarding source of Lactulose along with requisite fee and confirmation of renewal status from RRR section.**

**Case No.15: Request for Change in Registration Status of Products From M/s. Spencer & Company, Karachi to M/s. Zafa Pharmaceutical Laboratories (Private) Ltd., Karachi.**

M/s. Zafa Pharmaceutical Laboratories (Private) Ltd., L-1/B Block 22 Federal B Industrial Area Karachi (DML# 000513) has requested for change of registration status of following products from M/s. Spencer & Company, D-105, SITE, Karachi to their name. The details are given as under:

| S.No. | Reg.No. | Name of Drug(s) | Approved Pack/MRP | Registration History | Remarks |
|---|---|---|---|---|---|
| I | II | III | IV | V | VI |
| 1 | 035455 | Ficobal Injection<br>Each 1ml ampoule contains:<br>Mecobalamine….500ug | Rs.460.00/<br>10x1ml | Initial date of Reg.<br>23-12-2004<br>Renewal of registration letter issued on 27-04-2010, stating renewal valid upto:<br>23-12-2014<br>Last Renewal<br>18-12-2014 | Dy.No.3417<br>11-02-2019<br>Rs.20,000/- |
| 2 | 035456 | Ficobal 500mcg Tablets<br>Each tablets contains:<br>Mecobalamine...500mcg | Rs.573.00/<br>10x10's | Initial date of Reg.<br>23-12-2004<br>Renewal of registration letter issued on 27-04-2010, stating renewal valid upto:<br>23-12-2014<br>Last Renewal<br>18-12-2014 | Dy.No.3418<br>11-02-2019<br>Rs.20,000/-<br>Standard Formulation approved by RRAs is sugar coated, however the firm has applied for "film coated tablet". JP monograph is available for Mecobalamin Tablet. |

The management of the firm has provided following documents:-

i. Original challan Fee of Rs. 20,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column V above.
iii. Section (Tablet & Liquid Injectable) approval of M/s. Zafa Pharmaceutical Laboratories (Private) Ltd., L-1/B Block 22 Federal B Industrial Area Karachi (DML# 000513), verified from Panel Inspection Report for renewal of DML dated 17-12-2013.
iv. Copy of last GMP inspection report of M/s. Zafa, Karachi dated 03-01-2018 indicating "Good" level.
v. NOC from M/s. Spencer & company (Pvt) Ltd, Karachi dated 04h February, 2019.
vi. DML of M/s. Zafa, Karachi dated 26-06-2013 with renewal applied on 26-09-2017.
vii. Licensing Division's Letter F.No.2-3/88-Lic (Vol-III) as evidence for validity of DML of M/s Spencer & Company till 18-07-2015 with renewal applied on 22-07-2015.
viii. Undertakings in the light of SOPs approved vide M-283.

**Decision: Registration Board decided as follows:**

**i. Cancellation of registration of products at S.No. 1-2 from the name of M/s. Spencer & Company, D-105, SITE, Karachi.**

**ii. Approved registration of products at S.No. 1-2 in the name of M/s. Zafa Pharmaceutical Laboratories (Private) Ltd., L-1/B Block 22 Federal B Industrial Area Karachi (DML# 000513). Furthermore, formulations shall be standardized in accordance with that approved by Reference Regulatory Authorities.**

**iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.16: Request for Change in Registration Status of Products from M/s Novartis Pharma (Pakistan) Ltd., Karachi to M/s GlaxoSmithKline OTC (Pvt) Ltd., Karachi.**

Registration Board, in its 269th meeting held on 27-28th April, 2017, deferred the request of M/s GlaxoSmithKline OTC (Pvt) Ltd., 35 Dockyard Road, West Wharf, Karachi 74000 for change in registration status of a number of products from M/s Novartis Pharma (Pakistan) Ltd., 15-West Wharf, P.O Box 100 & 7247, Karachi-74000, (which the firm was manufacturing at Jamshoro Plant) as per following details:

*Products neither approved in Reference Regulatory Authorities/Agencies nor available in monograph of any Pharmacopoeia of Reference Regulatory Authorities/Agencies.*

| S. No | Reg. No. | Name of drug(s) & Composition | Initial Registration Letter Date | Deferred for | Current Renewal Status/ International Availability (as presented in M-269) |
|---|---|---|---|---|---|
| 1. | 024662 | Triaminic-Chest Congestion Cough Syrup<br>Each 5ml contains:<br>Pseudoephedrine HCl …..15mg<br>Guaifenesin……..50mg | 26.07.2002 | Deferred for approval status in reference regulatory authorities /agencies. | Double Strength Available in MHRA UK<br><br>Exact reference not available |
| 2. | 024663 | Triaminic-Cold and Allergy Syrup<br>Each 5ml contains:<br>Pseudoephedrine HCl…..15mg<br>Chlorpheniramine Maleate……1mg | 26.07.2002 | Deferred for approval status in reference regulatory authorities /agencies. | Double Strength Available in MHRA UK<br><br>Exact reference not available |
| 3. | 024661 | Triaminic-Cough Syrup<br>Each 5ml contains:<br>Pseudoephedrine HCl …..15mg<br>Dextromethorphan HB r…..5mg | 26.07.2002 | Deferred for approval status in reference regulatory authorities/agencies. | Double Strength Available in MHRA UK<br><br>Exact reference not available |
| 4. | 000510 | Tandegyl Syrup<br>Each 5ml contains:-<br>Clemastine … 0.25mg<br>(as Hydrogen Fumarate) | 17.04.1976 | Deferred for approval status in reference regulatory authorities/agencies. | Double Strength Available in MHRA UK<br>Exact reference not available |
| 5. | 006432 | Triaminic-Syrup<br>Each 5ml contains:<br>Pseudoephedrine HC1..30mg<br>Pheniramine Maleate …12.5mg | 11.07.1982 | Deferred for approval status in reference regulatory authorities/agencies. | Different Combinations available in TGA Australia |
| 6. | 035413 | Triaminic Flu, Cough and Fever Syrup<br>Each 5ml contains:<br>Paracetamol……160mg<br>Pseudoephedrine HCl ……15mg<br>Dextromethorphan HBr …….7.5mg | 15.01.2005 | Deferred for approval status in reference regulatory authorities/agencies. | Different Combinations available in TGA Australia |
| 7. | 014317 | Triaminic Tablet (Triaminic Sandoz Tablets) name change dated 03.05.2008<br>Each tablet contains:<br>Pheniramine Maleate……..25mg<br>Pseudoephedrine HCl ……7.5mg | 17.10.1993 | Verification of fee challans and approval status of Reference Regulatory Authorities | Renewal status OK in light of Registration Board's Decision taken in 264th meeting<br><br>Different combinations available in TGA Australia |

| | | | | | |
|---|---|---|---|---|---|
| 8. | 000172 | Neo-Intestopan Syrup<br>Each 10 ml contains:<br>Attapulgite…1 gm | 20-05-2016 | Deferred for approval status in reference regulatory authorities/agencies. | Molecule in Health Canada as submitted by firm |
| 9. | 002406 | Optalidon Tablet<br>Each tablet contains:<br>Propyphenazone..175mg<br>Caffeine Anhydrous…25mg | 17.04.1989 | Deferred for approval status in reference regulatory authorities/agencies. | Reference not available |
| 10. | 000937 | Spasmo Cabalgin tablets<br>Each tablet contains:-<br>Propyphenazone … 220mg<br>Hexahydroediphenine HCl … 20mg | 18.03.1980 | Deferred for approval status in reference regulatory authorities/agencies. | Reference not available |
| 11. | 007719 | Tandegyl-D tablet<br>Each tablet contains:<br>Clemastine (as Hydrogen Fumarate)…..1mg<br>Pseudoephedrine HCl….90mg | 12.11.1984 | Deferred for approval status in reference regulatory authorities/agencies. | Reference not available |
| 12. | 008949 | Neo Intestopan Tablets<br>Each tablet contains:-<br>Activated Attapulgite……..0.630gm | 25.11.1986 | Renewal application received within stipulated time accompanied with prescribed fee. | Molecule in Health Canada as submitted by firm |

***Decision of M-269:*** *Mr. Mazhar Shams, Regulatory Manager, GlaxoSmithKline OTC (Pvt) Ltd., Jamshoro appeared before the Board and shared the approval status of their above mentioned applied products in Reference Regulatory authorities/agencies as mentioned in the last column of the above table. He also mentioned that although certain cough syrups are approved in reference regulatory authorities but in double strengths to their applied products in Pakistan. Registration Board asked the representative of the firm to submit safety and efficacy justification of half dose of certain APIs in the formulation which they applied for registration. In response to which, Mr. Mazhar Shams sought time of 20 days from Registration Board to submit safety and efficacy data of the product mentioned in the above table.*

*Keeping in view the availability of medicine, Registration Board acceded to this request of firm's representative and directed him to submit the requisite data within 20 days for aforementioned products for further consideration of the Registration Board.*

Formulation at S.No.12 i.e., of Neo Intestopan Tablets (R#008949) is licensed as a natural health product in Canada while for product at S.No.09 i.e., Optalidon Tablet (R#002406), approval status of formulation has been confirmed in Spanish Medicine Agency "As Dragees".

**Decision: Registration Board decided as follows:**

i. **Cancellation of registration of products at S.No.09 &12 from the name of M/s Novartis Pharma (Pakistan) Ltd., 15-West Wharf, P.O Box 100 & 7247, Karachi-74000.**
ii. **Approved registration of products at S.No.09 &12 in the name of M/s GlaxoSmithKline OTC (Pvt) Ltd., 35 Dockyard Road, West Wharf, Karachi 74000. Furthermore, formulations shall be standardized in accordance with that approved by Reference Regulatory Authorities.**
iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**
iv. **Deferred the products at S.No.1-8 & 10-11 for confirmation of availability/approval status in Reference Regulatory Authorities.**

**Case No.17: Registration of Products of M/s Tagma Pharma (Pvt) Ltd, Lahore.**

Registration Board in its 283rdmeeting held on 27th -29th June, 2018 considered the following product of M/s Tagma Pharma Lahore for registration and decided as per detailed below:-

| Sr. No. | Name of Product & Composition | Demanded Pack size | Demanded MRP | Decision |
|---|---|---|---|---|
| 1 | Butag Tablets<br>Each tablet contains:-<br>Buprenorphine as HCl…….0.2mg | 5×10's | As Per SRO | Approval status in reference countries not confirmed<br>Decision (M-226)<br>Approved subject to fulfillment of policy |

Now the Firm has submitted documented evidence that Buprenorphine HCl 200 microgram is approved as uncoated tablet (Route of Administration: sublingual) by Therapeutic Good Administration, Australia. Firm has requested for issuance of registration letter.

**Decision: Registration Board approved above product as per following composition;**
**''Butag Tablets**
**Each sublingual tablet contains:-**
**Buprenorphine as HCl ……0.2mg''**

**Case No.18: Registration of Products of M/s Mediceena Pharmaceuticals Pvt Ltd. Lahore.**

Registration Board in its 234th meeting held on 16-07-2012 approved the following Products of M/s. Mediceena Pharma, Lahore and decided as under:-

| S. No. | Name of Drugs & Composition | Demanded MRP & Pack Size | Decision |
|---|---|---|---|
| 1. | Klaridox Injection<br>Each vial contains:-<br>Clarithromycin Lactobionate eq.to Clarithromycin.....500mg (antibiotics) | 1's<br>As per SRO | Approved subject to verification of dry powder injection General from Licensing Section. |
| 2. | Lyphocin Infusion<br>Each vial contains:-<br>Vancomycin hydrochloride eq. to vancomycin….1gm (antibiotics) | 1's<br>As per SRO | Approved subject to verification of dry powder injection General from Licensing Section. |
| 3. | Rabizol Injection<br>Each vial contains:-<br>Rabeprazole.....20mg | 1's<br>As per SRO | Approved subject to verification of dry powder injection General from Licensing Section. |
| 4. | Fosfomin Injection<br>Each vial contains:-<br>Fosfomycin Sodium eq.to fosfomycin….....1gm | 1's<br>As per SRO | Approved subject to verification of dry powder injection General from Licensing Section. |

| | | | |
|---|---|---|---|
| 5. | Azimycin Injection<br>Each vial contains:-<br>Azithromycin dehydrate eq. to Azithromycin…....250mg<br>(Macrolides (Antibiotics) | 10ml<br>As per SRO | Approved subject to verification of dry powder injection General from Licensing Section. |

Firm has submitted following documents and requested for issuance of registration letters for above mentioned.

i. Differential fee of Rs. 12000/- for each product deposited (Yellow copies)

ii. GMP inspection reports conducted on dated 28-05-2013 and 14-07-2014 which are reflecting that firm has Dry Powder Injection (General) as dedicated area for manufacturing of dry powder injections.

**Decision: Registration Board referred to QA&LT Division for updated GMP status of the firm.**

## Human Cases

**Case No. 19: Registration of Clozaril Tablet 25mg & 100mg by M/s. AGP Ltd, Karachi.**

M/s. AGP Limited, B-23-C, SITE, Karachi has submitted application for registration of Clozaril 25mg & 100mg Tablet from the name of M/s.Novartis Pharma (Pakistan) Limited, Karachi to their own name. Detail of each product is as under: -

| **Product-1:** Clozaril 25mg Tablet (Reg.No. 016329) | | |
|---|---|---|
| **S. No.** | **Name / Detail of Documents** | **Documents / Information Provided by Firm** |
| 1. | Product Name / Composition | Clozaril 25mg Tablet<br>Each tablet contains:<br>Clozapine…….25mg |
| 2. | Name and address of Applicant (transferee) | M/s AGP Limited B-23-C, SITE, Karachi. |
| 3. | Name of Transferor | M/s Novartis Pharma (Pakistan) Limited, 15-West Wharf Road, Karachi. |
| 4. | Detail of Drug Sale License | M/s AGP Limited B-23-C, SITE, Karachi |
| 5. | Name and address of manufacturer. | M/s Novartis Saglik, Gida Ve Tarim Urunleri Sanayi ve Ticaret A.S. (Novartis Urunleri) Yenisehir Mahallesi Dedepasa Cadessi N 17 34912 Kurtkoy, Istanbul, Turkey (Pg-91/Corr). |
| 6. | Name and address of marketing authorization holder | M/s BGP Products Gmbh Neuhofstrasse 23 6341 Baar Switzerland. |
| 7. | Name of exporting country | Turkey |
| 8. | Diary No. & Date of R&I | Dy. No. 43856 Dated 26-12-2018 |
| 9. | Finished Product Specification | Manufacturer specifications |
| 10. | Shelf life | 36 months |
| 11. | Pack Size | 50’s Tablet |
| 12. | **Remarks:**<br>• Firm has requested manufacturer specifications however, the said formulation is included in USP. | |

| **Product-2:** Clozaril 100mg Tablet (Reg.No. 016330) | | |
|---|---|---|
| **S. No.** | **Name / Detail of Documents** | **Documents / Information Provided by Firm** |
| 1. | Product Name / Composition | Clozaril 100mg Tablet<br>Each tablet contains:<br>Clozapine…….100mg |
| 2. | Name and address of Applicant (transferee) | M/s AGP Limited B-23-C, SITE, Karachi. |
| 3. | Name of Transferor | M/s Novartis Pharma (Pakistan) Limited, 15-West Wharf Road, Karachi. |
| 4. | Detail of Drug Sale License | M/s AGP Limited B-23-C, SITE, Karachi |
| 5. | Name and address of manufacturer. | M/s Novartis Saglik, Gida Ve Tarim Urunleri Sanayi ve Ticaret A.S. (Novartis Urunleri) Yenisehir Mahallesi Dedepasa Cadessi N 17 34912 Kurtkoy, Istanbul, Turkey (Pg-91/Corr). |
| 6. | Name and address of marketing authorization holder | M/s BGP Products Gmbh Neuhofstrasse 23 6341 Baar Switzerland. |
| 7. | Name of exporting country | Turkey |
| 8. | Diary No. & Date of R&I | Dy. No. 43857 Dated 26-12-2018 |
| 9. | Finished Product Specification | Manufacturer specification |
| 10. | Shelf life | 36 months |
| 11. | Pack Size | 50’s Tablet |
| 12. | **Remarks:**<br>• Firm has requested manufacturer specifications however, the said formulation is included in USP. | |

The firm has submitted the following supporting documents / information for approval of registrations of above mentioned products: -

a) Fee of Rs. 100,000/- (for each product)
b) Applications on Form-5A.
c) Copy of initial registration letters with complete post registration variation and renewal status.
d) Authority letter (original & notarized) issued by Product License Holder (M/s. BGP Products GmbH) for new proposed sole agent (M/s AGP Ltd, Karachi)
e) Original & legalized CoPPs for above products issued by Swissmedic.
f) Copy of GMP certificate of M/s Novartis Saglik, Gida Ve Tarim Urunleri Sanayi ve Ticaret A.S. (Novartis Urunleri) Yenisehir Mahallesi Dedepasa Cadessi N 17 34912 Kurtkoy, Istanbul, Turkey issued by Turkish Ministry of Health.
g) Copy of valid DSL.
h) NOC (original) from M/s Novartis Pharma (Pakistan) Limited, 15-West Wharf Road, Karachi in favor of M/s AGP Ltd, Karachi (dated 25th October, 2018)

It is pertinent to inform that the firm has not provided termination letter from the manufacturer/product license holder in favor of current importer i.e M/s. Novartis Pharma (Pakistan) Ltd, Karachi.

Registration Board deliberated the matter in detail regarding the provision of termination letter by manufacturer/product license holder in favor of M/s. Novartis Pharma (Pakistan) Ltd, Karachi. Since the product license holder remains the same and authority letter (to M/s. AGP Ltd, Karachi) is also provided by the product license holder, therefore, Board decided to consider the firm's request.

**Decision:- Keeping in view the above stated position, Registration Board decided as follow;**

**i. Approved the cancellation of registration of Clozaril 25mg and 100mg Tablets (Reg.No. 016329 and 016330 respectively) from the name of M/s. Novartis Pharma (Pakistan) Ltd, Karachi.**

**ii. Approved the registration of Clozaril 25mg and 100mg Tablets in the name of M/s AGP Limited B-23-C, SITE, Karachi.**

**iii. A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of above mentioned products.**

**Case No.20: Request of M/s. Novartis Pharma (Pak) Ltd, Karachi for Correction of manufacturing site for their registered product Tobradex (Ophthalmic) ointment (Reg.No. 094745).**

M/s. Novartis Pharma (Pakistan) Ltd, Karachi has informed that the name of manufacturing site granted to them vide letter No.F.3-2/2018-Reg-I (M-279)/Human Import dated 11-01-2019 for product Tobradex (Ophthalmic) ointment is mentioned incorrectly as *"M/s. Alcon Cusi, S.A. Camil Fabra 58 08320 EI Masnou - Barcelona Spain***"** in registration letter instead of *"M/s SA Alcon-Courveur NV, Rijksweg 14, B-2870 Puurs, Belgium***".**

The manufacturer *"M/s. Alcon Cusi, S.A. Camil Fabra 58 08320 EI Masnou - Barcelona Spain*" was inadvertently incorporated agenda &minutes of the meeting (M-279) for product Tobradex (Ophthalmic) Ointment.

Accordingly, the correct/demanded manufacturer i.e "*M/s SA Alcon-Courveur NV, Rijksweg 14, B-2870 Puurs, Belgium*" for product Tobradex (Ophthalmic) Ointment has been granted to the firm via corrigendum.

**Decision:- Registration Board noted and endorsed the action taken.**

**Case No.21: Request of M/s. Apex Pharmaceutical (Pvt) Ltd, Karachi for registration of products in their name.**

The case of M/s. Apex Pharmaceuticals (Pvt) Ltd, Karachi was presented in 286th meeting of Registration Board for registration of Azastrole 1mg Tablet, Bicalox 50mg Tablet & Gynotril 2.5mg Tablet from the name of M/s Merixil Pharma to their own name as under: -

| **Product-1: Azastrole 1mg Tablet (Reg.No. 081807)** | | |
|---|---|---|
| **S#** | **Name / detail of documents** | **Documents / information provided by firm** |
| 1. | Product Name / Composition | Azastrole 1mg Tablet<br>Each film coated tablet contains:<br>Anastrozole…..1mg |
| 2. | Name and address of Applicant (transferee) | M/s. Apex Pharmaceuticals (Pvt) Ltd, D-21-A/1, SITE, super Highway, Karachi. |
| 3. | Name of Transferor | M/s. Merixil Pharma, Office No. 28, 2nd Floor, Rose Plaza I-8 Markaz, Islamabad. |
| 4. | Detail of Drug Sale License | M/s. Apex Pharmaceuticals (Pvt) Ltd, D-21, A/1, SITE, Super Highway, Karachi. |
| 5. | Name and address of manufacturer. | As per initial registration letter:-<br>M/s. Eris Pharmaceutical (Australia) Pty Ltd, 6 Eastern South Melbourne VIC 3205, Australia.<br>As per Form-5A &CoPP<br>Manufacturing Site<br>M/s. Douglas Manufacturing Ltd, Central Park Drive Lincoln Auckland, New Zealand.<br>Marketing authorization holder & release for supply:-<br>M/s. Eris Pharmaceutical (Australia) Pty Ltd, 6 Eastern South Melbourne VIC 3205, Australia. |
| 6. | Name and address of marketing authorization holder (as per Form-5A) | M/s. Eris Pharmaceutical (Australia) Pty Ltd, 6 Eastern South Melbourne VIC 3205, Australia. |
| 7. | Name of exporting country | Australia |
| 8. | Diary No. & Date of R& I | Dy. No. 20662 Dated 08-06-2018 |
| 9. | Finished Product Specification | (Manufacturer spec) |
| 10. | Shelf life | 36 months (as per approval & Form-5A) |
| 11. | Pack Size | Blister of 30's Tablets, (as per approval) |
| 12. | Remarks:<br>• The name of manufacturer (as per COPP & Form-5A) differ from the one mentioned in initial registration letter. However, the firm has informed that now manufacturing will be performed by *M/s. Douglas Manufacturing Ltd, Central Park Drive Lincoln Auckland New Zealand* while *M/s Eris Pharmaceutical (Australia) Pty Ltd, 6 Eastern South Melbourne VIC 3205, Australia* is the legal license holder of the product. | |

| **Product-2: Bicalox 50mg Tablet (Reg.No. 081809)** | | |
|---|---|---|
| **S#** | **Name / detail of documents** | **Documents / information provided by firm** |
| 1. | Product Name / Composition | Bicalox 50mg Tablet<br>Each film coated tablet contains:<br>Bicalutamide…..50mg |
| 2. | Name and address of Applicant (transferee) | M/s. Apex Pharmaceuticals (Pvt) Ltd, D-21-A/1, SITE, super Highway, Karachi. |
| 3. | Name of Transferor | M/s. Merixil Pharma, Office No. 28, 2nd Floor, Rose Plaza I-8 Markaz, Islamabad. |
| 4. | Detail of Drug Sale License | M/s. Apex Pharmaceuticals (Pvt) Ltd, D-21, A/1, SITE, Super Highway, Karachi |
| 5. | Name and address of manufacturer | *Same as in product 1* |
| 6. | Name and address of marketing authorization holder | M/s. Eris Pharmaceutical (Australia) Pty Ltd, 6 Eastern South Melbourne VIC 3205, Australia. |
| 7. | Name of exporting country | Australia |
| 8. | Diary No. & Date of R& I | Dy. No. 20662 Dated 08-06-2018 |
| 9. | Finished Product Specification | USP Specifications |

| | | |
|---|---|---|
| 10. | Shelf life | 36 months (as per approval & Form-5A) |
| 11. | Pack Size | 28's & 10's |
| 12. | Remarks:<br>• Same as for product 1 | |

| **Product-3: Gynotril 2.5mg Tablet (Reg.No.081808)** | | |
|---|---|---|
| **S#** | **Name / detail of documents** | **Documents / information provided by firm** |
| 1. | Product Name / Composition | Gynotril 2.5mg Tablet<br>Each film coated tablet contains<br>Letrozole …..2.5mg |
| 2. | Name and address of Applicant (transferee) | M/s Apex Pharmaceuticals (Pvt) Ltd, D-21-A/1, SITE, super Highway, Karachi. |
| 3. | Name of Transferor | M/s Merixil Pharma, Office No. 28, 2nd Floor, Rose Plaza I-8 Markaz, Islamabad. |
| 4. | Detail of Drug Sale License | M/s Apex Pharmaceuticals (Pvt) Ltd, D-21, A/1, SITE, Super Highway, Karachi |
| 5. | Name and address of manufacturer | *Same as in product 1* |
| 6. | Name and address of marketing authorization holder | M/s Eris Pharmaceutical (Australia) Pty Ltd, 6 Eastern South Melbourne VIC 3205, Australia. |
| 7. | Name of exporting country | Australia |
| 8. | Diary No. & Date of R& I | Dy. No. 20662 Dated 08-06-2018 |
| 9. | Finished Product Specification | USP Spec |
| 10. | Shelf life | 36 months (as per approval & Form-5A) |
| 11. | Pack Size | 30's |
| 12. | Remarks:<br>• Same as for product 1 | |

The firm has submitted the following supporting documents / information for approval of registration of above mentioned products: -

a) Fee of Rs.100,000/- for each product.
b) Applications on Form-5A.
c) Copy of initial registration letter (renewal valid as registration granted on 15-09-2016).
d) Copy of Termination letter from manufacturer / product license holder in favor of current registration holder i.e. M/s. Merixil Pharma, Islamabad.
e) Authority letter (original & notarized) issued by manufacturer / product license holder for new proposed sole agent.
f) Original & legalized CoPPs for above products issued by TGA Australia.
g) Original GMP certificate of M/s Douglas Manufacturing Ltd, New Zealand issued by Ministry of Health, New Zealand.
h) Copy of valid DSL.
i) NOC from M/s. Merixil Pharma, Office No. 28, 2nd Floor, Rose Plaza I-8 Markaz, Islamabad issued on 26th December, 2017.

Registration Board in its 286th meeting decided to defer the case for provision of fresh NOC from the current registration holder as more than six months have elapsed for the available NOC (dated 26th December, 2017) and original notarized termination letter from product license holder.

Now the firm has submitted fresh NOC from current registration holder (i.e. M/s. Merixil Pharma, Office No. 28, 2nd Floor, Rose Plaza I-8 Markaz, Islamabad) issued on *19th September, 2018* and termination letter in original (notarized) from product license holder in favor of current registration holder as per decision of Registration Board.

With reference to product-1 it is submitted that the same has already been granted registration in favor of M/s. RG Pharmaceutical (Pvt) Ltd, Karachi with brand name "DP-Anastrozole 1mg

Tablets" Reg.No. 080918 from the same manufacturer i.e M/s. Douglas Manufacturing Ltd., Central Park Drive Lincoln, Auckland, New Zealand, dated: 10-02-2017.

**Decision:- Registration Board decided as follow;**

a. **Approved the cancellation of registration of products 1-3 from the name of M/s. Merixil Pharma, Islamabad.**
b. **Approved the registration of products Bicalox 50mg Tablet and Gynotril 2.5mg Tablet in the name of M/s. Apex Pharmaceuticals (Pvt) Ltd, Karachi as per policy for imported finished drug registration.**
c. **A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of products-2 and 3.**
d. **For product-1 (Azastrole 1mg Tablet), the Board decided to defer the case for obtaining clarification from M/s. RG Pharmaceutical (Pvt) Ltd, Karachi regarding the current status of product.**

**Case No.22: Request of M/s. OBS Pakistan (Pvt) Ltd, C-14, Manghopir Road, Site Karachi for change of manufacturing site of Cosopt Ophthalmic Solution.**

M/s OBS Pakistan (Pvt) Ltd, C-14, Manghopir Road, SITE Karachi has applied for change of manufacturing site of their following already registered product as per details given below: -

| S. # | Reg. No. | Product Name & Composition | Existing approved site (as per approval letter) | New Proposed Site / Manufacturer / Product License Holder |
|---|---|---|---|---|
| 1. | 025294 | Cosopt Ophthalmic Solution<br>Each ml contains:<br>22.26mg Dorzolamide HCL eq to Dorzolamide 20mg base.<br>6.83mg Timolol Maleate USP eq to 5mg Timolol base. | **Manufacturer:**<br>M/s Laboratoires Merck Sharp & Dohme- Chibret, Route de Marsat, Riom, 63963 Clermont Ferrand Cedex 9, France.<br>**Marketing Authorization Holder:**<br>M/s MSD France, 34, avenue Leonard de Vinci, 92400 Courbevoie, France. | **Name & Address of Manufacturer:**<br>M/s Santen Pharmaceutical Co., Ltd. Noto Plant,<br>2-14, Shikinami, Hodatsushimizu-cho, Hakui-gun, Ishikawa, Japan.<br>**Marketing Authorization Holder:**<br>M/s Santen Oy Niittyhaankatu 20 33720 Tampere, Finland |

The firm has submitted the following supporting documents: -

a) Application on Form-5A.
b) Fee of Rs.100,000/-
c) Copy of initial registration letter and renewal status.
d) Original and legalized COPPs issued by Japanese Authority & Finnish Medicine Agency.
e) Copy of GMP certificate of new site (issued by Japanese Authority).
f) Authorization letter in the name of M/s OBS Pakistan Pvt (Ltd) Karachi, from new manufacturer i.e. M/s Santen Pharmaceutical Co., Ltd, Japan.
g) Site master file for new site.

With reference to the above mentioned product, it is informed that initially the firm has provided COPP from Japanese Authority wherein, it is mentioned that the product is not on free sale in exporting country i.e. Japan. In order to provide Free sale status of the said product in reference regulatory authority the firm has provided valid legalize COPP issued by Finland Medicine Agency.

Furthermore, the request of M/s OBS Pakistan for change of marketing authorization holder for the said product has already been approved by Registrations Board in its 282nd meeting

from*M/s. MSD France, 34 Avenue Leonard de vinci, 92400 Courbevoie, France* to *M/s. Santen Oy, Niittyhaankatu 20, 3370 Tampere, Finland* which is also evident in the new submitted COPP (issued by Finnish Authority).

**Decision:- Registration Board approved the following changes in respect of registered product Cosopt Ophthalmic Solution (Reg.No. 025294) subject to policy for imported finished drug registration. Other terms and conditions remain the same.**

| S.No. | Reg.No. | Product Name & Composition | Previously approved Site(s) | New Approved Site(s) |
|---|---|---|---|---|
| **1.** | **025294** | **Cosopt Ophthalmic Solution**<br>**Each ml contains:**<br>**22.26mg Dorzolamide HCL eq to Dorzolamide 20mg base.**<br>**6.83mg Timolol Maleate USP eq to 5mg Timolol base** | **Manufacturer:**<br>**M/s Laboratoires Merck Sharp & Dohme- Chibret, Route de Marsat, Riom, 63963 Clermont Ferrand Cedex 9, France.**<br>**Marketing Authorization Holder:**<br>**M/s MSD France, 34, avenue Leonard de Vinci, 92400 Courbevoie, France** | **Name & Address of Manufacturer:**<br>**M/s Santen Pharmaceutical Co., Ltd. Noto Plant,**<br>**2-14, Shikinami, Hodatsushimizu-cho, Hakui-gun, Ishikawa, Japan.**<br>**Marketing Authorization Holder:**<br>**M/s Santen Oy Niittyhaankatu 20 33720 Tampere, Finland.** |

**Case No.23: Request of M/s. Getz Pharma (Pvt) Ltd, Karachi for registration of Product in their own name.**

The case of M/s. Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area Karachi for registration of following imported human product in its name and cancellation of the same from the name of M/s. Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Karachi was discussed in 279th meeting of Registration Board. Details are as under.

| S. No. | Reg. No. | Name & Composition of Products (as per initial registration letter) | Name & Composition of Products (as per CoPP) | Manufacturer/ product license Holder (as per registration letter) | Manufacturer/product license Holder. (as |
|---|---|---|---|---|---|
| 1. | 025293 | Lucrin Depot 3.75mg Injection Each vial contains:- Leuprorelin Acetate…3.75mg | Lucrin Depot **PDS** 3.75mg Injection Each vial contains:- **Leuprolide Acetate…**3.75mg | **Manufacturer:** M/s. Tekeda Pharmaceutical Company Limited Osaka, Japan. | **Product license holder:** M/s. Abbvie Farmaceutica, S.L.U. Avda. de Burgos, 91 28050 Madrid , Spain**.** **Manufacturer: (manufacturer of vial & ampoules):** M/s. Takeda Pharmaceutical Company Ltd. 1-1 Doshomachi 4-chome, 540-8645 Chuo-ku, Osaka, Japan. **Packaging of Finished Product:** M/s. Abbott Laboratories, S.A. Avda. De Burgos, 91, 28050 Madrid Spain. |

The firm has deposited fee of Rs. 1,00,000/- and provided the following supporting documents:

i. Application on Form 5A.
ii. Copy of registration letters and last renewal status. With reference to renewal it is submitted that Renewal is due in Nov-2015. However, the firm had applied for registration of the product in their name in Aug-2015. Therefore, keeping in view the previous decisions of Board in such cases, the renewal may consider as valid.

iii. Termination letter (original) from manufacturer for previous importer.
iv. Authority letter/sole agent letter (original) from manufacturer.
v. NOC from existing registration holder for transfer of registration. (issued on 18-9-2014).

The case was considered in 277th meeting of Registration Board and the Board decided as under:

"*Keeping in view the previous decisions of Registration Board in such cases, Board deferred the case for provision of fresh NOC from existing registration holder i.e M/s. Abbott Laboratories (Pakistan) Limited, Karachi as the already submitted NOC was issued in September 2014."*

In compliance to Registration Board decision, the firm submitted fresh NOC (dated: 12-01-2018) from the M/s. Abbott Laboratories (Pakistan) Limited, Karachi.

The case was considered in 279th meeting and the Board decided to advised the firm for provision of valid, legalized and attested CoPP for the said product.

In light of above decision the firm has submitted original and legalized CoPP, wherein the following points were observed to which the firm has replied as under (mentioned in remarks column).

| S. No | Details | As per previous COPP | As per new COPP | Remarks (reply from firm) |
|---|---|---|---|---|
| 1 | Brand Name in Pakistan | Lucrin Depot PDS | Lucrin | This is to inform you that the brand name in Pakistan is "Lucrin Depot". However, erroneously in the COPP it is mentioned only "Lucrin". |
| 2 | Product License Holder | M/s. Abbvie Farmaceutica, S.L.U. Avda. de Burgos, 91 28050 Madrid , Spain. | M/s. Abbvie Farmaceutica, S.L.U. Avda. de Burgos, 91 28050 Madrid , Spain. | This is to inform you that in October, 2014, name of M/s Abbvie Farmaceutica S.L.U. has been changed to M/s Abbvie Spain S.L.U. Firm has provided copy of approval letter / notification issued by Spanish Agency for Medications and Healthcare. |
| 3 | Manufacturer (Manufacturer of vial & ampoule) | M/s. Takeda Pharmaceutical Company Ltd. 1-1 Doshomachi 4-chome, 540-8645 Chuo-ku, Osaka, Japan. | M/s. Takeda Pharmaceutical Company Ltd, Osaka Plant, 1785, Juso-Honmachi, 2-Chome Yodogawa-ku Osaka 532-0024, Japon/Japan. | Kindly note that there is no change in the manufacturing site. However, previous COPP contains company's / head office address and not the manufacturing plant's address. The manufacturing plant address is mentioned in new COPP. |

**Decision: Registration Board decided to defer the case for obtaining clarification from the firm that whether the said product is in "depot" form or otherwise and, if so, the same shall be mentioned in the CoPP of the said product.**

**Case No.24: Request of M/s. Al-Hameed Agencies (Pvt) Ltd, Rawalpindi for Change of Address (Local) for their registered products.**

M/s Al-Hameed Agencies (Pvt) Ltd, Rawalpindi has requested for change of local address for their following registered products as per following details:-

| S. No | Reg. No. | Name of Drug/ Composition | Name & Address of Importer (as per Previous DSL) | Proposed Name & Address of Importer (as per New DSL) |
|---|---|---|---|---|
| 1. | 021092 | Intapan Injection Each ml contains:- Nalbuphine HCl 10mg | M/s Al-Hameed Agencies (Pvt) Ltd, 187-C, Rashid Minhas Road | M/s Al-Hameed Agencies (Pvt) Ltd, 20, Opp, Ayub National |

| | | | | |
|---|---|---|---|---|
| 2. | 025295 | Torapan 30mg Injection<br>Each 1 ml ampoule contains: -<br>Ketorolac Trometamo 30mg | (Mayo Road) P.O. Box No. 808, Rawalpindi. | Park, Jhelum Road, Rawalpindi. |
| 3. | 025296 | Monasan 25mg Injection<br>Each 1 ml ampoule contains: -<br>Fluphenazine Decanoate 25mg | | |

The firm has deposited fee of Rs.5000/- (for each product)and submitted following documents:-

a) Copy of DSL of previous distribution address.
b) Copy of DSL of new / proposed distribution address.
c) Initial registration letters and renewal trail.

**Decision:-** **Registration Board approved firm's request for change of (local) address of importer from *M/s Al-Hameed Agencies (Pvt) Ltd, 187-C, Rashid Minhas Road (Mayo Road) P.O. Box No. 808, Rawalpindi* to *M/s Al-Hameed Agencies (Pvt) Ltd, 20, Opp, Ayub National Park, Jhelum Road, Rawalpindi* for following registered products, in accordance with DSL and on same terms & conditions. Approval letter shall be issued after verification of storage facility of new site.**

| S.No | Reg. No. | Name of Drug/Composition |
|---|---|---|
| **1.** | **021092** | **Intapan Injection<br>Each ml contains:-<br>Nalbuphine HCl… 10mg** |
| **2.** | **025295** | **Torapan 30mg Injection<br>Each 1 ml ampoule contains: -<br>Ketorolac Trometamo… 30mg** |
| **3.** | **025296** | **Monasan 25mg Injection<br>Each 1 ml ampoule contains:-<br>Fluphenazine Decanoate… 25mg** |

**Case No. 25: Request of M/s. Medi Mark Pharmaceuticals, Sahiwal for change of address (local) for their registered product.**

M/s. Medi Mark Pharmaceuticals, Sahiwal has requested for change of local address for their following registered product as per following details:-

| S. No | Reg. No. | Name of Drugs/ Composition | Name & Address of importer (as per initial registration letter) | Proposed Name & Address of Importer (as per New DSL) |
|---|---|---|---|---|
| 1. | 031302 | Dobamin Injection<br>Each ampoule contains:-<br>Dobutamine as HCI…..250mg | M/s. Medi Mark Pharmaceuticals,<br>6-Civic Centre, Moon Market, Gulshan-e-Ravi, Lahore. | M/s. Medi Mark Pharmaceuticals, 588/B1, LiaquatChowk, Karbala Road, Sahiwal. |

Firm has deposited fee of Rs. 5000/- and provided the following documents:-

(i) Copy of initial registration letter.
(ii) Copy of last renewal status.
(iii) Copy of Drug Sale License (new and old DSL)

It is pertinent to inform that inspection of local storage facility located at "588/B1, Liaquat Chowk, Karbala Road, Sahiwal" has already been verified by the concerned FID.

**Decision:-** **Registration Board approved firm's request for change of (local) address of importer from *M/s. Medi Mark Pharmaceuticals, 6-Civic Centre, Moon Market, Gulshan-e-Ravi, Lahore* to *M/s. Medi Mark Pharmaceuticals, 588/B1, Liaquat Chowk, Karbala Road, Sahiwal* in accordance with DSL for registered product *Dobamin Injection* (Reg.No. 031302) on same terms and conditions. Approval letter shall be issued after verification of storage facility of new site.**

**Case No.26: Registration of Drugs under the Drugs Act, 1976-Inspection Reports of Manufacturer Abroad.**

The Registration Board approved drugs in various meetings subject to inspection of manufacturer abroad as per import policy. The inspections were accordingly carried out by the approved inspection panel. The following panel inspection reports of manufacturer abroad have reported certain observations as per details mentioned below:-

**(A) M/s. Cisen Pharmaceutical Co. Ltd. Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone, Jining, Shadong, China.**

<table>
<tr><th>S. No.</th><th>Name of Importer/ Manufacturer & meeting number</th><th>Name of Drug/ Composition/</th><th>Panel of Inspector(s)/ Date of inspection</th></tr>
<tr><td>1.</td><td>M/s. Mehran International, Pliva Avenue Hume Road Near World Map Karachi./<br><br>Manufacturer & Marketing Authorization Holder:-<br>M/s. Cisen Pharmaceutical Co. Ltd. Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone, Jining, Shadong, China.</td><td>Ondansetron injection 8mg/4ml<br>Each 4ml ampoule contains:-<br>Ondansetron Hydrochloride eq. to Ondansetron……...8mg<br>Approved with USP specifications and a shelf life of 2 years as per Policy for inspection of Manufacturer abroad. The inspection panel may be requested to verify the following:<br>Real-time stability study data (conducted as per Zone IV-A) of 3 batches 17051, 17052 and 17053 which were manufactured in May 2017.<br>Impact of the difference in the specifications on which stability studies were conducted (i.e. Chinese Pharmacopoeia) and the specifications which are approved by Registration Board (i.e. USP specification).
<table>
<tr><td>Test</td><td>Submitted specification</td><td>USP specification</td></tr>
<tr><td>pH</td><td>3 – 4</td><td>3.3 – 4</td></tr>
<tr><td>Assay</td><td>93 – 107%</td><td>95 – 105%</td></tr>
</table>
Ofloxacin infusion 200mg/100ml<br>Each 100ml infusion bottle contains:-<br>Ofloxacin…200mg/100ml<br><br>Ciprofloxacin infusion 200mg/100ml<br>Each 100ml infusion bottle contains:-<br>Ciprofloxacin lactate eq to ciprofloxacin……200mg<br><br>Omipen Injection 40mg<br>Each vial contains:-<br>Omeprazole sodium eq to omeprazole (lyophilized powder)……..40mg</td><td>(i) Dr. Fakhruddin Aamir, Additional Director, Drug Regulatory Authority of Pakistan, Islamabad.<br><br>(ii) Mr.Zaheer-ud-Din Muhammad Babar, Deputy Director, Drug Regulatory Authority of Pakistan, Islamabad.<br><br>7th& 8th December, 2018</td></tr>
</table>

**Comments/ Remarks of the Panel.**

(i) The CoPP of all the four products i.e. *Ondansetron Injection 8mg/4ml, Ofloxacin Infusion 200mg/100ml, Ciprofloxacin Infusion 200mg/100ml and Omipen Injection 40mg* mentions manufacturer and product license holder as *Cisen Pharmaceutical Co., Ltd, Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining. Shandong Province*. However, Ondansetron Injection 8mg/4ml, Ofloxacin Infusion 200mg/100ml and Ciprofloxacin Infusion 200mg/100ml are manufactured at the premises situated at *Haichuan Road, Jining High & New Technology Industries Development Zone*, while Omipen Injection 40mg is manufactured at premises located mentioned in the CoPP, which is few street away from the Haichuan Road premises. The management of the firm informed that the COPP are issued at the legal / Head Office address, which in this case is, Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining. Shandong Province, while

the GMP certificate mentions the manufacturing site and facilities. The manufacturing and quality control facilities at Cisen Pharmaceutical Co., Ltd, Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining. Shandong Province premises appears to comply GMP requirements as observed at the time of visit.

(ii) The report of Haichuan Road Jining High & New Technology Industries Development Zone, which manufactures ,Ondansetron Injection 8mg/4ml, Ofloxacin Infusion 200mg/100ml and Ciprofloxacin Infusion 200mg/100ml was submitted on separate proforma, which, in addition to above details reported that the manufacturing and quality control facilities at Haichuan Road Jining High & New Technology Industries Development Zone premises appears to comply GMP requirements as observed at the time of visit.

(iii)With regards to specification of ondansetron Injection 8mg/4ml, the management informed that they follow the in-house specifications, which are at par with USP. The firm has also provided a copy of the documents relating to real time stability study of three batches of ondansetron Injection 8mg/4ml in support of its aforementioned claim (Appended). The stability data indicates that a specification including those of pH and Assay comforms to USP.

As per CoPP and Form-5A submitted by the applicant the name and address of the manufacturer and product license holder of all the above four products is as under:-

- M/s. Cisen Pharmaceutical Co. Ltd. Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone, Jining, Shadong, China.

While as per copies of GMP certificate submitted to the inspection panel by the firm the manufacturing site addresses are as under: -

- M/s. Cisen Pharmaceutical Co. Ltd. Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone.
  Lyophilized Powder for Injection; small volume parenteral solution(terminally sterilized non-terminally sterilized, including hormones).
- M/s Haichuan Road, Jining High & New Technology Industries Development Zone.
  Small volume parenteral solutions; large volume parenteral solutions (vertical plypropylene infusion bag, jubingxiShuye Ping PP Infusion Bottles).

**Decision:-** **Keeping in view the above stated position, Registration Board decided as follow;**

**i. Approved processing of issuance of registration letter for product "Omipen Injection 40mg" to be manufactured at "*M/s. Cisen Pharmaceutical Co. Ltd. Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone, Jining, Shadong, China"* in accordance with the recommendation of said site by nominated inspection panel.**

**ii. For products "Ondansetron injection 8mg/4ml", "Ofloxacin infusion 200mg/100ml" and "Ciprofloxacin infusion 200mg/100ml" firm shall be advised to provide revised Form-5A along with requisite fee and all other credentials/documentations for the manufacturing site "*M/s. Cisen Pharmaceutical Co. Ltd., Haichuan Road, Jining High & New Technology Industrial Development Zone, China*" for consideration of Registration Board.**

**B. M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China.**

| S. No. | Name of Importer/ Manufacturer & meeting number | Name of Drug/ Composition/ | Panel of Inspector(s)/ Date of inspection |
|---|---|---|---|
| 1. | M/s. S.K. Enterprises, Office No. 701, 7th floor KS trade tower, Shahrah e Liaquat Karachi./<br>M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China.<br>**Manufacturer & Market Authorization Holder:-**<br>M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China.<br>**(M-278)** | SK+METROSIM Infusion<br>Solution for IV infusion<br>Each 100 ml contains:-<br>Metronidazole…500mg<br>(ANTIPROTOZOALS)<br><br>SK+CIPROSIM Injection<br>Solution for IV Injection<br>Each 100 ml contains:-<br>Ciprofloxacin (as lactate)…200mg<br>(Quinolones)<br><br>SK+RINGERSIM Infusion<br>Solution for IV Infusion<br>Each 500ml contains:-<br>Sodium lactate…….1.6g<br>Potassium chloride..0.2g<br>Calcium chloride dehydrate….0.135g<br>Sodium chloride……3g<br>(electrolytes) | (i) Dr. FakhruddinAamir, Additional Director, Drug Regulatory Authority of Pakistan, Islamabad.<br>(ii) Mr.Zaheer-ud-Din Muhammad Babar, Deputy Director, Drug Regulatory Authority of Pakistan, Islamabad.<br><br>10th& 11th December, 2018 |

**Comments/ Remarks of the Panel.**

i. The CoPP of all the three products i.e. SK+Metrosim Infusion solution for IV infusion, SK+Ciprosim Injection solution for IV Injection and SK+Ringersim Infusion Solution for IV Infusion mentions manufacturer and product license holder as M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High & New tech Development Zone, Shijiazhuang, Hebei, China, Yangzi Road, Shijiazhunang Economic and Technological Development Zone Hebei PRC. The SK+Metrosim Infusion solution for IV infusion and SK+Ciprosim Injection solution for IV Injection are manufactured at the premises located at No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang while the product is manufactured at another premises located few streets away having address M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang, Hebei, China. However, the Quality Control and Batch release is done at the premises situated at No.288 Zhujiang Road.

ii. The management of the firm informed that the COPP are issued at the legal address, which mentions both above premises, while the GMP certificate mentions the manufacturing site and facilities. The manufacturing facility at No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang are well designed and adequately equipped having effective system and controls for cGMP compliance.

iii. The report of the premises situated at Yangzi Road, Economic and Technological Development Zone Shijiazhunang, Hebei, China., which manufactures SK+Ringersim Infusion Solution for IV Infusion, in addition to above details, states that the manufacturing facility of SK+Ringersim Infusion Solution is state of art facility and all the process from dispensing of raw material to the manufacturing of finished products are automatic with least involvement of workers. The facility have latest HVAC and WFI system. The firm claims to be the largest manufacturing of IV solutions in china. The premises appears to comply GMP requirements as observed at the time of visit.

The details regarding manufacturer / MH Holder as per Form-5A, CoPP& GMP submitted by the firm are as under:

| Product Name | Manufacturer / MA Holder as per Form-5A | Manufacturer / MA Holder as per CoPP | Manufacturer as per GMP |
|---|---|---|---|
| SK+METROSIM Infusion<br>Solution for IV infusion<br>Each 100 ml contains:-<br>Metronidazole…500mg<br>(ANTIPROTOZOALS) | M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang, China | M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High & New tech Development Zone, Shijiazhuang, Hebei, China, Yangzi Road, Shijiazhunang Economic and Technological Development Zone Hebei PRC. | M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No.288 Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang, |
| SK+CIPROSIM Injection<br>Solution for IV Injection<br>Each 100 ml contains:-<br>Ciprofloxacin (as lactate)…200mg<br>(Quinolones) | -do- | -do- | -do- |
| SK+RINGERSIM Infusion<br>Solution for IV Infusion<br>Each 500ml contains:-<br>Sodium lactate…….1.6g<br>Potassium chloride..0.2g<br>Calcium chloride dehydrate…….0.135g<br>Sodium chloride……3g<br>(electrolytes) | M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang China | -do- | M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang City. |

**Decision:-** **Keeping in view the above stated position, Registration Board approved the correction in address of manufacturer in minutes of the meeting for product "*SK+RINGERSIM Infusion Solution for IV Infusion*" from "*M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China*" to "*M/s Shijiazhuang No. 4 Pharmaceutical Co., Ltd., Yangzi Road, Economic and Technological Development Zone Shijiazhunang China*" in accordance with Form-5A, CoPP and GMP certificate. Furthermore, as reported by the inspection panel, quality control of product "*SK+RINGERSIM Infusion Solution for IV Infusion*" is performed by "*M/s. Shijiazhuang No. 4 Pharmaceutical Co., Ltd., No. 288, Zhujiang Road, High Tech Industrial Development Zone, Shijiazhunang, Hebei, China*".**

**Firm will submit correct CoPP and revised Form-5 for consideration of Registration Board.**

## VETERINARY CASES

### Case No.27: Contract Manufacturing of Already Registered Products:

M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5Km Sheikhupura Road, Lahore has requested for contract manufacturing of their following already registered products from M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura as per details mentioned below. Citing the reason for the contract manufacturing, the firm stated that they are in process of developing new dedicated facilities for Oral and Injectable veterinary sections which hopefully will be completed within the period of two and half years.

| S. No. | Name of Applicant and Manufacturer | Name of Drug(s)/ Composition& Pack Size | Reg. No./ Date of Initial Registration and Renewal status | Approval status in RRAs and Me-too status | Remarks/ Shortcomings | Reply of the firm |
|---|---|---|---|---|---|---|
| 1. | M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5KmSheikhupura Road, Lahore **contract manufacturing** from M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura. | Rimoxyn Injection (Vet) Each ml contains:- Oxytetracycline HCI eq. Oxytetracycline …..50mg (Composition as perForm-5)<br><br>2ml<br>50ml<br>100ml | 002152 Renewal submitted as per copies provided. 24-09-1985 (MOH letter renewal dates not specified) 05-10-1986 25-09-1991 08-09-1996 25-09-2001 (Receipt in MOH not provided). 19-10-2006 02-11-2011 16-11-2016 | Limoxin-50 Injection (Holland, Interchemie Werken)<br><br>Me-too B.G. Oxy-50 Injection M/s. Biogen Pharma Rawat. | i) Initial registration letter not provided.<br><br>ii) The registration renewal letter (issued in 1985) does not contain detail.<br><br>iii) Composition and renewal date in National Formulary of Pakistan the product appear as Oxytetracycline injection having composition each 2ml contains Oxytetracycline (as HCI) 50mg.<br><br>iv) Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor.<br><br>v) Finished | **i)**Initialregistration certificate is not available at this time.<br>**ii)** Regarding the renewal letter (issued in 1985) does not contain composition, it is to inform you that this practice had not practiced by the MOH that time.<br>**iii)**The composition as per National Formulary of Pakistan of Oxytetracycline injection is written by mistake. The actual formulation is "Each ml contains Oxytetracycline (as HCI) 50mg**"** which is appliedat the time of registration. Copy of letters for approval of additional pack and new design/color scheme are attached for reference.<br><br>**iv)**Form 5 dully signed by the contract giver/registration holder provided. |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | product specification not provided. | **v)**Finished product specification provided. |
| 2. | -do- | Evomec Injection 1% W/V Contains:- Ivermectin……1% w/v (Composition as per initial registration letter) 10ml 50ml 100ml | 043506<br><br>18-07-2006 Renewal submitted 06-08-2011 (Last renewal application submission) 15-07-2016 | a. Bimectin (Canada, Bimeda-MTC Animal Health Inc)<br><br>Me-too Ivotek Injection 1% W/V M/s. Star Laboratories (Pvt) Ltd. Lahore. | **i)** First renewal due on 17-7-2011 was submitted on 06-08-2011 with fee of Rs.8000/-<br><br>**ii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor.<br><br>**iii)** Finished product specification not provided. | **i)**Submitted renewal on 06-08-2011 with late fee (Rs.8000) within the validity period of 60 days after expiry date of renewal. Copy of challan form is attached for reference.<br><br>**ii)** Form 5 dully signed by the contract giver/registration holder provided.<br><br>**iii)** Finished product specification provided. |
| 3. | -do- | Levopower Drench Contains:- Levamisole HCI B.P…… 1.5% w/v Oxyclozanide B.P (Vet)…….3 .0% w/v Cobalt Sulphate……0.3 82% w/v **(Composition as per initial registration letter)**<br><br>100ml 500ml 1000ml 5000ml | 043507<br><br>18-07-2006<br><br>Last renewal application submission date 15-07-2016. | **a.** Levafas Cluke and Worm (Drench. Rep. of Ireland. Norbrook Laboratorries (Ireland) Ltd.)<br><br>**Me-too** Levozan Plus Suspension M/s. Star Laboratories (Pvt) Ltd. Lahore. | **i)** First renewal due on 17-07-2011 was submitted on 06-08-2011 with fee of Rs.8000/-<br><br>**ii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor.<br><br>**iii)** Finished product specification not provided.<br>**iv)** Latest inspection report of M/s. Intervac for Liquid Section.<br><br>**v)** Master formula is not correct. | **i)**Submitted renewal on 06-08-2011 with late fee (Rs.8000) within the validity period of 60 days after expiry date of renewal. Copy of challan form is attached for reference.<br><br>**ii)** Form 5 dully signed by the contract giver/registration holder provided.<br><br>**iii)** Finished product specification provided.<br>**iv)** Latest inspection report of M/s. Intervac(Pvt) Ltd. For liquid section.<br><br>**v)** Master formula of Levopower Drench provided. |
| 4. | -do- | Levozide Solution Contains:- Levamisole HCI | 008038<br><br>27-02-1985 | a. Chanaverm Plus Oral Solution (Ireland. | i) As per Form-5 the firm has changed | **i)** Regarding change of brand name, it is a typographic |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | B.P. (Vet)……1.5 % w/v<br><br>(Composition as per Form-5)<br><br>100ml<br>250ml<br>500ml<br>1 Litre | Already renewed upto 26-02-2015. Last renewal application submitted on 10-02-2015. | Chanelle Pharmaceuticals Manufacturing Ltd.)<br><br>Me-too Nayverm 1.5% W/V Oral Solution M/s. Saymans Pharmaceuticals (Pvt) Ltd. Lahore. | brand name to Levozide Worm Drench 1.5% w/v (vet).<br><br>ii) Moreover, the initial original registration letter (issued in 1985) does not contain detail composition.<br><br>iii) Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor.<br><br>iv) Latest inspection report of M/s. Intervac for Liquid Section. | mistake. We feel sorry for that and again submitting the Form-5.<br><br>**ii)** Regarding initial original registration letter does not contain detail composition, it is not practiced by the MOH that time.<br><br>**iii)** Form 5 dully signed by the contract giver/registration holder provided.<br><br>**iv)** Latest inspection report of M/s. Intervac (Pvt) Ltd. For liquid section provided. |
| 5. | -do- | Fendanid Plus Liquid Contains:- Oxfendazole..2.265% w/v Oxyclozanide..6.25% w/v Selenium…….0.05% w/v Cobalt...0.167% w/v (Composition as per initial registration letter)<br>100ml<br>250ml<br>500ml<br>1000ml<br>5000ml | 031478<br><br>06-10-2003<br>26-09-2008<br>03-10-2013 | a. N.A<br><br>Me-too Oxarex Gold Drench M/s. Star Laboratories (Pvt) Ltd., Lahore, | i) Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor.<br><br>ii) Latest inspection report of M/s. Intervac for Liquid Section.<br><br>iii) Master formula is not correct. | **i)** Form 5 dully signed by the contract giver/registration holder provided.<br><br>**ii)** Latest inspection report of M/s. Intervac (Pvt) Ltd. For liquid section provided.<br><br>**iii)** Master formula of Fendanid Plus Liquid provided. |
| 6. | -do- | Sulphadin Injection (Vet) Each 100ml contains:- Sulphadimidine Sodium……33.33gm<br><br>(Composition as per Form-5) | 000789<br><br>01-07-1976<br>Last renewal application submission date 29-06-2016. | | i) Initial registration letter not provided. | **i)**Initial registration certificate is not available at this time. We are submitting a copy of "The Gazette of Pakistan, Extra dated October, 14, 1981".<br><br>**ii)** Regarding the |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | 100ml | | | ii) The change of brand name letter (issued in 2002) does not contain detail composition. However the composition can be confirmed from National Formulary of Pakistan.<br><br>iii) Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. | change of brand name letter does not contain details composition, it is not practiced by the MOH that time. For detail composition we are submitting a copy of "The Gazette of Pakistan, Extra dated October, 14, 1981".<br><br>**iii)** Form 5 dully signed by the contract giver/registration holder provided. |

The firm has provided following documents for this purpose:

i. Application on Form-5 with fee of Rs.50,000/- for each product.
ii. Copy of initial registration letters.
iii. Copy of last renewal status.
iv. Latest GMP inspection report of M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura (dated 28.02.2017 & 17-03-2017). Having evidence of section availability of M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura.
v. Copy of DML M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5KmSheikhupura Road, Lahore & M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura.
vi. Undertaking contract manufacturing through M/s. Intervac (Pvt) Ltd. for two and half years for above mentioned drugs.
vii. Copy of contract manufacturing agreement b/w M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5KmSheikhupura Road, Lahore & M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura. (dated 08-08-2017).
viii. Copy of CRF of M/s. Intervac (Pvt) Ltd. valid upto 31-12-2017.

Registration Board in its 279th meeting deferred M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5 Km Sheikhupura Road, Lahore request for confirmation of status of renovation plan and timelines of their oral and injectable veterinary sections from Licensing Division of DRAP.

Letter issued to Licensing Division for confirmation of status of renovation plan and timelines of their oral and injectable veterinary section. In response Licensing Division has informed that layout plan for following sections of M/s. PDH Laboratories (Pvt) Ltd, Lahore was approved on 08-01-2019.

1. Tablet (Penicillin) Section (New).
2. Capsule (Penicillin) Section (New).
3. Dry Powder Suspension (Penicillin) Section (New).
4. Dry Powder Injection (Cephalosporin) (Revised).
5. Syrup (General) Section (New).
6. Capsule (General) Section (New).
7. Sachet (General) Section (New).
8. Tablet (General) Section (New).
9. Narcotics (General) (Human) (Revised).

10. Drench (General) (Veterinary) Section (Revised).
11. Injectable (Vial) (General) (Veterinary) Section (Revised).

**Decision:- Registration Board decided to defer the case for seeking following clarifications:**

- **Timelines for completion of renovation of Oral and Injectable veterinary sections.**
- **Status of other registered products of Oral and Injectable veterinary sections as firm has not applied for contract manufacturing**

**Case No. 28: Request of M/s. Leads Pharma (Pvt) Ltd., Islamabad for Correction of Pack Sizes.**

Registration Board in its 277th meeting approved following locally manufactured veterinary drug of M/s. Leads Pharma (Pvt) Ltd., 81-A, Street # 6, I-10/3, Islamabad.

| S.No | Name of Manufacturer | Name of drug(s) & Composition | Approved Packs Sizes | Remarks |
|---|---|---|---|---|
| 1. | M/s. Leads Pharma (Pvt) Ltd., 81-A, Street # 6, I-10/3, Islamabad. | Levacare Bolus 600mg<br>Each Bolus contains:-<br>Levamisole HCl……600mg | 100ml<br>200ml<br>500ml<br>1 Litre | Approved<br>USP specifications |

Further processing of the registration letter of above mentioned product was withheld as the product is in Bolus form while the pack sizes demanded by the firm were mentioned as 100ml, 200ml, 500ml& 1Litre.The firm has now provided revised Form-5 wherein the demanded pack sizes are mentioned as 5 Bolus, 50 Bolus & 100 Bolus. Firm has deposited fee of Rs.5000/- along with revised Form-5.

**Decision:- Registration Board approved the correction in pack sizes of already approved product "Levacare Bolus 600mg" from *100ml, 200ml, 500ml and 1 Lit* to *5 Bolus, 50 Bolus and 100 Bolus.***

**Case No. 29: Registration of Product Lincomycin-40S Oral Powder in favor of M/s. Orient Traders International, Karachi.**

The Registration Board in its 277th meeting considered request of M/s. Orient Traders International, Karachi regarding change of registration status of following veterinary products from M/s. Orient Animal Health (Pvt) Ltd, Karachi to M/s. Orient Traders International, Karachialong with change of manufacturer.

| S. No. | Name of Drug(s) Composition as per CoPP | Pack Sizes (as mentioned in 236th Meeting) | Previous Manufacturer | Decision of Reg. Board in 277th Meeting |
|---|---|---|---|---|
| 1. | Lincomycin-40S Oral Powder<br>Each gm contains:-<br>Lincomycin hydrochloride equivalent to Lincomycin …..400mg/g | 100gm<br>500gm<br>1Kg<br>10Kg<br>25Kg | M/s. V.M.D.N.V Hoge Mauw Arendonk Belgium. | **Manufacturer:**<br>M/s. Biove, 3 Rue de Lorraine, 62510 Arques, France.<br>(manufacturer of the finished product, Packager, Labeling, QC)<br>**Labeling & Batch Release:**<br>M/s. V.M.D. n.v. Hoge, Mauw 900,2370, Arendonk, Belgium.<br>**Product License Holder:**<br>M/s. V.M.D. n.v. HogeMauw 900, 2370, Arendonk, Belgium.<br>Shelf life 41 months |

Later, the firm has provided new valid legalized CoPP (issued by Belgium Authority) along with revised Form-5A (and fee of Rs.5000/-) wherein the details of manufacturer/product license holder is mentioned as;

**Manufacturer**
M/s. Laboratoires Biove, 3 Rue de Lorraine, 62510 Arques, France.
(Manufacturer of the finished product, Packager, Labeling, QC).

**Producct License Holder:-**
M/s. V.M.D. n.v.
Hauw 900, 2370, Belgium.

Registration letter for the said product has been issued with name and address of manufacturer and product license holder in accordance with details pesent in new CoPP.

**Decision:- Registration Board noted and endorsed the action taken.**

**Case No.30:- Cancellation of Registration of Oxytocin Multi-Dose Vials in Veterinary.**

The Registration Board in its 278th meeting held on 29-31st January, 2018 while considering their agenda item viz "Manufacture & Sale of Adulterated & Sub-Standard "Oxytocin Injection (for vet only)", *interalia*, decided as under:-

*"Registration Board advised PE&R Division to present case regarding alleged use of Oxytocin multi-dose vials for enhancement of milk production in the animals."*

The Board agreed to issue show cause notice of multi-dose vials on the same lines which have been adopted by India. They allow only one mL Oxytocin ampoule for human use only. Later, Registration Board in its 286th meeting was informed that show cause notices have been issued to following 25 firms having registration of Oxytocin Multi-dose vials.

| S. No. | Name of Firm's |
|---|---|
| 1. | M/s. Elko Organization (Pvt.) Ltd, Karachi. |
| 2. | M/s. International Pharma Labs. Lahore. |
| 3. | M/s. Intervac (Pvt) Ltd., Sheikhupura. |
| 4. | M/s. BiogenPharma, Chakbeli Road, Rawat. |
| 5. | M/s. Epoch Pharmaceuticals, Karachi. |
| 6. | M/s. Zakfas Pharmaceuticals Pvt Ltd., Multan. |
| 7. | M/s. Tabros Pharma (Pvt) Ltd., Karachi. |
| 8. | M/s. Dosaco Laboratories, Lahore. |
| 9. | M/s. Geofman Pharmaceuticals, Karachi. |
| 10. | M/s. Vetcon Pharmaceuticals Pvt. Ltd., Azad Kashmir. |
| 11. | M/s. Venus Pharma, Lahore. |
| 12. | M/s. Imran & Company, Karachi. |
| 13. | M/s. ISIS Pharmaceuticals & Chemical Works,<br>(Formerly M/s. Krka-Pak Pharmaceutical), Karachi. |
| 14. | M/s. Kakasian Pharmaceuticals (Pvt) Ltd., Lahore. |
| 15. | M/s. Amrose Pharmaceuticals, Karachi. |
| 16. | M/s. Lawarlance Pharma, Lahore. |
| 17. | M/s. S.J & G Fazul Ellahie (Pvt.) Ltd, Karachi. |
| 18. | M/s. Sanna Laboratories, Faisalabad. |
| 19. | M/s. Biorex Pharmaceuticals, Islamabad. |
| 20. | M/s. Rex Pharmaceuticals, Karachi. |
| 21. | M/s. Avicenna Laboratories (Pvt) Ltd., Sheikhupura. |
| 22. | M/s. Jfrin Pharmaceutical Laboratories, Balochistan. |
| 23. | M/s. Manhattan Pharma, Karachi |
| 24. | M/s. Alina Combine Pakistan (Pvt) Ltd., Karachi. |
| 25. | M/s. Eros Pharmaceuticals (Private) Limited, Karachi. |

So far reply from 11 firms have been received wherein they have responded with their point of view including request for personal hearings.

The salient points, of the responses received are summarized as under:-

i) Oxytocin Injection is not used for the enhancement of milk product in dairy animal. Oxytocin is a pituitary hormone that has very short span of effectiveness - it is absorbed immediately after natural release or injection it lasts around three minutes in the bloodstream of a healthy animal before it is completely absorbed and metabolized.

ii) Oxytocin is used as uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and resistance to the large inflow of blood. It contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

iii) Oxytocin is not intended for milk enhancement but to facilitate milking letdown process and to maximize the efficient removal of milk. Oxytocin is used to letdown the milk worldwide.

iv) A firm has requested for providing the necessary record.

v) Instead of cancelling the registration and manufacturing of this product, its misuse be stopped by regulating prescription and sales.

vi) A number of firms have requested chance to be heard in person.

**Decision:- Keeping in view the above stated position, Registration Board decided to call up all the firms, having registration of multi-dose vials containing Oxytocin in veterinary, for personal hearing before Registration Board.**

**Case No. 31: Manufacturing Site Transfer of Currently Toll Manufacturing Products from M/s Akhai Pharma, Karachi to M/s GSK, 35-Dockyard Road, West Wharf, Karachi.**

***Previous Case History(M-287):***

*"Termination of Contract Manufacturing and Registration of Drugs For Manufacturing on their Own Facility.*

M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi has intimated that they intend to terminate the contract manufacturing from M/s Akhai Pharma, Karachi under DRA permission letter dated 15th October, 2015 due to some capacity constraints. As a part their future manufacturing and Supply plan, they have now increased the Manufacturing Capacity of West Whraf site to commence production of all these product in-house. This arrangement will also contribute to ensure long term supply sustainability of these products in local market. The details of the products are as under:

| Sr.# | Reg. No. | Name of drug(s). | International Availability |
|---|---|---|---|
| **1.** | 019464 | **Brevoxyl Cream**<br>Each gm contains:<br>Benzoyl peroxide……...4 % | Approved by MHRA, UK<br>Brevoxyl 4 % Cream by GSK Consumer Healthcare |
| **2.** | 043657 | **Clinagel**<br>Each gm contains:<br>Clindamycin phosphate...10mg | Approved by US FDA,<br>CLINDAGEL 1 % by Precision Dermat |
| **3.** | 019738 | **Lacticare 1% Lotion**<br>Each gm contains:<br>Hydrocortisone……..1.06% | Approved by US FDA,<br>ACTICORT 1 % Lotion by Baker Norton (Marketing status Discontinued) |
| **4.** | 019739 | **Lacticare 2.5% Lotion**<br>Each gm contains:<br>Hydrocortisone……2.5% | US FDA,<br>ALA-SCALP **2 %** Lotion by Crown Labs |
| **5.** | 005039 | **Lacticare Lotion**<br>Each gm contains:<br>Sodium pyrrolidone Carboxylate……....2.75%<br>Lactic acid……..5.70% | Evidence of approval in Reference regulatory authorities required from the firm |
| **6.** | 024757 | **Stiemazole Lotion**<br>Each gm contains:<br>Clotrimazole……..1% | MHRA, UK<br>Canestene 1 % w/v Solution by Byer plc |
| **7.** | 048074 | **Stieproxal Liquid**<br>Each gm contains:<br>Ciclopiroxolamine…15mg<br>Salicylic acid……30mg | Evidence of approval in Reference regulatory authorities required from the firm. |
| **8.** | 026392 | **Stieprox Liquid**<br>Each gm contains:<br>Cyclopirox Olamine...1.5% | Health Canada<br>Stieprox Shampoo (cicolpirox olamine 1.5%) |

**Details of M-274:** Above products were considered and approved by the Registration Board in its 250th meeting on contract manufacturing basis from M/s Akhai Pharma, Karachi vide letter No.F. 3-4/2015-Reg-II-(M-250), dated 15.10.2015 valid up to 30.06.2020.

**Decision of M-274:** *Registration Board was apprised that M/s GlaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi has now withdrawn their request for termination of contract manufacturing of the above mentioned products, which was acceded accordingly.*

**Details of M-287:** Then, the firm has requested for reconsideration of above request for transfer of registration of the subject products to their name with documents submitted previously.

**Decision of M-287:** *Registration Board deferred the case for submission of fresh application along with requisite fee for each product."*

**Detail of Current Submission:**

Now, the firm has submitted following documents/ details transfer of currently toll manufacturing products from M/s Akhai Pharma, Karachi to their own site, i.e., GSK 35-Dockyard Road, West Wharf, Karachi:

i. Fresh application on form-5 with its enclosures and 20,000/- fee for each product.
ii. Copy of Registration certificates and last renewal status.
iii. Section approval.
iv. Copy of last inspection report.
v. Undertaking that the applicant do not have registration of same products.
vi. Undertaking that the firm will conduct real time stability data.
vii. Undertaking that the firm will submit the validated method of analysis, master formula & product development data.
viii. Undertaking that in case of any quality complaint/OOS result observed as a result of change, same shall be reported to registration board immediately.
ix. Undertake that the provided information is true & correct.

**Decision: Registration Board deferred the case for submission of latest GMP inspection report of M/s GlaxoSmithKline Pakistan Ltd, Karachi.**

**Case No.32: Change of Brand Name of Products of M/s. High-Q Pharmaceuticals Karachi.**

M/s. High-Q Pharmaceuticals, B-64,KDA-1, Karachi Road, Karachi has requested for change of brand name of their following registered products. The details are as under:-

| *Sr. #* | *Regn. No.* | *Existing Name* | *Proposed Name* | *Initial Reg. with renewal* | *Justification* | *Remarks* |
|---|---|---|---|---|---|---|
| **I** | **II** | **III** | **IV** | **V** | **VI** | **VII** |
| 1. | 076201 | Velker Plus Tablet<br>Each film coated tablet contains:<br>Valsartan ……...160mg<br>Hydrochlorthiazide..25mg | Co-Velker | Date of registration 29-01-2014 | They want to interchange the brand name with their other brand name Co-Velker to avoid confusion in the market. | Dy# 36921 Date 07-11-18 |
| 2. | 076205 | Co-Velker Tablet<br>Each film coated tablet contains:-<br>Amlodipine as besylate…10mg<br>Valsartan……160mg | Velker Plus | -do- | They want to interchange the brand name with their other brand name Velker Plus to avoid confusion in the market. | Dy# 36917 Date 07-11-18 |
| 3. | 076207 | Velker Plus Tablet<br>Each film coated tablet contains:-<br>Valsartan …….80mg<br>Hydrochlorthiazide….12.5mg | Co-Velker | -do- | They want to interchange the brand name with their other brand name Co-Velker to avoid confusion in the market. | Dy# 36920 Date 07-11-18 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 4. | 076206 | Co-Velker Tablet<br>Each film coated tablet contains:-<br>Amlodipine as besylate……....5mg<br>Valsartan ……160mg | Velker Plus | -do- | They want to interchange the brand name with their other brand name Velker Plus to avoid confusion in the market. | Dy# 36918 Date 07-11-18 |
| 5. | 076210 | Velker Plus Tablet<br>Each film coated tablet contains:<br>Valsartan ……...160mg<br>Hydrochlorthiazide...12.5mg | Co-Velker | -do- | They want to interchange the brand name with their other brand name Co-Velker to avoid confusion in the market. | Dy# 36922 Date 07-11-18 |
| 6. | 076208 | Co-Velker Tablet<br>Each film coated tablet contains:-<br>Amlodipine as besylate……...5mg<br>Valsartan ……80mg | Velker Plus | -do- | They want to interchange the brand name with their other brand name Velker Plus to avoid confusion in the market. | Dy # 36919 Date07-11-18 |

The firm has submitted following has submitted following documents:

| ***Sr.#*** | ***Required documents*** | ***Submitted documents*** |
|---|---|---|
| **a.** | Application with required fee as per relevant SRO (in case of similarity / resemblance with already registered drug, fee will not be required) | Deposited fee of Rs.20,000/- |
| **b.** | Copy of registration letters & and renewal status | Copy of registration letter is not provided. |
| **c.** | Justification for proposed change. | Stated as above |
| **d.** | Information regarding previous change of brand name since registration of drug. | Provided |
| **e.** | Details (batch number, date of manufacture, quantity and stock position) regarding last batch manufactured | Provided. |
| **f.** | An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/similarity with already registered drug, the applicant will be liable to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter. | Provided |

*The Post Registration Variation Committee, in its 19th meeting, referred the case to the Registration Board.*

**Decision of M-287:**

*Registration Board deferred the case & directed the firm to submit rational justification regarding change in brand name."*

**Detail of Current Submission:**

Now the firm has given justification that the brand names of other firms already using the brand names for their products with same combination in the country. Furthermore we have duly deposited the required fees. It is also to mention here that to date we have neither manufactured nor market these products.

**Decision: Registration Board approved the change of brand names as follows: -**

i. **Products at S. No. 01, 03 & 05 from "Velker Plus" to "Co-Velker".**
ii. **Products at S. No. 02, 04 & 06 from "Co-Velker" to "Velker Plus".**

**Case No.33: Change of Address of Manufacturing Site of Their Registered Imported Product i.e. Omega Infusion (M/s. Ferozsons Laboratories Ltd., Nowshera).**

M/s Ferozsons Laboratories Ltd, Nowshera, has informed that the principal manufacturer Changzhou Siyao Pharmaceuticals Co, Ltd China of their registered product i.e., Omgea Infusion (Omperazole), registration number 029023, registration date 02-12-2002, has changed its manufacturing site abroad i.e. From: Meilongba, Southern Suburbs, Changzhou, Jiangsu, China to No. 567 Zhongwu Avenue, Changzhou, Jiangsu-China.

Firm has submitted following documents:

- Form 5-A.
- Original deposit slip of fee Rs.5000/- (Bank Receipt No.0788874 dated. 22-10-2018.)
- Copy of registration letter and last renewal status.
- Certificate of Pharmaceutical Product.
- Original and legalized GMP certificate.
- Summary drug information.
- Original Free Sale Certificate.
- Site master file of new manufacturing site.
- Undertaking that the provided information / documents are true / correct.

***Decision of 22nd meeting of PRVC:*** *-The chairman in the light of the recommendations made by the committee decided to refer the above mentioned case for next Registration Board."*

**Detail of Current Submission:**

Now the firm has submitted differential fee Rs. 95,000/- date 08-02-19.

**Decision: Registration Board deferred for confirmation whether case pertains to change in address or manufacturing site.**

**Case No. 34: Request for Post Registration Variations in Registered Product of M/s Martin Dow Limited, Karachi.**

M/s Martin Dow Limited, Karachi has requested for following post registration variations w.r.t. Xenical Capsule 120mg (042142), registered in the name of M/s Martin Dow Pharmaceuticals Limited, Karachi:

1. Change in name/ title of importer from M/s Martin Dow Pharmaceuticals Limited, Karachi to M/s Martin Dow Limited, Karachi (Manufacturing site remains the same).
2. Change in name of manufacturer from M/s Roche S.p.A. Milan, Segrate, Italy to M/s Delpharm Milano S.R.L. via Carnevale 1, 20090 Segrate (MI), Italy (As per CoPP site is also responsible for quality control, primary & secondary packaging).
3. Change in license holder from F. Hoffmann La Roche Ltd, Basel, Switzerland to Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald-Germany.

| Sr. | Reg. No. | Product Name &Composition | Datewith Dy. No. and fee |
|---|---|---|---|
| 1 | 042142 | **Xenical Capsule 120mg**<br>Each capsule contains:<br>Orlistat……120mg | 10-12-2018<br>Dy. 2506<br>Rs.100,000/- |

**Detail of documents submitted by the firm:**

a) Application on Form-5 with fee of Rs.100,000/-
b) Copy of registration letter (Issued date 22.12.2010) and last renewal status (Submitted on 22.06.2015).
c) Approval of new name / title from CLB.
d) Undertaking that:
   i. The formulation, API source & Specifications, manufacturing process, release & shelf life specifications have not changed.

ii. Provided information is true & correct.

e) Original and legalized Certificate of Pharmaceutical Product of Xenical Capsule (Certificate No. 04/18/122120, certified by EMA) indicating free sale in exporting country.
f) Original and legalized transfer agreement between Roche Switzerland and Cheplapharm-Arzneimittel GmbH-Germany.
g) Original and legalized copy of GMP certificate of Delpharm Milano S.R.L Italy.
h) Original and legalized copy of manufacturing License of Delpharm Milano S.R.L Italy (with English translation).
i) Revised Sole Agency Agreement between Cheplapharm-Arzneimittel GmbH-Germany and M/s Martin Dow Limited, Karachi dated 12-09-2018.
j) Agreement between Cheplapharm-Arzneimittel GmbH-Germany and Delpharm Milano S.R.L.
k) Proof/evidence of contract between Product License Holder & manufacturer (with changed/new name), where manufacturer and product license holder are different entities.

**Decision: Registration Board deferred the case for submission of original agency agreement of the applicant with Product License Holder as the manufacturer and product license holder are different entities.**

**Case No.35: Application for Change of Contract Manufacturing of Drug for Local Manufacturing Namely Esorok 40mg Injection, Pack Size: 1's.**

M/s Rakaposhi pharmaceutical (Pvt) Ltd. Peshawar, hereby apply for change of toll manufacturing for local manufacturing of our drug Esorok 40mg injection from M/s Weather folds Pharmaceuticals, 69/2, phase-II, industrial estate, Hattar to M/s Mediate pharmaceutical (Pvt) Ltd, 150-151, sector 24, Korangi Industrial area, Karachi.

**Detail of documents submitted by the firm:**

a). Application on Form-5 and Bank deposited slip number 0766246 dated 04.02.2019 for Rs.50,000/-(Fifty thousand only)
**b).** Registration letter of Esorok 40mg is attached (issued date 16.02.2018)
**c).** Agreement between M/s Rakaposhi pharmaceutical (Pvt) Ltd. Peshawar and M/s Mediate Pharmaceutica (Pvt) Ltd. 150-151, sector 24, Korangi Industrial area, Karachi.
**d).** Copy of DML and relevant section approval of M/s **M/s mediate** pharmaceutical (Pvt) Ltd, 150-151, sector 24, Korangi Industrial area, Karachi from Licensing Division.
**e).** Firm also submitted Undertaking statements as per SOP.
**f).** GMP inspection report conducted on 20.07.2018 with satisfactory level of compliance.

**Decision: Registration Board approved the request of M/s Rakaposhi Pharmaceutical (Pvt) Ltd. Peshawar, for contract manufacturing by M/s Mediate pharmaceutical (Pvt) Ltd, 150-151, sector 24, Korangi Industrial area Karachi, for production of "Esorok 40mg injection, pack size: 1's" with cancellation of contract manufacturing M/s Weather folds Pharmaceuticals, 69/2, phase-II, industrial estate, Hattar.**

**Case No.36: Change of Contract Manufacturer of Drug(s) of M/s. High-Q Pharmaceuticals, Karachi.**

***Previous Case History(M-286):***

M/s. High-Q Pharmaceuticals B 64, KDA-1, Karsaz Raod, Karachi has requested for change of contract manufacturer of following product from M/s. Nabiqasim Industries Pvt. Ltd, Karachi to M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore:-

| S.No. | Name of Drug(s) | Regn. No. |
|---|---|---|
| 1. | **Ruling 40mg I.V Injection**<br>Each vial contains:-<br>Omeprazole (as Sodium) ……. 40mg | 045616 |

**The firm has submitted following documents:**

i. Form-5 and Fee of Rs. 50,000/- (Duplicate)
ii. Contract agreement.
iii. Section Approval and GMP Certificate (dated 20-02-2018) of new manufacturer.
iv. Copy of initial letter of registration and the registration is valid till 30-06-2020.

***Decision:***
*Registration Board deferred the case for assessment and confirmation of manufacturing capacity of Injectable section of M/s English Pharmaceutical Industries, Lahore.*

**Detail of documents submitted by the firm:**

Now, the firm has submitted the panel inspection report of M/s English Pharmaceutical Industries, Lahore conducted on 18-01-2019, in response to letter no. F.3-9/2018 Reg-II (M-286) (Misc.), for the purpose of assesment and confirmation of manufacturing capacity for contract manufacturing of Omeprazole dry powder Injection wherein the panel of inspectors has reported as under:

- As per record the firm has manufactured 16 batches of different products to a total number of 127,490 vials during year 2018 with an average production of 1499 vials per day. Hence utilized capacity of the firm was about 4%.
- Firm has provided necessary equipment for carrying out the required QC testing of the products.

**Decision:** **Registration Board approved the request of M/s High- Q Pharmaceuticals, Karachi for contract manufacturing by M/s. English Pharmaceutical Industries, Lahore for production of Ruling 40mg I.V Injection [Each vial contains:- Omeprazole (as Sodium)… 40mg].**

**Case No.37: Transfer of registered products from previous site (I-10/3) to new site (National Industrial Zone, Chamber Industrial Area, Rawat, Rawalpindi) of M/s. Benson Pharmaceuticals:**

M/s Benson Pharmaceuticals, Islamabad have requested for transfer of registration of below mentioned products form their previous site i.e. Plot No. 119, Street No.8, I-10/3, Islamabad to new site Plot No. 3, Main Road, National Industrial Zone (Chamber Industrial Area) Rawat, Rawalpindi as per detailed below:-

| S. No. | Product for Registration with Generic Name | Reg. No. | Initial registration date | Renewal Status | Remarks |
|---|---|---|---|---|---|
| 1. | Benprol 40mg capsules<br>Each capsule contains:-<br>Esomeprazole Magnesium Trihydrate enteric coated pellets equivalent to Esomeprazole ……. 40mg<br>(Benson specs.) | 066247 | 12-10-2010 | 01-10-2015<br>23-11-2016 | **Source of pellets:**<br>M/s. Glenmark Generics, India<br><br>Official monograph of applied formulation exists in USP |
| 2. | Capzol 40mg capsules<br>Each capsule contains:-<br>Omeprazole enteric coated pellets eq. to Omeprazole…… 40mg<br>(USP Specifications) | 069867 | 06-04-2011 | 15-02-2016 | **Source of pellets:**<br>M/s. Titan Laboratories, India |
| 3. | Alerfree tablets<br>Each film coated tablet contains:-<br>Loratadine …….10mg | 024686 | 05-06-2002 | 08-05-2017 | Official monograph of applied formulation exists in USP. |
| 4. | Benalox 250mg tablets<br>Each film coated tablet contains:-<br>Levofloxacin (as hemihydrate) …….250mg<br>(BP Specs.) | 066560 | 08-11-2010 | 26-10-2015 | Official monograph of applied formulation exists in USP. |
| 5. | Benalox 500mg tablets<br>Each film coated tablet contains:-<br>Levofloxacin (as hemihydrate) ……..……500mg<br>(BP Specs.) | 066561 | 08-11-2010 | 26-10-2015 | Official monograph of applied formulation exists in USP and JP. |
| 6. | Benicef capsules 250mg<br>Each capsule contains:-<br>Cephradine as monohydrate ……250mg | 030458 | 11-06-2003 | 22-03-2018 | Official monograph of applied formulation exists in USP. |
| 7. | Benicef capsules 500mg<br>Each capsule contains:-<br>Cephradine as monohydrate …….500mg | 030459 | 11-06-2003 | 22-03-2018 | Official monograph of applied formulation exists in USP. |
| 8. | Benicef suspension 125mg<br>Each 5ml contains:-<br>Cephradine ……..125mg | 030460 | 11-06-2003 | 22-03-2018 | Official monograph of applied formulation exists in USP. |
| 9. | Benicef suspension 250mg<br>Each 5ml contains:-<br>Cephradine ……..250mg | 030461 | 11-06-2003 | 22-03-2018 | Official monograph of applied formulation exists in USP. |
| 10. | Benifime capsules<br>Each capsule contains:-<br>Cefixime Trihydrate eq. to Cefixime …….400mg | 001288-EX | 11-08-2009 | 19-06-2014 | Official monograph of applied formulation exists in JP. |
| 11. | Benifime suspension<br>Each 5ml contains:-<br>Cefixime Trihydrate eq. to Cefixime ……100mg | 001289-EX | 11-08-2009 | 19-06-2014 | Official monograph of applied formulation exists in USP. |

| | | | | | |
|---|---|---|---|---|---|
| 12. | Benifix DS Suspension<br>Each 5ml contains:-<br>Cefixime Trihydrate eq. to Cefixime……..…200mg<br>(USP Specs.) | 079512 | 01-06-2015 | 30-05-2020 | Official monograph of applied formulation exists in USP. |
| 13. | Benifix suspension<br>Each 5ml contains:-<br>Cefixime Trihydrate eq. to Cefixime ……100mg | 030463 | 11-06-2003 | 22-03-2018 | Official monograph of applied formulation exists in USP. |
| 14. | Benkast 4mg sachet<br>Each Sachet contains:<br>Montelukast as sodium……..…4mg | 091655 | 23-10-2018 | 22-10-2023 | Official monograph of applied formulation exists in USP and BP. |
| 15. | Benmether 40/240mg tablets<br>Each tablet contains:-<br>Artemether…….. 40mg<br>Lumefantrine …….240mg<br>(USP Salmous Specs.) | 077780 | 27-03-2014 | 26-03-2019 | Official monograph of applied formulation exists in Int. pharmacopoeia. |
| 16. | Benmether 80/480mg tablets<br>Each tablet contains:-<br>Artemether…….. 80mg<br>Lumefantrine ……..480mg<br>(USP Salmous Specs.) | 077781 | 27-03-2014 | 26-03-2019 | Official monograph of applied formulation exists in Int. pharmacopoeia. |
| 17. | Benmox tablets<br>Each film coated tablet contains:-<br>Moxifloxacin HCl eq. to Moxifloxacin …….. 400mg<br>(Benson Specification) | 079513 | 01-06-2015 | 30-05-2020 | Official monograph of applied formulation exists in USP. |
| 18. | Benmycin 250mg capsule<br>Each capsule contains:-<br>Azithromycin as dehydrate…250mg<br>(USP Specification) | 087387 | 19-02-2018 | 18-02-2023 | |
| 19. | Benprofen tablet 100mg<br>Each film coated tablet contains:-<br>Flurbiprofen…….. 100mg<br>(USP Specifications) | 062331 | 22-12-2009 | 11-11-2014 | |
| 20. | Benprol 20mg capsules<br>Each Capsule Contains:-<br>Esomeprazole Magnesium Trihydrate enteric coated pellets equivalent to esomeprazole …….20mg<br>(Benson Specs.) | 066246 | 12-10-2010 | 01-10-2015<br>23-11-2016 | Source M/s. Glenmark Generics limited, India to local M/s. Vision Pharmaceuticals, Islamabad.<br>Official monograph of applied formulation exists in USP. |
| 21. | Benroxim suspension 125mg<br>Each 5ml contains:-<br>Cefuroxime (as Axetil)……125mg<br>(USP Specification) | 056790 | 20-05-2009 | 03-04-2014 | |
| 22. | Bentoril 25mg tablets<br>Each tablet contains:<br>Captopril…… 25mg | 021571 | 02-05-1998 | 22-03-2018 | Official monograph of applied formulation exists in USP |
| 23. | Bentos-f chewable tablet<br>Each chewable tablet contains:-<br>Iron (III) hydroxide Polymaltos complex equivalent to elemental iron……..100mg<br>Folic Acid…….. 0.35mg<br>(Benson Specification) | 062334 | 22-12-2009<br>Brand name change (Ihpoc)<br>31-12-2010 | 05-11-2014 | Official monograph of applied formulation does not exist in any available editions of pharmacopoeia. |

| | | | | | |
|---|---|---|---|---|---|
| 24. | Bepsin tablets<br>Each film coated tablet contains:-<br>Famotidine ……20mg | 021569 | 02-05-1998 | 22-03-2018 | Official monograph of applied formulation exists in USP |
| 25. | Bepsin tablets 40mg<br>Each film coated tablet contains:-<br>Famotidine……. 40mg | 021570 | 02-05-1998 | 22-03-2018 | Official monograph of applied formulation exists in USP |
| 26. | Capzol 20mg capsules<br>Each capsule contains:-<br>Omeprazole enteric coated Pellets eq. to Omeprazole…….. 20mg<br>(USP Specs.) | 069866 | 06-04-2011 | 06-04-2021 (RRR Letter dated 24-01-2017) | Source M/s. Thexa Pharma, India to local M/s. Vision Pharmaceuticals, Islamabad |
| 27. | Cardi 50mg tablets<br>Each film coated tablet contains:-<br>Atenolol…….. 50mg | 021587 | 02-05-1998 | 22-03-2018 | Official monograph of applied formulation exists in USP |
| 28. | Domotin tablets<br>Each tablet contains:-<br>Domperidone as maleate..…10mg | 021591 | 02-05-1998 | 22-03-2018 | Official monograph of applied formulation exists in BP |
| 29. | Fluoxoben 12/25mg capsule<br>Each capsule contains:-<br>Olanzapine …….12mg<br>Fluoxetine as hydrochloride ……..25mg | 087388 | 19-02-2018 | 18-02-2023 | Official monograph of applied formulation exists in USP |
| 30. | Fobin 250mg tablets<br>Each tablet contains:-<br>Ciprofloxacin as HCl…. 250mg<br>(USP Specs.) | 066562 | 08-11-2010 | 26-10-2015 | |
| 31. | Fobin 500mg tablets<br>Each tablet contains:-<br>Ciprofloxacin as HCl… 500mg<br>(USP Specs.) | 066563 | 08-11-2010 | 26-10-2015 | |
| 32. | Gaboben 150mg capsule<br>Each capsule contains:-<br>Pregabalin ……150mg<br>(As per *Innovator's Specifications) | 087384 | 19-02-2018 | 18-02-2023 | |
| 33. | Gaboben 75mg capsule<br>Each capsule contains:-<br>Pregabalin……75mg<br>(As per *Innovator Specification) | 087385 | 19-02-2018 | 18-02-2023 | |
| 34. | Keygesic 75mg tablet<br>Each film coated tablet contains:-<br>Diclofenac potassium… 75mg | 021577 | 02-05-1998 | 27-03-2018 | |
| 35. | Keygesic tablet<br>Each film coated tablet contains:-<br>Diclofenac Potassium….. 50mg | 021576 | 02-05-1998 | 27-03-2018 | Official monograph of applied formulation exists in USP |
| 36. | Lovin tablets<br>Each tablet contains:<br>Clomiphene Citrate…… 50mg | 022541 | 26-11-1998 | 29-10-2018 | Official monograph of applied formulation exists in USP |
| 37. | Mebenzadole tablet<br>Each tablet contains:-<br>Mebendazole ……100mg | 025538 | 22-01-2000 | 16-12-2014 | Official monograph of applied formulation exists in USP |
| 38. | Piclo 20mg tablet<br>Each tablet contains:-<br>Piroxicam as beta cyclodextrin ……..……20mg<br>(Benson specification) | 079514 | 01-06-2015 | 30-05-2020 | Official monograph of applied formulation does not exist in any available editions of pharmacopoeia. |
| 39. | Tamsuben 0.4mg capsule<br>Each capsule contains:-<br>Tamsulosin hydrochloride sustained release pellets eq. To tamsulosin …….0.4mg | 088463 | 25-04-2018 | 24-04-2023 | Source:-<br>M/s. Vision Pharmaceuticals, Islamabad |

| | | | | | |
|---|---|---|---|---|---|
| | (USP Specification) | | | | |
| 40. | Zithben 250mg tablets<br>Each film coated tablet contains:-<br>Azithromycin as dihydrate<br>…….250mg<br>(USP Specs.) | 086129 | 18-12-2017 | 17-12-2022 | |
| 41. | Zithben 500mg tablets<br>Each film coated tablet contains:-<br>Azithromycin as dihydrate<br>……. 500mg<br>(USP Specifications) | 086130 | 18-12-2017 | 17-12-2022 | |
| 42. | Foliron tablet<br>Each film coated tablet contains:-<br>Ferrous Fumarate…..150mg<br>Folic Acid……..0.5mg | 024905 | 15-07-1999 | 30-05-2014 | Official monograph of applied formulation exists in BP |
| 43. | Bencetamol tablets 500mg<br>Each tablet contains:-<br>Paracetamol…….500mg | 033027 | 30-09-2009 | 12-08-2014 | Official monograph of applied formulation exists in USP |

The firm have provided following documents in support of their request as per approved SOP:

a) Application with form 5 and requirement fee amounting to Rs.100,000/- sr. no. 1 & 2.
b) Application with form 5 and requirement fee amounting to Rs.20,000/-.
c) Copy of registration letter and renewal.
d) Evidence of Section as revealed by the GMP certificate (Tablet General, Capsule General, General Sachet powder, Dry Powder Suspension (Cephalosporin), Capsule Section (Cephalosporin)
e) DML of new site issued on 08-01-2019.
f) Copy of last inspection report: N/A as it is a new manufacturing facility.

**Decision:** **Registration Board considered request of M/s Benson Pharmaceuticals, Plot No. 119, Street No.8, I-10/3, Islamabad for registration of their products from Plot No. 119, Street No.8, I-10/3, Islamabad to new site Plot No. 3, Main Road, National Industrial Zone (Chamber Industrial Area) Rawat, Rawalpindi as per following details:-**

i. **Approved the above product at Sr. No. 1-7, 9-33, 35-43 with finished product specifications mentioned in the last coloumn against each.**
ii. **Deferred the above product at Sr. No. 8 for evidence of availability in RRA.**
iii. **Rejected the above product at Sr. No. 34 since the applied formulation is not approved in any of the RRAs as adopted by Registration Board.**

**Case No.38: Change in Contract Manufacturer from M/s Bio-Labs (Pvt.) Limited, Islamabad to M/s Nicholas Pharmaceuticals, Rawat, Islamabad.**

M/s. Caliph Pharmaceuticals (Pvt.) Ltd, Risalpur, KPK have requested for change in contract manufacturer from M/s Bio-Labs (Pvt.) Ltd, Islamabad to M/s Nicholas Pharmaceuticals, Rawat, Islamabad for the following registered products. Their previous approval was granted by the Registration Board in its 271st meeting dated 10th November, 2017 valid for **five years** from the date of issuance as per detailed below:-

| S. No. | Name of Applicant | Existing Manufacturer | New Manufacturer | Reg. No. | Name of drug(s) & Composition | Date of application, Diary No. & Form | Initial registration date and validity |
|---|---|---|---|---|---|---|---|
| 1. | M/s. Caliph Pharmaceuticals, Plot no. 17, Special Industrial Zone, | M/s. Bio-Labs (Pvt) Limited, Plot # 145, Industrial | M/s. Nicholas Pharmaceuticals, Plot No. 34, street no. SS-2, National | 082560 | Grancef Dry Suspension 100mg/5ml<br>Each 5ml contains:-<br>Cefixime (as trihydrate)<br>……..…..100mg | 12-10-2018<br>Dy.No.81<br>DDC Reg-IV<br>Rs.50,000/= | 10-11-2017 valid for **five years** from the date of issuance |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Raisalpur, KPK | triangle, Kahuta Road, Islamabad | Industrial Zone, Rawat Islamabad | | (USP Specifications) | | |
| 2. | -do- | -do- | -do- | 082561 | Grancef Dry Suspension 200mg/5ml<br>Each 5ml contains:-<br>Cefixime (as trihydrate) …..…..200mg<br>(USP Specifications) | 15-10-2018<br>Dy.No.82<br>DDC Reg-IV<br>Rs.50,000/= | 10-11-2017<br>valid for **five years** from the date of issuance |
| 3. | -do- | -do- | -do- | 082555 | Unixone injection 1g IV<br>Each vial contains:-<br>Ceftriaxone Sodium<br>Equivalent to Ceftriaxone ……...1gm<br>(USP Specifications) | 15-10-2018<br>Dy. #80 DDC<br>Reg-IV<br>Rs. 50,000/- | 13-10-2017<br>valid for **five years** from the date of issuance |
| 4. | -do- | -do- | -do- | 082556 | Unixone injection 250mg IM<br>Each vial contains:-<br>Ceftriaxone Sodium<br>Equivalent to Ceftriaxone ……..250mg<br>(USP Specifications) | 15-10-2018<br>Dy. #78 DDC<br>Reg-IV<br>Rs. 50,000/- | 13-10-2017<br>valid for **five years** from the date of issuance |
| 5. | -do- | -do- | -do- | 082557 | Unixone injection 500mg IM<br>Each vial contains:-<br>Ceftriaxone Sodium<br>Equivalent to Ceftriaxone …….500mg<br>(USP Specifications) | 15-10-2018<br>Dy. #79 DDC<br>Reg-IV<br>Rs. 50,000/- | 13-10-2017<br>valid for **five years** from the date of issuance |
| 6. | -do- | -do- | -do- | 085919 | Grancef Capsule 400mg<br>Each Capsule contains:-<br>Cefixime (as trihydrate)……..…..400mg<br>(JP Specifications) | 15-10-2018<br>Dy. #83 DDC<br>Reg-IV<br>Rs. 50,000/- | 27-11-2017<br>valid for **five years** from the date of issuance |

Firm has submitted following documents in this regard:

i. Application/Form 5 along with fee of Rs.50,000/- for each product.
ii. Copy of contract manufacturing agreement between M/s. Caliph Pharmaceuticals, Risalpur and M/s. Nicholas Pharmaceuticals, Islamabad dated 24-09-2018.
iii. Panel GMP inspection report of M/s Nicholas Pharmaceuticals, Islamabad (dated 03rd August, 2018) concluding that panel unanimously recommended grant of DML.
iv. DML of both contract giver (06-11-2018) and acceptor (29-08-2018).
v. NOC from Existing manufacturing i.e. M/s. Bio-Labs, Islamabad.
vi. Copy of letter for Approval of Cephalosporin (Capsule) Section, Cephalosporin (Dry Suspension) and Cephalosporin (Injection) Section, (M/s Nicholas Pharmaceuticals, Rawat, Islamabad).
vii. Undertaking as per SOPs.

**Decision:** **Registration Board acceded to the request of M/s. Caliph Pharmaceuticals (Pvt) Limited, Risalpur, KPK for change in contract manufacturer from M/s. Bio-Labs (Pvt) Limited, Plot # 145, Industrial triangle, Kahuta Road, Islamabad to M/s. Nicholas Pharmaceuticals, Plot No. 34, street no. SS-2, National Industrial Zone, Rawat Islamabad is at same terms and shall not be considered towards extension/renewal of products.**

**Case No.39: Change in Specifications (M/s. Aurik Pharmaceuticals, Islamabad).**

M/s. Aurik Pharmaceuticals, Islamabad have requested for change in finished product specification of their following registered products as per details below:-

| S.No. | Reg.No. | Name of Drug(s) with Composition and Approved Specifications | Name of Drug(s) with Composition with Proposed Specifications |
|---|---|---|---|
| 1. | 078051 | Aurofloc tablet 250mg<br>Each film coated tablet contains:-<br>Levoflocacin Hemihydrate eq. to Levofloxacin…….250mg<br>(Aurik Specifications) | Aurofloc tablet 250mg<br>Each film coated tablet contains:-<br>Levoflocacin Hemihydrate eq. to Levofloxacin…….250mg<br>(USP Specifications) |
| 2. | 078052 | Aurofloc tablet 500mg<br>Each film coated tablet contains:-<br>Levoflocacin Hemihydrate eq. to Levofloxacin…….500mg<br>(Aurik Specifications) | Aurofloc tablet 500mg<br>Each film coated tablet contains:-<br>Levoflocacin Hemihydrate eq. to Levofloxacin…….500mg<br>(USP Specifications) |
| 3. | 078054 | Cipaur tablet 500mg<br>Each film coated tablet contains:-<br>Ciprofloxacin Hydrochloride eq. to Ciprofloxacin ……500mg<br>(BP Specifications) | Cipaur tablet 500mg<br>Each film coated tablet contains:-<br>Ciprofloxacin Hydrochloride eq. to Ciprofloxacin ……500mg<br>(USP Specifications) |
| 4 | 078048 | Airon tablet 10mg<br>Each film coated tablet contains:-<br>Montelukast sodium eq. to Montelukast ……10mg<br>(Aurik Specifications) | Airon tablet 10mg<br>Each film coated tablet contains:-<br>Montelukast sodium eq. to Montelukast ……10mg<br>(USP Specifications) |
| 5. | 078053 | Moxrik tablet 400mg<br>Each tablet contains:-<br>Moxifloxacin ……..400mg<br>(Aurik Specifications) | Moxrik tablet 400mg<br>Each **film coated** tablet contains:-<br>Moxifloxacin HCl eq. to. Moxifloxacin ……..400mg<br>(USP Specifications) |
| 6 | 078055 | Pext Tab 20mg tablet<br>Each film coated tablet contains:-<br>Paroxetine (as hydrochloride)…….20mg<br>(BP Specifications) | Pext Tab 20mg tablet<br>Each film coated tablet contains:-<br>Paroxetine (as hydrochloride)…….20mg<br>(USP Specifications) |
| 7 | 080545 | Pext-CR 12.5mg tablet<br>Each SR tablet contains:-<br>Paroxetine hydrochloride eq. to Paroxetine……...12.5mg<br>(Manufacturer's Specifications) | Pext-CR 12.5mg tablet<br>Each SR tablet contains:-<br>Paroxetine hydrochloride eq. to Paroxetine……...12.5mg<br>(USP Specifications) |

The details of requirement as per SOPs and the documents submitted by the firm are as under:-

| Requirement as per SOPs | Documents submitted by the Firm. |
|---|---|
| Application with required fee as per relevant SRO. If error is on part of firm. | Fee of Rs.5000/- deposited for each product dated 30-01-2019 |
| Copy of registration letter and renewal status. | Initial Registration: 05-11-2014 (at Sr. No. 1-4)<br>Renewal due: 04-11-2019<br>Renewal is Ok<br>Initial Registration: 13-09-2018 (at Sr. No. 5)<br>Renewal due: 12-09-2023<br>Renewal is Ok.<br>Initial Registration: 12-05-2016 (at Sr. No. 6)<br>Renewal due: 11-05-2021<br>Renewal is Ok.<br>Initial Registration: 22-04-2016 (at Sr. No. 7)<br>Renewal due: 21-04-2021<br>Renewal is Ok. |
| Documents in support of proposed correction | The firm has provided copy of USP monograph for product. The product at Sr. No. 5 is approved by USFDA as film coated tablet. |

Now, the firm has requested for approval of finished product specifications of above product to "USP".

The firm has submitted an undertaking that:-

i. The change is made exclusively to comply with the pharmacopeia of RRA or as per innovator product specifications.
ii. No case is pending at any forum/court of law regarding this product.
iii. In case of any quality complain/OOS result of observed by the marketing authorization holder as a result of this change, the same shall be reported to Registration Board and all the stock shall be recalled from the market immediately.
iv. The provided information/documents are true and correct.

**Decision: Registration Board approved the correction in dosage form of above product from uncoated tablet to "film coated tablet" at Sr. No. 5 and approved finished product specifications of above products i.e. USP Specifications.**

**Case No. 40: Change in specifications (M/s. Fynk Pharmaceuticals, Lahore)**

M/s. Fynk Pharmaceuticals, Lahore have requested for change in finished product specification of their following registered products as per details below:-

| S.No. | Reg.No. | Name of drug(s), Composition and Specifications | Name of drug(s), Composition with desired Specifications |
|---|---|---|---|
| 1. | 038512 | Lurk 250mg tablet<br>Each tablet contains:-<br>Levofloxacin (as Hemihydrate)….250mg | Lurk 250mg tablet<br>Each **film coated** tablet contains:-<br>Levofloxacin (as Hemihydrate)….250mg<br>(USP Specifications) |
| 2 | 038513 | Lurk 500mg tablet<br>Each tablet contains:-<br>Levofloxacin (as Hemihydrate)….500mg | Lurk 500mg tablet<br>Each **film coated** tablet contains:-<br>Levofloxacin (as Hemihydrate)….500mg<br>(USP Specifications) |

The details of requirement as per SOPs and the documents submitted by the firm are as under:-

| Requirement as per SOPs | Documents submitted by the Firm. |
|---|---|
| Application with required fee as per relevant SRO. If error is on part of firm. | Fee of Rs.5000/- deposited for each product dated 31-01-2019 |
| Copy of registration letter and renewal status. | Initial Registration: 27-05-2005<br>Renewal valid till 26-05-2020 vide letter No. 2-1/ 2017-RRR (M-264) dated 28-04-2017<br>Renewal is Ok |
| Documents in support of proposed correction | The firm has provided copy of USP monograph for product. The product is approved by MHRA as film coated tablet. |

Now, the firm has requested for approval of finished product specifications of above product to "USP".

The firm has submitted an undertaking that:-

i. The change is made exclusively to comply with the pharmacopeia of RRA or as per innovator product specifications.
ii. No case is pending at any forum/court of law regarding this product.
iii. In case of any quality complain/OOS result of observed by the marketing authorization holder as a result of this change, the same shall be reported to Registration Board and all the stock shall be recalled from the market immediately.
iv. The provided information/documents are true and correct.

**Decision:** **Registration Board approved the correction in dosage form of above product from uncoated tablet to "film coated tablet" and approved finished product specifications of above products i.e. USP Specifications.**

**Case No.41: Change in specifications (M/s. Focus & Rulz Pharmaceuticals, Islamabad)**

M/s. Focus & Rulz Pharmaceuticals (Pvt.) Limited, Islamabad have requested for change in finished product specification of their following registered products as per details below:-

| S.No. | Reg.No. | Name of drug(s), Composition and Specifications | Name of drug(s), Composition with desired Specifications |
|---|---|---|---|
| 1. | 011003 | Ulfam tablet 20mg<br>Each tablet contains:-<br>Famotidine…….20mg | Ulfam tablet 20mg<br>Each tablet contains:-<br>Famotidine…….20mg<br>**(USP Specifications)** |
| 2. | 011004 | Ulfam tablet 40mg<br>Each tablet contains:-<br>Famotidine…….40mg | Ulfam tablet 40mg<br>Each tablet contains:-<br>Famotidine…….40mg<br>**(USP Specifications)** |

The details of requirement as per SOPs and the documents submitted by the firm are as under:-

| Requirement as per SOPs | Documents submitted by the Firm. |
|---|---|
| Application with required fee as per relevant SRO. If error is on part of firm. | Fee of Rs.5000/- for each product, deposited dated 07-12-2016 |
| Copy of registration letter and renewal status. | Initial Registration: 15-09-2009<br>Renewal due: 14-09-2014<br>Renewal applied: 16-09-2014<br>Renewal is Ok. |
| Documents in support of proposed correction | The firm has provided copy of USP monograph for product. |

Now, the firm has requested for approval of finished product specifications of above product to "USP".

The firm has submitted an undertaking that:-

i. The change is made exclusively to comply with the pharmacopeia of RRA or as per innovator product specifications.
ii. No case is pending at any forum/court of law regarding this product.
iii. In case of any quality complain/OOS result of observed by the marketing authorization holder as a result of this change, the same shall be reported to Registration Board and all the stock shall be recalled from the market immediately.
iv. The provided information/documents are true and correct.

**Decision:** **Registration Board approved finished product specifications of above products i.e. USP Specifications.**

**Case No.42: Change in specifications (M/s. Innvotek Pharmaceuticals, Islamabad)**

M/s. Innvotek Pharmaceuticals, Islamabad have requested for change in finished product specification of their following registered products as per details below:-

| S.No. | Reg.No. | Name of drug(s), Composition and Specifications | Name of drug(s), Composition with desired Specifications |
|---|---|---|---|
| 1. | 094169 | Delot tablet 5mg<br>Each film coated tablet contains:-<br>Desloratadine……..5mg<br>(As per *innovator's Specification) | Delot tablet 5mg<br>Each film coated tablet contains:-<br>Desloratadine……..5mg<br>**(USP Specification)** |

The details of requirement as per SOPs and the documents submitted by the firm are as under:-

| Requirement as per SOPs | Documents submitted by the Firm. |
|---|---|
| Application with required fee as per relevant SRO. If error is on part of firm. | Fee of Rs.5000/- deposited dated 16-01-2019 |
| Copy of registration letter and renewal status. | Initial Registration: 24-12-2018<br>Renewal due: 23-12-2023<br>Renewal is Ok. |
| Documents in support of proposed correction | The firm has provided copy of USP monograph for product. |

Now, the firm has requested for approval of finished product specifications of above product to "USP".

The firm has submitted an undertaking that:-

i. The change is made exclusively to comply with the pharmacopeia of RRA or as per innovator product specifications.
ii. No case is pending at any forum/court of law regarding this product.
iii. In case of any quality complain/OOS result of observed by the marketing authorization holder as a result of this change, the same shall be reported to Registration Board and all the stock shall be recalled from the market immediately.
iv. The provided information/documents are true and correct.

**Decision: Registration Board approved finished product specifications of above products i.e. USP Specifications.**

**Case No.43: Grant of Registration of M/s. Bayer Pakistan (Pvt.) Ltd, Lahore (Formerly M/s. Medipharm (Pvt.) Ltd, Lahore at New Manufacturer title.**

M/s. Bayer Pakistan (Pvt.) Ltd, Lahore (Formerly M/s. Medipharm (Pvt.) Ltd, Lahore) has requested for grant of registration of below mentioned product at new manufacturer title i.e. M/s. Bayer Pakistan (Pvt.) Ltd, Lahore as per detailed below:-

| Sr No. | Reg. No. | Name of Product and composition | Remarks |
|---|---|---|---|
| 1. | 019520 | Microgynon ED Fe tablet<br>Each coated tablet contains:-<br>Levonorgestrel Micro 20 = 0.150mg<br>Ethinyl estradiol Micro 20 = 0.030mg<br>Each placebo sugar coated tablet contains:-<br>Ferrous fumarate = 75.000mg | The composition mentioned in submitted copy of COPP (stamped and dated 24-10-2012) is different from the applied formulation. |

The firm has submitted following documents.

i. Application with fee of Rs.100,000/- Form-5.
ii. Copy of Registration letters with renewal status.
iii. Copy of new title of firm from CLB.
iv. M/s. Medipharm (Pvt) Limited, Change of Brand Name product Nova tablet to "**Microgynon ED Fe**" vide Letter No. 5-110/2013 Reg.-V dated 09-11-2016.

**Decision: Registration Board deferred the request of firm since the composition mentioned on CoPP is different from the applied formulation and submission of undertaking as per SOPs approved in 283rd Meeting of RB.**

**Case No 44: Change in specifications of M/s. Winlet Pharmaceuticals, Sargodha**

M/s. **Winlet** Pharmaceuticals, Sargodha have requested for change in specifications of their following registered product with details below:-

| | Reg. No. | Name of drug(s) with formulation | Desired specifications |
|---|---|---|---|
| 1. | 092038 | Rocxi Tablet 20mg<br>Each tablet contains:-<br>Piroxicam as (beta-cyclodextrin)……20mg<br>(USP Specification) | Rocxi Tablet 20mg<br>Each tablet contains:-<br>Piroxicam as (beta-cyclodextrin)……20mg<br>(As per Innovator's Specification) |

The details of requirements as per SOP's and the documents submitted by the firm are as under:-

| Requirement as per SOPs | Documents submitted by the Firm. |
|---|---|
| Application with required fee as per relevant SRO. If error is on part of firm. | Fee Rs.5000/- dated 02-01-2019<br>(Pages 388-389/C) |
| Copy of registration letter and renewal status. | Copy of Registration letter dated 08-10-2018 (Page 393-398/C)<br>Last renewal due: 07-10-2023<br>Renewal is not required |
| Documents in support of proposed correction | The product is not available in any pharmacopoeia. Firm has applied with manufacturer's specifications but approved with USP specifications in 282nd meeting of RB. |

**Decision: Registration Board approved finished product specifications of above product i.e. As per Innovator's Specification.**

**Case No 45: Change in specifications of M/s. Quaper Pharmaceuticals, Sargodha**

M/s. Quaper Pharmaceuticals, Sargodha have requested for change in specifications of their following registered product with details below:

| S. No. | Reg. No. | Name of drug(s) with formulation | Desired specifications |
|---|---|---|---|
| 1. | 048927 | Quvin 250mg<br>Each tablet contains:-<br>Levofloxacin……..250mg<br>(Quaper's Specs.) | Quvin 250mg<br>Each tablet contains:-<br>Levofloxacin……..250mg<br>**(USP Specs.)** |
| 2. | 048928 | Quvin 500mg<br>Each tablet contains:-<br>Levofloxacin……..500mg<br>(Quaper's Specs.) | Quvin 500mg<br>Each tablet contains:-<br>Levofloxacin……..500mg<br>**(USP Specs.)** |

The details of requirements as per SOP's and the documents submitted by the firm are as under:-

| Requirement as per SOPs | Documents submitted by the Firm. |
|---|---|
| Application with required fee as per relevant SRO. If error is on part of firm. | Fee Rs.5000/- only dated 28-11-2018<br>(Pages 310-311/C) |
| Copy of registration letter and renewal status. | Copy of Registration letter dated 06-02-2008 (Page 312-314/C)<br><br>Last renewal due: 05-02-2018<br>Last Renewal applied: 08-01-2018 (page 316/C) |
| Documents in support of proposed correction | The firm has provided copy of USP monograph for product. The product is approved by MHRA as **film coated tablet**. |

**Decision: Registration Board approved the correction in dosage form of above product from uncoated tablet to "film coated tablet" and approved finished product specifications of above products i.e. USP Specifications.**

**Case No. 46: Cases for Correction in Registration/Approval Letter.**

Following firms applied for correction in registration letter regarding address of manufacturing sites as per DML.

**a. M/s. Medizan Laboratories (Pvt.) Limited**

M/s. Medizan Laboratories (Pvt) Limited, Islamabad have requested for correction of address in letters issued by DRAP as per following details.

| Sr # | Letter Ref. No | Date |
|---|---|---|
| 1. | F.11-24/2005-Reg-II(North) | 08-07-2013 |
| 2. | F.11-24/2006-Reg-II(North) Vol-II | 07-05-2011 |
| 3. | F.11-24/2006-Reg-II(North) Vol-II | 02-11-2010 |
| 4. | F. 8-7/2016 Reg-III (M-262) | 26-11-2017 |
| 5. | F. 8-8/2016 Reg-III (M-263) | 26-04-2017 |
| 6. | F. 14-5/2018 Reg.III (PRVC-05) | 19-03-2018. |

The firm has submitted that the letters are issued with address as M/s. Medizan Laboratories, Plot# 313, Industrial Triangle Kahuta Road, Islamabad while correct address mentioned on DML is M/s. Medizan Laboratories (Pvt.) Limited, Plot # 313, Industrial Triangle Kahuta Road, Islamabad.

The firm has submitted following documents:

i. Copies of above letter
ii. Copy of DML valid at the time of issuance of letters
iii. Renewal of DML dated 11-05-2015

**Decision: Registration Board acceded to the request of firm.**

**b. M/s. Honig Pharmaceuticals Laboratories, Rawalpindi**

M/s. Honig Pharmaceuticals Laboratories, Rawalpindi have requested for correction of address in letters issued by DRAP as per following details.

| Sr # | Letter Ref. No | Date |
|---|---|---|
| 1. | No. F. 3-4/2004 Reg-II (M-186) | 09-02-2005 |
| 2. | No. F. 3-4/2004 Reg-II (M-186) | 03-05-2007 |
| 3. | No. F. 3-4/2004 Reg-II (M-186) | 10-11-2004 |
| 4. | No. F. 3-4/2004 Reg-II (M-186) | 02-12-2004 |
| 5. | No. F. 8-7/2017 Reg-III (M-271) | 17-10-2017 |
| 6. | No. F. 8-10/2017 Reg-III (M-274) | 27-12-2017 |
| 7. | No. F. 14-8/2018 Reg-III (PRVC-09) | 26-06-2018 |

The firm has submitted that the letters are issued with following address:

M/s. Honig Pharmaceuticals, 14th km, Adayala Road, Rawalpindi while the correct address mentioned on DML is M/s. Honig Pharmaceutical Laboratories, 14 km, Adayala Road, Rawalpindi

The firm has submitted following documents:

i. Copies of above letter
*ii.* Copy of DML valid at the time of issuance of letters dated 28-08-2004

**Decision: Registration Board acceded to the request of firm.**

**c. M/s. Bio-Labs, Islamabad**

M/s. Bio-Labs, Rawalpindi have requested for correction of address in letters issued by DRAP as per following details.

| Sr # | Letter Ref. No | Date |
|---|---|---|
| 2 | F. No. 13-8/2007 Reg-II (M-205) | 07-05-2007 |

The firm has submitted that the letters are issued with following address:
M/s. Bio-Labs (Pvt) Limited. 7, 2nd Floor, Allied Plaza, Chandni Chowk, Murree Road, Rawalpindi while the correct address mentioned on DML is M/s. Bio-Labs, (Pvt.), Limited, Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad

The firm has submitted following documents:
i. Copy of above letter
ii. Copy of DML valid at the time of issuance of letters

**Decision: Registration Board acceded to the request of firm.**

**d. M/s. Agror Pharma, Islamabad**

M/s. Agror Pharma, Islamabad have requested for correction of address in letters issued by DRAP as per following details:

| Sr # | Letter Ref. No | Date |
|---|---|---|
| 1. | No. F. 8-2/2014 Reg-III (M-243) | 18-06-2014 |

The firm has submitted that the letters are issued with following address:

M/s. Agror Pharma, plot No. 4, street SS-4, national Industrial Zone, Rawat while the correct address mentioned on DML is M/s. Agror Pharma (Pvt.) Limited, plot No. 4, street SS4, National Industrial Zone, Rawat, Rawalpindi

The firm has submitted following documents:
i. Initial Reg. letter no. 18-06-2014
*ii.* Copy of DML valid at the time of issuance of letters

**Decision: Registration Board acceded to the request of firm.**

**e. M/s. Ipram International, Islamabad**

M/s. Ipram International, Islamabad have requested for correction of address in letters issued by DRAP as per following details.

| Sr # | Letter Ref. No | Date |
|---|---|---|
| 1. | No. F. 8-6/2017 Reg-III (M-270) | 26-09-2017 |

The firm has submitted that the letters are issued with following address:-

M/s. Ipram International Pharmaceuticals, Plot No. 26, Street no/ S.S-3, National Industrial Zone (RCCI), Rawat, Islamabad while the correct address mentioned on DML is M/s. Ipram International, Plot No. 26, Street no. S.S-3, National Industrial Zone, Rawat, Rawalpindi

The firm has submitted following documents:
i. Initial Reg. letter no. 26-09-2017
ii. Copy of DML valid at the time of issuance of letters

**Decision: Registration Board acceded to the request of firm.**

**f. M/s Fredmann Pharmaceuticals Pvt. Limited, Mirpur, Azad Kashmir**

M/s. Fredmann Pharmaceuticals Pvt. Limited, Mirpur Azad Kashmir have requested for correction of address in letters issued by DRAP as per following details.

| Sr # | Letter Ref. No. | Date |
|---|---|---|
| 1. | No. F. 8-2/2018 Reg-III (M-278) | 21-05-2018 |
| 2. | No. F. 8-3/2018 Reg-III (M-279) | 25-06-2018 |
| 3. | No. F. 8-3/2018 Reg-III (M-279) | 09-07-2018 |
| 4. | No. F. 8-5/2018 Reg-III (M-281) | 26-06-2018 |

The firm has submitted that the letters are issued with following address:

M/s. Fredmann Pharmaceuticals, Plot No. 82 & 83-B, old industrial Area, Mirpur, Azad Kashmir while the correct address mentioned on DML is M/s. Fredmann Pharmaceuticals Pvt. Limited, Plot No. 82/83-B, Old industrial Area, Mirpur, Azad Kashmir

The firm has submitted following documents:

i. Initial Reg. letter No.
ii. Copy of DML valid at the time 21-12-2012
iii. Renewal of Applied dated 10-01-2018

**Decision: Registration Board acceded to the request of firm.**

**g. M/s. Bio-Labs, Islamabad**

M/s. Bio-Labs, Rawalpindi have requested for correction of address in letters issued by DRAP as per following details.

| Sr # | Letter Ref. No | Date |
|---|---|---|
| 1. | F. No. 13-8/2007 Reg-II (M-205) | 26-04-2007 |
| 2. | F. No. 13-8/2007 Reg-II (M-205) | 05-05-2007 |

The firm has submitted that the letters are issued with following address:

M/s. Bio-Labs (Pvt) Limited. 7, 2nd Floor, Allied Plaza, Chandni Chowk, Murree Road, Rawalpindi While the correct address mentioned on DML is M/s. Bio-Labs, (Pvt.), Limited, Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad

The firm has submitted following documents:

i. Fee Rs. 5000/- for each letter
ii. Copies of above letter
iii. Copy of DML valid at the time of issuance of letters

**Decision: Registration Board acceded to the request of firm.**

**h. M/s. Webros Pharmaceuticals, Islamabad.**

M/s. Webros Pharmaceuticals, Islamabad have requested for correction of address in letters issued by DRAP as per following detail.

| Sr # | Letter Ref. No | Date |
|---|---|---|
| 1. | No. F. 3-1/2004 Reg-II (M-182) | 21-05-2018 |

The firm has submitted that the letters are issued with following address:

M/s. Webros Pharmaceuticals, Plot # 1, Street No. S-9, RCCI, Industrial Estate Islamabad while the correct address mentioned on DML is M/s. M/s. Webros Pharmaceuticals, Plot # 1, Street No.10, RCCI, Industrial Estate Islamabad.

The firm has submitted following documents:

i. Initial Reg. letter
ii. Copy of DML valid at the time 01-04-2004
iii. Renewal of Applied dated 10-01-2018

**Decision: Registration Board acceded to the request of firm. The Board further authorized Chairman for correction in address in registration letter as per DML applicable at that time**

## COMPLETE CASES

### a. Locally Manufactured Registered Drugs (Human).

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

| Sr. No | Reg. No. | Brand Name, Composition & Specification | Initial date of Registration | Date of application (R&I) Fee submitted | Renewal validity | Decision |
|---|---|---|---|---|---|---|
| i. | **M/s Adamjee Pharmaceuticals, Plot No. 39, Sector 15, Korangi Industrial Area, Karachi.** | | | | | |
| 1. | 048757 | Arfacobal Tablet<br>Each Tablet Contains:<br>Mecobalamin…500mcg | 18-07-2008 | Dy. No. 20291 dated 05-6-2018<br>20000/- | 17-7-2023 | w.e.f. 18-7-2018 to 17-7-2023 as per description of innovator brand. |
| ii. | **M/s. AGP Limited, B-23-C, S.I.T.E., Karachi.** | | | | | |
| 2. | 048800 | QTP 100mg Tablet<br>Each Tablet Contains:<br>Quetiapine Fumarate eq. to Quetiapine …100mg | 21-07-2008 | Dy. No. 21871 dated 22-06-2018<br>10,000/- | 20-7-2023 | w.e.f. 21-7-2018 to 20-7-2023. |
| 3. | 048801 | QTP 200mg Tablet<br>Each tablet contains:<br>Quetiapine Fumarate eq. to Quetiapine …..200mg | 21-07-2008 | Dy. No. 21871 dated 22-06-2018<br>10,000/- | 20-7-2023 | w.e.f. 21-7-2018 to 20-7-2023. |
| 4. | 048719 | QTP 25mg Tablet<br>Each tablet contains:<br>Quetiapine Fumarate eq. to Quetiapine …..25mg | 16-07-2008 | Dy. No. 21869 dated 22-06-2018<br>10,000/- | 15-7-2023 | w.e.f. 16-7-2018 to 15-7-2023 |
| 5. | 014888 | Dolofen Cream<br>Each 100gm contains:<br>Ibuprofen B.P …..100gm | 24-02-1994<br>Transfer of registration 17-7-2008 | Dy. No. 21854 dated 22-6-18<br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 6. | 015107 | Oslin Injection<br>Each ml contains:<br>Lincomycin HCl equivalent to 300mg Lincomycin base | 05-03-1994<br>Transfer of registration dated: 17-7-2008 | Dy. No. 21855 dated 22-6-18<br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 7. | 014885 | Afiten Syrup<br>Each ml contains:<br>Ketotifen…..1mg | 24-02-1994<br>Transfer of registration 17-7-2008 | Dy. No. 21859 dated 22-6-18<br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 8. | 014886 | Afiten Syrup<br>Each ml contains:<br>Ketotifen…..0.2mg | 24-02-1994<br>Transfer of registration dated: 17-7-2008 | Dy. No. 21860 dated 22-6-18<br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 9. | 014242 | Gluconorm Tablet<br>Each tablet contains:<br>Gliclazide…..80mg | 05-08-1993<br>Transfer of registration dated: 17-7-2008 | Dy. No. 21846 dated 22-6-2018<br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 10. | 021625 | Lidocaine 1% Injection | 20-05-1998<br>Transfer of registration dated 17-7-2008 | Dy. No. 21845 dated 22-6-2018<br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |

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| 11. | 022992 | Neuroptal Injection<br>Each ml contains:<br>Thiamine HCl.100mg<br>Pyridoxine HCl..100mg<br>Cyanocobalamin<br>…….100mcg | 11-02-1999<br><br>Transfer of registration dated 17-7-2008 | Dy. No. 21844 dated 22-6-2018<br><br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 12. | 048717 | Esi-dep 10mg Tablets<br>Each tablet contains:<br>Escitalopram (as oxalate)….10mg | 16-07-2008 | Dy. No. 21857 dated 22-6-2018 | 15-7-2023 | w.e.f. 16-7-2018 to 15-7-2023 |
| 13. | 016909 | Algocin Infusion<br>Each 100ml contains:<br>Ciprofloxacin Lactate….254.4mg (corresponding to ciprofloxacin)….200mg | 16-04-1995<br>Transfer of registration dated 17-7-2008 | Dy. No. 21847 dated 22-6-2018<br><br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 14. | 022945 | Dagravit Tablets<br>Each tablet contains:<br>Vitamin A….2500IU<br>Vitamin B1…..1.5mg<br>Vitamin B2….1.5mg<br>Nicotinamide……10mg<br>Calcium d Pentothenate ……1.5mg<br>Vitamin B6……0.5mcg<br>Vitamin B12…..0.5mcg<br>Folic Acid…..50mcg<br>Biotin…..12.5mcg<br>P. Aminobenz Acid ….2mg<br>Vitamin C….20mg<br>Vitamin D3…..500IU<br>Vitamin E…..1mg<br>Vitamin K3….0.5mg<br>MINERALS<br>Iron……5mg<br>Calcium Cal.<br>Phosphorus Phosph ……250mg<br>Potassium…..5mg<br>Magnesium……5mg<br>Aluminium…….5mg<br>Copper…..0.5mg<br>Maganese……0.5mg<br>Zinc……0.5mg<br>Iodine……50mcg<br>Molydenium…50mcg<br>Fluorine……50mcg<br>Nickle……50mcg<br>Selenium……..50mcg | 11-02-1999<br><br>Transfer of registration dated 17-7-2008 | Dy. No. 21853 dated 22-6-2018<br><br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 15. | 014436 | Spasler Plus Capsules<br>Each capsule contains:<br>Paracetamol B.P……500mg<br>Hyoscine Butyl bromide B.P……10mg | 14-10-1993<br>Transfer of registration dated 2-7-1999 & 17-7-2008 | Dy. No. 21856 dated 22-6-2018<br><br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 16. | 016912 | Afoxin Tablet<br>Each tablet contains:<br>Enoxacin Sesquihydrate …..400mg | 16-04-1995<br>Transfer of registration 17-7-2008 | Dy. No. 21848 dated 22-6-2008<br><br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |

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| 17. | 048718 | Esi-dep 20mg Tablet<br>Each tablet contains:<br>Escitalopram (as Oxalate) ….20mg | 16-07-2008 | Dy. No. 21858 dated 22-6-18<br><br>10000/- | 15-7-2023 | w.e.f. 16-7-2018 to 15-7-2023 |
| 18. | 048716 | Lucast Sachet<br>Each sachet contains:<br>Montelukast (as sodium) …..4mg | 16-07-2008 | Dy. No. 21851 dated 22-6-18<br><br>10000/- | 15-7-2023 | w.e.f. 16-7-2018 to 15-7-2023 |
| 19. | 021624 | Water for Injection | 20-5-1998<br>Transfer of registration dated 17-7-2008 | Dy. No. 21850 dated 22-6-18<br><br>10000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| iii. | **M/s Akhai Pharmaceuticals (Pvt) Ltd., A-248 toA-256, H.I.T.E., Lasbela, Baluchistan.** | | | | | |
| 20. | 015744 | Aclova 5% Cream<br>Each gm contains:<br>Acyclovir…50mg | 07-09-1994<br>Transfer from import to local dated 19-7-2008 | Dy. No. 22657 dated 29-06-2018<br>10000/- | 18-7-2023 | w.e.f. 19-7-2018 to 18-7-2023 |
| 21. | 015743 | Aclova 200mg Tablet<br>Each tablet contains:<br>Acyclovir…200mg | 07-09-1994<br>Transfer from import to local dated 19-7-2008 | Dy. No. 22656 dated 29-06-2018<br>10000/- | 18-7-2023 | w.e.f. 19-7-2018 to 18-7-2023 |
| 22. | 021188 | Aclova 400mg Tablet<br>Each tablet contains:<br>Acyclovir…400mg | 15-10-1998<br>Transfer from import to local dated 19-7-2008 | Dy. No. 22655 dated 29-06-2018<br>10000/- | 18-7-2023 | w.e.f. 19-7-2018 to 18-7-2023 |
| iv. | **M/s Ali Industries, 239-C, Sundar Industrial Estates, Raiwind Road, Lahore** | | | | | |
| 23. | 076920 | Jazofen Suspension<br>Each 5ml contains:<br>Ibuprofen…100mg | 21-06-2013 | Dy. No. 21120 dated 12-06-2018<br>10000/- | 20-06-2023 | w.e.f. 21-6-2018 to 20-6-2023 |
| 24. | 076922 | Co-Trifa Suspension<br>Each 5ml contains:<br>Trimethoprim…40mg<br>Sulphamethoxazole ……200mg | 21-06-2013 | Dy. No. 21119 dated 12-06-2018<br>10000/- | 20-06-2023 | w.e.f. 21-6-2018 to 20-6-2023 |
| 25. | 076919 | Dilonide Syrup<br>Each 10ml Contains:<br>Metronidazole Benzoate eq. to metronidazole…200mg<br>Diloxanide Furoate…250mg | 21-06-2013 | Dy. No. 21121 dated 12-06-2018<br>10000/- | 20-06-2023 | w.e.f. 21-6-2018 to 20-6-2023 |
| 26. | 076921 | Almage Syrup<br>Each 5ml contains:<br>Aluminum Hydroxide…215mg<br>Magnesium Hydroxide…80mg<br>Simethicone…25mg | 21-06-2013 | Dy. No. 21123 dated 12-06-2018<br>10000/- | 20-06-2023 | w.e.f. 21-6-2018 to 20-6-2023 |
| 27. | 076918 | Alimol Syrup<br>Each 5ml contains:<br>Paracetamol…120mg | 21-06-2013 | Dy. No. 21122 dated 12-06-2018<br>10000/- | 20-06-2023 | w.e.f. 21-6-2018 to 20-6-2023 |

| v. | M/s Amson Vaccines & Pharma, 154, Industrial Triangle, Kahuta Road, Islamabad | | | | | |
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| 28. | 029071 | Loramine Syrup<br>Each 5ml Contains:<br>Loratadine…5mg | 31-12-2002<br>Transfer of registration dated: 25-06-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 24-06-2023 | w.e.f. 25-06-2018 to 24-06-2023. |
| 29. | 029072 | Loramine Tablet 10mg<br>Each Tablet Contains:<br>Loratadine…10mg | 31-12-2002<br>Transfer of registration dated: 25-06-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 24-06-2023 | w.e.f. 25-06-2018 to 24-06-2023. |
| 30. | 029971 | Amsozine Syrup<br>Each 5ml Contains:<br>Cetirizine HCl eq. to Cetirizine…5mg | 06-03-2003<br>Transfer of registration dated: 25-06-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 24-06-2023 | w.e.f. 25-06-2018 to 24-06-2023. |
| 31. | 029972 | Amsozine 10 Tablet<br>Each Tablet Contains:<br>Cetirizine…10mg | 06-03-2003<br>Transfer of registration 25-06-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 24-06-2023 | w.e.f. 25-06-2018 to 24-06-2023. |
| 32. | 030991 | Rifason Tablet<br>Each Tablet Contains:<br>Rifampicin…60mg<br>Isoniazid…30mg | 06-09-2003 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 05-09-2023 | w.e.f. 06-09-2018 to 05-09-2023. |
| 33. | 030992 | Amzid Tablet<br>Each Tablet Contains:<br>Rifampicin…150mg<br>Isoniazid…75mg | 06-09-2003 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 05-09-2023 | w.e.f. 06-09-2018 to 05-09-2023. |
| 34. | 030993 | Pisoriz Tablet<br>Each Tablet Contains:<br>Rifampicin…60mg<br>Isoniazid…30mg<br>Pyrazinamide…150mg | 06-09-2003 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 05-09-2023 | w.e.f. 06-09-2018 to 05-09-2023. |
| 35. | 030994 | Ethrifin Tablet<br>Each Tablet Contains:<br>Ethambutol HCl…300mg<br>Rifampicin…150mg<br>Isoniazid…75mg | 06-09-2003 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 05-09-2023 | w.e.f. 06-09-2018 to 05-09-2023. |
| 36. | 050189 | Famcivir Tablet 250mg<br>Each Tablet Contains:<br>Famciclovir…250mg | 22-07-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 21-07-2023 | w.e.f. 22-07-2018 to 21-07-2023 |
| 37. | 050190 | Sindam-P Tablet<br>1st Tablet Contains:<br>Artesunate…50mg<br>2nd Tablet Contains:<br>Sulfadoxine…500mg<br>Pyrimethamine….25mg | 22-07-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 21-07-2023 | w.e.f. 22-07-2018 to 21-07-2023 |
| 38. | 050191 | Sindam-P DS Tablet<br>1st Tablet Contains:<br>Artesunate…100mg<br>2nd Tablet Contains:<br>Sulfadoxine…500mg | 22-07-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 21-07-2023 | w.e.f. 22-07-2018 to 21-07-2023 |
| 39. | 050192 | Migrex Tablet 50mg<br>Each Tablet Contains:<br>Sumatriptan as Succinate…50mg | 22-07-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 21-07-2023 | w.e.f. 22-07-2018 to 21-07-2023 |
| 40. | 050193 | Oxiflox Tablet 400mg<br>Each Tablet Contains:<br>Moxifloxacin as HCl…400mg | 22-07-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | 21-07-2023 | w.e.f. 22-07-2018 to 21-07-2023 |

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| 41. | 050849 | Geman Tablet<br>Each Tablet Contains:<br>Gemifloxacin (as Mesylate)…320mg | 01-08-2008 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | 31-07-2023 | w.e.f. 01-08-2018 to 31-7-2023 |
| vi. | **M/s Atco Laboratories, B/18, S.I.T.E., Karachi.** | | | | | |
| 42. | 030904 | Bracin D Sterile Ophthalmic Suspension<br>Each ml contains:<br>Tobramycin…3.00mg<br>Dexamethasone..1.00mg | 25-07-2003 | Dy. No. 22653 dated 29-06-2018<br><br>10000/- | 24-7-2023 | w.e.f 25-7-2018 to 24-7-2023 |
| 43. | 030905 | Merol 25mg Tablet<br>Each tablet contains:<br>Metoprolol Tartrate…25mg | 25-07-2003 | Dy. No. 22653 dated 29-06-2018<br><br>10000/- | 24-7-2023 | w.e.f 25-7-2018 to 24-7-2023 |
| 44. | 030903 | Polytrol Sterile Ophthalmic Suspension<br>Each ml contains:<br>Neomycin Sulphate…6.78mg<br>Dexamethasone.1.00mg<br>Polymyxin B Sulphate …1.15mg | 25-07-2003 | Dy. No. 22653 dated 29-06-2018<br><br>10000/- | 24 -7-2023 | w.e.f 25-7-2018 to 24-7-2023 |
| vii. | **M/s. Ethical Laboratories, 26-Shahrah-e-Quaid-e-Azam, Lahore** | | | | | |
| 45. | 006248 | Pilocar Eye Drops 4%<br>Contains:<br>Pilocarpine HCl…4%<br>Boric Acid…0.140%<br>Potassium Chloride ……0.06%<br>Sodium Carbonate ……0.022% | 13-04-1982 Change of brand name (Ethicar) dated 22-06-1998 | Dy. No. 20731 dated 08-06-2018<br><br>10,000/- | 21-06-2023 | w.e.f. 22-6-2018 to 21-6-2023 |
| 46. | 006247 | Pilocar Eye Drops 2%<br>Contains:<br>Pilocarpine Hcl…2%<br>Boric Acid…0.413%<br>Potassium Chloride…0.25%<br>Sodium Carbonate …….0.006% | 13-04-1982 Change of brand name (Ethicar) dated 22-06-1998 | Dy. No. 20730 dated 08-06-2018<br><br>10,000/- | 21-06-2023 | w.e.f. 22-6-2018 to 21-6-2023 |
| viii. | **M/s Fredmann Pharmaceuticals Pvt. Ltd. AJK** | | | | | |
| 47. | 075445 | Fenacare 60mg Tablet<br>Each Tablet Contains:<br>Fexofenadine HCl…60mg | 14-06-2013 | Dy. No. 20957 dated 11-06-2018<br><br>10000/- | 13-06-2023 | w.e.f 14-6-2018 to 13-06-2023 |
| 48. | 075446 | Amlow 5mg Tablet<br>Each Tablet Contains:<br>Amlodipine (as Besylate)…5mg | 14-06-2013 | Dy. No. 20957 dated 11-06-2018<br><br>10000/- | 13-06-2023 | w.e.f 14-6-2018 to 13-06-2023 |
| 49. | 075447 | Amlow 10mg Tablet<br>Each Tablet Contains:<br>Amlodipine (as Besylate)…10mg | 14-06-2013 | Dy. No. 20957 dated 11-06-2018<br><br>10000/- | 13-06-2023 | w.e.f 14-6-2018 to 13-06-2023 |
| ix. | **M/s FYNK Pharmaceuticals, 19-Km, G.T. Road, Kalashah Kaku, Lahore** | | | | | |
| 50. | 030336 | Lopemid Capsule 2mg<br>Each Capsule Contains:<br>Loperamide HCl…2mg | 27-06-2003 | Dy. No. 21125 dated 12-06-2018<br>10000/- | 26-6-2023 | w.e.f 27-06-2018 to 26-06-2023 |
| 51. | 030335 | Fycam Capsule<br>Each Capsule Contains:<br>Piroxicam…10mg | 27-06-2003 | Dy. No. 21125 dated 12-06-2018<br>10000/- | 26-6-2023 | w.e.f 27-06-2018 to 26-06-2023 |

| x. | **M/s GlaxoSmithKline Pakistan Limited,35- Dockyard Road West Wharf Karachi.-** | | | | | |
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| 52. | 000249 | Betnsol Eye Ointment<br>Contains:<br>Betamethasone sodium phosphate B.P….0.1% | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22502 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 53. | 004506 | Betnesol Injection<br>Each 1ml contains:<br>Betamethasone as sodium phosphate BP…..4mg | 20-11-1978<br>Transfer of registration: 30-08-2003 | Dy. No. 22502 dated 28-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 54. | 000251 | Betnesol N Eye Ointment<br>Contains:<br>Betamethasone sodium phosphate B.P….0.1%<br>Neomycin sulphate BP …….0.5% | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22502 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 55. | 000254 | Betnovate N Cream<br>Contains:<br>Betamethasone as Betamethasone valerate BP ….0.1%<br>Neomycin sulphate BP ….0.5% | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22501 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 56. | 000255 | Betnovate N Ointment<br>Contains:<br>Betamethasone as Betamethasone valerate BP….0.1%<br>Neomycin sulphate BP….0.5% | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22501 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 57. | 000252 | Betnovate N Lotion 20ml<br>Contains:<br>Betamethasone as Betamethasone valerate BP….0.1% w/v<br>Neomycin sulphate BP….0.5% w/v | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22501 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 58. | 000256 | Betnovate Cream 5gm<br>Contains:<br>Betamethasone as Betamethasone valerate BP….0.1% w/v | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22501 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 59. | 000257 | Betnovate Ointment 5gm<br>Contains:<br>Betamethasone as Betamethasone valerate BP….0.1% w/w | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22501 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 60. | 000253 | Betnovate Lotion 20ml<br>Contains:<br>Betamethasone as Betamethasone valerate BP….0.1% w/v | 20-4-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22501 dated 28-06-2018 10000 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 61. | 000348 | Actidil Elixir<br>Each 5ml contains:<br>Triprolidine HCl…1.25mg | 17-04-1976<br>Transfer of registration: 30-08-2003 | Dy. No. 22297 dated 26-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 62. | 010399 | Bactroban Ointment<br>Contains: | 19-02-1990<br>Transfer of | Dy. No. 22297 dated 26-06-2018 | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |

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| | | Mupirocin 2% w/w in Water Soluble Base | registration: 30-08-2003 | 10000/- | | |
| xi. | **M/s GlaxoSmithKline Pakistan Limited F-268 SITE Karachi.** | | | | | |
| 63. | 006669 | Amoxil Capsule 500mg Each Capsule Contains: Amoxycillin as Amoxycillin Trihydrate…500mg | 20-07-1999 Transfer of registration: 30-08-2003 | Dy. No. 22298 dated 26-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 64. | 000509 | Amoxil Drops 125mg Each 1.25ml Contains: Amoxycillin as Trihydrate Amoxycillin…125mg | 16-04-1976 Transfer of registration: 30-08-2003 | Dy. No. 22298 dated 26-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 65. | 000508 | Amoxil Syrup 125mg Each 5ml contains: Amoxycillin as Trihydrate Amoxycillin…125mg | 16-04-1976 Transfer of registration: 30-08-2003 | Dy. No. 22298 dated 26-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 66. | 006814 | Amoxil Forte Syrup 250mg Each 5ml contains: Amoxycillin as Trihydrate Amoxycillin …..…250mg | 07-03-1986 Transfer of registration: 30-08-2003 | Dy. No. 22298 dated 26-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 67. | 000182 | Ampiclox Capsule 500mg Each Capsule Contains: Ampicillin as Ampicillin Trihydrate…250mg Cloxacillin as Cloxacillin Sodium …250mg | 17-04-1976 Transfer of registration: 30-08-2003 | Dy. No. 22499 dated 28-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 68. | 000183 | Ampiclox Drops 90mg Each 0.6ml Contains: Ampicillin as Ampicillin Trihydrate ……60mg Cloxacillin as Cloxacillin Sodium ……30mg | 16-04-1976 Transfer of registration: 30-08-2003 | Dy. No. 22499 dated 28-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 69. | 000194 | Ampiclox Syrup 250mg Each 5ml contains: Ampicillin as Ampicillin Trihydrate ……..…125mg Cloxacillin as Cloxacillin Sodium ……125mg | 17-04-1976 Transfer of registration: 30-08-2003 | Dy. No. 22499 dated 28-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 70. | 000248 | Betnesol Drops Contains: Betamethasone Sodium Phosphate…0.1% w/v | 20-04-1976 Transfer of registration: 30-08-2003 | Dy. No. 22296 dated 26-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 71. | 000250 | Betnesol N Drops Contains: Betamethasone Sodium Phosphate…0.1% w/v Neomycin Sulphate …0.5% w/v | 20-04-1976 Transfer of registration: 30-08-2003 | Dy. No. 22296 dated 26-06-2018 10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |

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| 72. | 013113 | Panadol CF Tablet<br>Each tablet contains:<br>Paracetamol…..500mg<br>Pseudoephedrine HCl ….60<br>Chlorpheniramine Maleate ….4mg | 12-12-1991<br>Transfer of registration: 22-08-2013 | Dy. No. dated 13-06-2018<br><br>10000/- | 21-8-2023 | w.e.f 22-8-2018 to 21-8-2023. |
| 73. | 000394 | Iodex Ointment | 24-03-1976<br>Transfer of registration: 30-08-2003 | Dy. No. dated 13-06-2018<br><br>10000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| 74. | 016868 | ENO Fruit Salt Lemon<br>Contains:<br>Sodium Bicarbonate ……..34.16%w/w<br>Sodium Bicarbonate Fine….11.39%w/w<br>Citric Acid Anhydrous …..….43.10%<br>Sodium Carbonate (anhydrous) …10.00%w/w<br>Sodium Carbonate Decahydrate….0.25% | 18-04-1995<br><br>Transfer of registration: 30-08-2003 | Dy. No. dated 13-06-2018<br><br>10,000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |
| xii. | **M/s. Genix Pharma, 44, 45-B, Korangi Creek Road, Karachi** | | | | | |
| 75. | 050322 | Gen-Art SP Tablet<br>Each co-blister contains:<br>Three tablets contain:<br>Sulfadoxine…..500mg<br>Primethamine…25mg<br>Six tablets contain:<br>Artesunate…….100mg<br>(Mfg.Specification) | 26-07-08 | Dy. No. 19673 dated 29-05-2018<br>10000/- | 25-7-2023 | w.e.f 26-7-2018 to 25-7-2023 |
| 76. | 048741 | RBC-F Chewable Tablet<br>Each Chewable tablet contains:<br>Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron…..100mg<br>Folic Acid…….0.35mg<br>(Manufacturer's Specification) | 17-07-08 | Dy. No. 19673 dated 29-05-2018<br>10000/- | 16-07-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 77. | 048742 | RBC Syrup<br>Each 5ml contains:<br>Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron …..50mg<br>(Manufacturer's Specification) | 17-07-08 | Dy. No. 19673 dated 29-05-2018<br>10000/- | 16-07-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 78. | 075970 | X-Gen Infusion<br>Each ml contains:<br>Moxifloxacin HCl eq. to Moxifloxacin …..1.6mg<br>(Manufacturer's Specification) | 04-07-13 | Dy. No. 19673 dated 29-05-2018<br>10000/- | 03-07-2023 | w.e.f. 4-7-2018 to 3-7-2023 |

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| xiii. | **M/s. Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi** | | | | | |
| 79. | 00996-EX | Geof-Cefixime 100 Suspension<br>Each 5ml Sachet Upon Reconstitution Contains:<br>Cefixime Trihydrate (Micronized)…118.00 mg<br>Citric Acid…4.80mg<br>Sodium Benzoate…2.66mg<br>Xanthan Gum…5.00mg<br>Aerosil…33.00mg<br>Banana Flavor…13.33mg<br>Sugar/Sucrose…2490.33mg | 13-06-2008 | Dy. No. 20738 dated 08-06-2018<br><br>10,000/- | 12-6-2023 | w.e.f. 13-6-2018 to 12-6-2023 |
| xiv. | **M/s. Hilton Pharma, Plot 13 & 14, Sector 15, Korangi Industrial Area, Karachi.** | | | | | |
| 80. | 022107 | Hinit Oral Suspension<br>Each 5ml contains:<br>Cefuroxime Axetil …125mg | 11-07-1998 | Dy. No. 21928 dated 22-06-2018<br><br>10,000/- | 10-7-2023 | w.e.f. 11-7-2018 to 10-7-2018 |
| 81. | 022108 | Cefim Suspension<br>Each 5ml contains:<br>Cefixime…100mg | 11-07-1998 | Dy. No. 21928 dated 22-06-2018 10,000/- | 10-7-2023 | w.e.f. 11-7-2018 to 10-7-2018 |
| 82. | 048773 | Xofi 400mg Tablet<br>Each Tablet Contains:<br>Doxofylline…400mg | 18-07-2008 | Dy. No. 21928 dated 22-06-2018 10,000/- | 17-7-2023 | w.e.f. 18-7-2018 to 17-7-2023 |
| 83. | 048774 | Zepla 20mg Capsule<br>Each Capsule Contains:<br>Ziprasidone (as HCl Monohydrate)…20mg | 18-07-2008 | Dy. No. 21928 dated 22-06-2018<br><br>10,000/- | 17-7-2023 | w.e.f. 18-7-2018 to 17-7-2023 |
| 84. | 048775 | Zepla 40mg Capsule<br>Each Capsule Contains:<br>Ziprasidone (as HCl Monohydrate)…40mg | 18-07-2008 | Dy. No. 21928 dated 22-06-2018<br><br>10,000/- | 17-7-2023 | w.e.f. 18-7-2018 to 17-7-2023 |
| 85. | 030926 | Gevolox Plus Tablet<br>Each Tablet Contains:<br>Glucosamine Sulphate…500mg<br>Chondroitin Sulphate ……200mg<br>Calcium Carbonate ……75mg<br>Vitamin C…25mg | 31-07-2003 | Dy. No. 21928 dated 22-06-2018<br><br>10,000/- | 30-7-2023 | w.e.f. 31-7-2018 to 30-7-2023 |
| xv. | **M/s Helix Pharma, Hakimsons House, A-56, S.I.T.E., Manghopir Road, Karachi** | | | | | |
| 86. | 030596 | Diaxin Oral Suspension<br>Each 5ml Contains:<br>Clarithromycin….125mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 87. | 030605 | Efectal Tablet 120mg<br>Each Tablet Contains:<br>Fexofenadine HCl…120mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 88. | 030595 | Floral Eye Drops 0.1%<br>Each ml Contains:<br>Flurometholone…1mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 89. | 030602 | Floral Forte Eye Drops 0.25% | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |

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| | | Each ml Contains: Flurometholone…2.5mg | | 10000/- | | |
| 90. | 030286 | Ironal Tablet<br>Each Tablet Contains: Iron (III) Hydroxide Polymaltose Complex is eq. to 100mg of Iron Elemental Iron | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 91. | 030287 | Ironal-F Tablet<br>Each Tablet Contains: Iron (III) Hydroxide Polymaltose Complex is eq. to 100mg of Iron Elemental Iron<br>Folic Acid…0.35mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 92. | 030603 | Ironal Syrup<br>Each 5ml Contains: Iron (III) Hydroxide Polymaltose Complex is eq. to Elemental Iron…50mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 93. | 030604 | Oflocin Tablet 400mg<br>Each Tablet Contains: Ofloxacin…400mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 94. | 030594 | Oflocin Eye Drops 0.3%<br>Each ml Contains: Ofloxacin…3mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 95. | 030598 | Recept Tablet 2mg<br>Each Tablet Contains: Risperidone…2mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| 96. | 030599 | Recept Tablet 4mg<br>Each Tablet Contains: Risperidone…4mg | 14-06-2003 | Dy. No. 20960 dated 11-06-2018 10000/- | 13-6-2023 | w.e.f. 14-6-2018 to 13-6-2023 |
| xvi. | **M/s. Indus Pharma, Plot No. 65 Sector-27, Korangi Industrial Area, Karachi** | | | | | |
| 97. | 030610 | Lignocaine Hydrochloride 1% W/V Injection<br>Each ml contains: Lignocaine HCl…10mg | 30-06-2003 | Dy. No. 21268 dated 13-06-2018 10,000/- | 29-6-2023 | w.e.f 30-6-20158 to 29-6-2023 |
| xvii. | **M/s. Leads Pharma, Plot # 81-A, Street # 6, I-10/3, Islamabad** | | | | | |
| 98. | 035878 | Levocin 250mg Tab<br>Each tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin…250mg | 10-01-2005 Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018 10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 99. | 035879 | Levocin 500mg Tab<br>Each tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin…500mg | 10-01-2005 Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018 10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 100. | 035880 | Lefox 250mg Tablet<br>Each tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin ……..…250mg | 10-01-2005 Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018 10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 101. | 035881 | Lefox 500mg Tablet<br>Each tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin | 10-01-2005 Transfer of registration 25-6-2008 | Dy. No. 21286 dated 13-06-2018 10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |

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| | | …500mg | | | | |
| 102. | 035882 | Leceph 250mg Capsule<br>Each capsule contains:<br>Cephradine…250mg | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 103. | 035883 | Leceph 500mg Capsule<br>Each capsule contains:<br>Cephradine…500mg | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 104. | 035885 | Leceph 250mg Suspension<br>Each 5ml contains:<br>Cephradine…250mg | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 105. | 035887 | Klaricil 250mg Tablet<br>Each tablet contains:<br>Clarithromycin …250mg | 10-01-2005<br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 106. | 035888 | Klaricil 500mg Tablet<br>Each tablet contains:<br>Clarithromycin …500mg | 10-01-2005<br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 107. | 035889 | Ratadil 10mg Tablet<br>Each tablet contains:<br>Loratadine…10mg | 10-01-2005<br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 108. | 035892 | Penapol 40mg Tablet<br>Each tablet contains:<br>Pantoprazole (as Sodium)…40mg | 10-01-2005<br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 109. | 035893 | Flurle 100mg Tablet<br>Each tablet contains:<br>Flurbiprofen…100mg | 10-01-2005<br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 110. | 035894 | Azimik 250mg Capsule<br>Each capsule contains:<br>Azithromycin (as Dihydrate)…250mg | 10-01-2005<br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 111. | 035895 | Azimik 200mg Suspension<br>Each 5ml contains:<br>Azithromycin (as Dihydrate)…200mg | 10-01-2005<br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 112. | 035896 | Ceftrol 250mg Injection<br>Each Vial Contains:<br>Ceftriaxone Sodium eq. to Ceftriaxone…250mg | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 113. | 035897 | Ceftrol 500mg Injection<br>Each Vial Contains:<br>Ceftriaxone Sodium eq. to Ceftriaxone…500mg | 10-01-2005<br>Transfer of registration 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |

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| 114. | 035898 | Ceftrol 1000mg Injection<br>Each Vial Contains:<br>Ceftriaxone Sodium eq. to Ceftriaxone ……1000mg | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br><br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 115. | 035899 | Futazim 250mg Injection<br>Each vial contains:<br>Cefotaxime Sodium eq. to Cefotaxime…250mg | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br><br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 116. | 035900 | Futazim 500mg Injection<br>Each Vial Contains:<br>Cefotaxime Sodium eq. to Cefotaxime…500mg | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br><br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 117. | 036301 | Futazim 1gm Injection<br>Each Vial Contains:<br>Cefotaxime Sodium eq. to Cefotaxime…1gm | 10-01-2005<br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br><br>10,000/- | 07-07-2023 | w.e.f. 08-07-2018 to 07-07-2023 |
| 118. | 035891 | Leazole 30mg Capsule<br>Each capsule contains:<br>Lansoprazole as enteric coated pellets…30mg<br><br>Source: M/s Smilex Laboratories Limited; Plot No.44, CIE, Ghandhi Naggar Balanagar, Hyderabad - 500 037 AP India. | 10-01-2005<br><br>Transfer of registration dated 25-6-2008 | Dy. No. 21286 dated 13-06-2018<br><br>10,000/-<br>10000/- dated 30-1-2019 | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| xviii. | **M/s Mediate Pharmaceuticals (Pvt) Ltd,150-151 Sector 24, Korangi Industrial Area Karachi** | | | | | |
| 119. | 048693 | Medisid 100mg Tablet<br>Each tablet contains:<br>Flurbiprofen…100mg<br>(USP Specification) | 15-07-2008 | Dy. No. 1724 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 120. | 048694 | M-Kort 4mg Tablet<br>Each tablet contains:<br>Triamcinoloneacetonide ….4mg<br>(USP Specification) | 15-07-2008 | Dy. No. 1725 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 121. | 048695 | Domprog 10mg Tablet<br>Each tablet contains:<br>Domperidone maleate eq. to Domperidone ……10mg<br>(USP Specification) | 15-07-2008 | Dy. No. 1716 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 122. | 048696 | M-Naxem 250mg Tablet<br>Each tablet contains:<br>Naproxen as sodium ……250mg<br>(USP Specification) | 15-07-2008 | Dy. No. 1723 dated 07-06-2018<br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 123. | 048697 | M-Naxem 500mg Tablet<br>Each tablet contains:<br>Naproxen as sodium ……500mg<br>(USP Specification) | 15-07-2008 | Dy. No. 1722 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |

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| 124. | 048698 | Domprog 5mg/ 5ml Suspension<br>Each 5ml contains:<br>Domperidone ……5mg<br>(USP Specification) | 15-07-2008 | Dy. No. 1717 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 125. | 048699 | Antidine 20mg Tablet<br>Each tablet contains:<br>Famotidine……20mg<br>(BP Specification) | 15-07-2008 | Dy. No. 1721 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 126. | 048700 | Antidine 40mg Tablet<br>Each tablet contains:<br>Famotidine……20mg<br>(BP Specification) | 15-07-2008 | Dy. No. 1728 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 127. | 048701 | Ulsac 1g Tablet<br>Each tablet contains:<br>Sucralfate……1g<br>(USP Specification) | 15-07-2008 | Dy. No. 1719 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 128. | 048702 | Medifenac 50mg Tablets<br>Each tablet contains:<br>Diclofenac sodium ……..50mg<br>(BP Specification) | 15-07-2008 | Dy. No. 1726 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 129. | 048703 | Medifenac SR 100mg Tablets<br>Each tablet contains:<br>Diclofenac sodium ….100mg<br>(BP Specification) | 15-07-2008 | Dy. No. 1727 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 130. | 048704 | Mexicam 7.5mg Tablet<br>Each tablet contains:<br>Meloxicam……..7.5mg<br>(BP Specification) | 15-07-2008 | Dy. No. 1720 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| 131. | 048705 | Mexicam 15mg Tablet<br>Each tablet contains:<br>Meloxicam……..15mg<br>(BP Specification) | 15-07-2008 | Dy. No. 1718 dated 07-06-2018<br><br>10000 | 14-7-2023 | w.e.f 15-7-2018 to 14-7-2023 |
| xix. | **M/s Metro Pharmaceutical, Plot 14, St#SS-2, National Industrial Zone, Rawat, Islamabad** | | | | | |
| 132. | 075441 | Emzol 20mg Capsule<br>Each Capsule Contains:<br>Esomeprazole (as Enteric Coated Pellets) eq. to Esomeprazole …20mg<br>**Source of Pellets:**<br>M/s Spansule Formulations, Sy. No. 172, Plot No. 154 /A /4, IDA Bollaram Village Jinnaram Mandal Medac District AndrPardesh Hyderabad India. | 13-06-2013 | Dy. No. 20958 dated 11-06-2018<br><br>20000/- | 12-6-2023 | w.e.f. 13-6-2018 to 12-6-2023 |
| 133. | 075442 | Emzol 40mg Capsule<br>Each Capsule Contains:<br>Esomeprazole (as Enteric Coated Pellets) eq. to Esomeprazole ……40mg<br>**Source of Pellets:**<br>M/s Spansule | 13-06-2013 | Dy. No. 20958 dated 11-06-2018<br><br>20000/- | 12-6-2023 | w.e.f. 13-6-2018 to 12-6-2023 |

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| | | Formulations, Sy. No. 172 , Plot No. 154 /A /4, IDA Bollaram Village Jinnaram Mandal Medac District AndrPardesh Hyderabad India. | | | | |
| 134. | 075443 | Omefit 20mg Capsule<br>Each Capsule Contains:<br>Omeprazole (as Enteric Coated Pellets) eq. to Omeprazole…20mg<br>**Source of Pellets:**<br>M/s Spansule Formulations, Sy. No. 172, Plot No. 154 /A /4, IDA Bollaram Village Jinnaram Mandal Medac District Andra Pardesh Hyderabad India. | 13-06-2013 | Dy. No. 20958 dated 11-06-2018<br><br>20000/- | 12-6-2023 | w.e.f. 13-6-2018 to 12-6-2023 |
| 135. | 075444 | Legzol 30mg Capsule<br>Each Capsule Contains:<br>Lansoprazole (as Enteric Coated Pellets) eq. to Lansoprazole …….30mg<br>**Source of Pellets:**<br>M/s Spansule Formulations, Sy. No. 172, Plot No. 154 /A /4, IDA Bollaram Village Jinnaram Mandal Medac District Andra Pardesh Hyderabad India. | 13-06-2013 | Dy. No. 20958 dated 11-06-2018<br><br>20000/- | 12-6-2023 | w.e.f. 13-6-2018 to 12-6-2023 |
| 136. | 075238 | Mestom Tablet<br>Each film coated tablet contains:<br>Escitalopram as Oxalate … 10mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 137. | 075239 | Melcin 250mg Tablet<br>Each film coated tablet contains:<br>Levofloxacin as Hemihydrate…250mg | 02-04-2013<br>Change of brand name dated 11-10-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 138. | 075240 | Melcin 500mg Tablet<br>Each film coated tablet contains:<br>Levofloxacin as Hemihydrate…500mg | 02-04-2013<br>Change of brand name dated 11-10-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 139. | 075241 | Metrose-F Tablet<br>Each chewable tablet contains:<br>Iron-III Hydroxide Polymaltose Complex eq. Elemental Iron ……100mg<br>Folic Acid…0.35mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |

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| 140. | 075242 | Mendon 10mg Tablet<br>Each film coated tablet contains:<br>Domperidone (as Maleate) …10mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 141. | 075243 | Metein-250 Tablet<br>Each film coated tablet contains:<br>Ciprofloxacin (as HCl) ……..…250mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 142. | 075244 | Metein-500 Tablet<br>Each film coated tablet contains:<br>Ciprofloxacin (as HCl)…500mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 143. | 075245 | Perzol 40mg Tablet<br>Each enteric coated tablet contains:<br>Pantoprazole as Sodium Sesquihydrate eq. to Pantoprazole…40mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 144. | 075246 | Metost 10mg Tablet<br>Each film coated tablet contains:<br>Montelukast as Sodium…10mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 145. | 075250 | Mezethro-250 Capsule<br>Each capsule contains:<br>Azithromycin as Dihydrate…250mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 146. | 075251 | M.Gob-300 Capsule<br>Each capsule contains:<br>Gabapentin…300mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 147. | 075252 | Metadryl Syrup<br>Each 5ml contains:<br>Aminophylline…32mg<br>Diphenhydramine HCl ……..…8mg<br>Ammonium Chloride ……..…30mg<br>Menthol…0.98mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 148. | 075253 | Myzine Syrup<br>Each 5ml contains:<br>Zinc Sulfate Monohydrate…20mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 149. | 075254 | Iromas Syrup<br>Each 5ml contains:<br>Iron-III Hydroxide Polymaltose Complex eq. Elemental Iron ……..…50mg | 02-04-2013<br>Change of brand name dated 15-7-2015 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 150. | 75255 | Mega-One Suspension<br>Each 5ml contains:<br>Magaldrate…540mg<br>Simethicone…20mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 151. | 75256 | Levotaiz Syrup<br>Each 5ml contains:<br>Levocetirizine Dihydrochloride…2.5mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |

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| 152. | 75257 | Mydin Syrup Each 5ml contains: Loratadine…5mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 153. | 75258 | Sofet Suspension Each 5ml contains: Sucralfate…1gm | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 154. | 75259 | Metofam Suspension Each 5ml contains: Famotidine…10mg | 02-04-2013 Change of brand name dated 15-7-2015 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 155. | 75260 | Mendon Suspension Each 5ml contains: Domperidone…5mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 156. | 75261 | Homglob Syrup Each 15ml contains: Iron Protein Succinylate……800mg eq. to Elemental Iron…40mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 157. | 75262 | Mezethro-200 Dry Suspension Each 5ml Contains: Azithromycin (as Dihydrate)…200mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 158. | 75267 | Lumet Dry Suspension Each 5ml Contains: Artemether…15mg Lumefantrine…90mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 159. | 75268 | Claramet 125mg Dry Suspension Each 5ml Contains: Clarithromycin..125mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 160. | 75269 | Fosic Cream Each gm contains: Fusidic Acid as Hemihydrate…20mg (2%) | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 161. | 75270 | Parten 5% Cream Each gm contains: Permethrin…50mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 162. | 75271 | Catazol-V 10% Cream Each gm contains: Clotrimazole…100mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 163. | 75272 | Mesocam 0.5% Gel Each 25gm Tube Contains: Piroxicam…0.5% | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 164. | 75273 | Demobid Gel Each 20gm tube Contain Diclofenac Diethylamine…1% | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 165. | 75275 | Meteda Sachet Each sachet contains: Sodium Bicarbonate…1.716gm Citric Acid…0.702gm Sodium Citrate …0.613gm Tartaric Acid..0.858gm | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |

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| 166. | 75276 | Metost 4mg Sachet<br>Each sachet contains:<br>Montelukast as (Sodium)…4mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| 167. | 75277 | Bestsol Sachet<br>Each sachet contains:<br>Sodium Chloride…2.6gm<br>Sodium Citrate…2.9gm<br>Potassium Chloride …….1.5gm<br>Dextrose Anhydrous ……..…13.5gm | 02-04-2013 | Dy. No. 20018 dated 01-06-2018<br><br>20000/- | 1-4-2023 | w.e.f. 02-04-2018 to 01-04-2023 |
| xx. | **M/s Moringa Pharmaceuticals, 35-A Sundar Industrial Estate, Raiwind Road, Lahore.** | | | | | |
| 168. | 074461 | Ad-Cough Syrup<br>Each 5ml Contains:<br>Aminophylline…32mg<br>Diphenhydramine HCl…8.0mg<br>Ammonium Chloride…30mg<br>Menthol …..0.98mg | 18-04-2013 | 01-06-2018<br>20000/-<br>(after due date but within sixty days) | 17-4-2023 | w.e.f. 18-4-2018 to 17-4-2023 |
| 169. | 074462 | L-Trizine Syrup<br>Each 5ml Contains:<br>Levocetirizine Dihydrochloride …….2.5mg | 18-04-2013 | 01-06-2018<br>20000/-<br>(after due date but within sixty days) | 17-4-2023 | w.e.f. 18-4-2018 to 17-4-2023 |
| 170. | 074463 | Gasidon Suspension<br>Each ml Contains:<br>Domperidone…1mg | 18-04-2013 | 01-06-2018<br>20000/-<br>(after due date but within sixty days) | 17-4-2023 | w.e.f. 18-4-2018 to 17-4-2023 |
| 171. | 074464 | Ibumor Suspension<br>Each 5ml Contains:<br>Ibuprofen…100mg | 18-04-2013 | 01-06-2018<br>20000/-<br>(after due date but within sixty days) | 17-4-2023 | w.e.f. 18-4-2018 to 17-4-2023 |
| 172. | 074469 | Moparum Dry Suspension<br>Each 5ml Contains:<br>Artemether…15mg<br>Lumefantrine…90mg | 18-04-2013 | 01-06-2018<br>20000/-<br>(after due date but within sixty days) | 17-4-2023 | w.e.f. 18-4-2018 to 17-4-2023 |
| 173. | 074459 | Amphozole Capsule 150mg<br>Each Capsule Contains:<br>Fluconazole…150mg | 18-04-2013 | 01-06-2018<br>20000/- (after due date but within sixty days) | 17-4-2023 | w.e.f. 18-4-2018 to 17-4-2023 |
| xxi. | **M/s Nabiqasim Industries, 17/24, Korangi Industrial Area, Korangi, Karachi** | | | | | |
| 174. | 00995-EX | Duosar Tablet<br>Each film coated tablet Contains:<br>Losartan Potassium …….50mg<br>Hydrochlorothiazide ……12.5mg | 13-06-2008 | Dy. No. 21118 dated 12-06-2018<br><br>10000/- | 12-6-2023 | w.e.f. 13-6-2018 to 12-6-2023 |
| xxii. | **M/s Noa Hemis Pharmaceuticals, Plot No. 154 Sector 23 Korangi Industrial Area Karachi** | | | | | |
| 175. | 075981 | Equp 100mg Tablet<br>Each tablet contains:<br>Quetiapine Fumarate…..100mg<br>(Mfg. Specifications) | 04-07-2013 | Dy. No. 22158 dated 07-06-2018<br><br>10000/- | 03-07-2023 | w.e.f. 4-7-2018 to 3-7-2023 |

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| 176. | 075982 | Equp-D 200mg Tablet<br>Each tablet contains:<br>Quetiapine Fumarate…..100mg<br>(Manufacturer Specifications) | 04-07-2013 | Dy. No. 22158 dated 07-06-2018<br><br>10000/- | 03-07-2023 | w.e.f. 4-7-2018 to 3-7-2023 |
| 177. | 075983 | Snapta 100mg Tablet<br>Each film coated tablet contains:<br>Sertraline HCl...100mg<br>(BP Specification) | 04-07-2013 | Dy. No. 22158 dated 07-06-2018<br><br>10000/- | 03-07-2023 | w.e.f. 4-7-2018 to 3-7-2023 |
| 178. | 075984 | Orthoflex Forte 50mg/ 650mg Tablet<br>Each tablet contains:<br>Orphenadrine Citrate…50mg<br>Paracetamol….650mg<br>(BP Specification) | 04-07-2013 | Dy. No. 22158 dated 07-06-2018<br><br>10000/- | 03-07-2023 | w.e.f. 4-7-2018 to 3-7-2023 |
| 179. | 050480 | Ucon Capsule<br>Each Capsule Contains:<br>Fluconazole…150mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 180. | 50481 | Gabagyl 100mg Capsule<br>Each Capsule Contains:<br>Gabapentin…100mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br><br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 181. | 50482 | Gabagyl 300mg Capsule<br>Each Capsule Contains:<br>Gabapentin…300mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br><br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 182. | 50483 | Gabagyl 400mg Capsule<br>Each Capsule Contains:<br>Gabapentin…400mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br><br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 183. | 50484 | Febagyl Tablet<br>Each Tablet Contains:<br>Flurbiprofen…100mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br><br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 184. | 50485 | Taixa Tablet<br>Each Tablet Contains:<br>Tizanidine HCl…2mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br><br>10,000/- | 20-8-2023 | w.e. f. 21-8-2018 to 20-8-2023 with label claim as per innovator i.e. Tizanidine hydrochloride 2.288 mg equivalent to 2 mg tizanidine base |
| 185. | 50486 | Rabista Tablet<br>Each Enteric Coated Tablet Contains:<br>Rabeprazole (as Sodium)…20mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br><br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 186. | 50487 | Oxiloc Tablet<br>Each Tablet Contains:<br>Moxifloxacin (as HCl)…400mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br><br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 187. | 50488 | Xoxilum 7.5mg Tablet<br>Each Tablet Contains:<br>Meloxicam…7.5mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018<br>10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 188. | 50489 | Xoxilum 15mg Tablet<br>Each Tablet Contains: | 21-08-2008 | Dy. No. 22159 dated 25-06-2018 | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |

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| | | Meloxicam…15mg | | 10,000/- | | |
| 189. | 50490 | Klarida Tablet Each Tablet Contains: Clarithromycin..250mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018 10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 190. | 50491 | Klarida DS Tablet Each Tablet Contains: Clarithromycin..500mg | 21-08-2008 | Dy. No. 22159 dated 25-06-2018 10,000/- | 20-8-2023 | w.e.f. 21-8-2018 to 20-8-2023 |
| 191. | 075979 | Rexa 30mg Capsule Each capsule contains: Duloxetine HCL enteric coated pellets eq. to Duloxetine….30mg **Source of Pellets:** M/s Spansule Formulations, Sy. No. 172, Plot No. 154 /A /4, IDA Bollaram Village Jinnaram Mandal Medac District AndrPardesh India. | 04-07-2013 | Dy. No. 22158 dated 07-06-2018 20000/- | 03-07-2023 | w.e.f 4-7-2018 to 3-7-2023. |
| 192. | 075980 | Rexa-D 60mg Capsule Each capsule contains: Duloxetine HCL enteric coated pellets eq. to Duloxetine….60mg **Source of Pellets:** M/s Spansule Formulations, Sy. No. 172, Plot No. 154 /A /4, IDA Bollaram Village Jinnaram Mandal Medac District AndrPardesh India. | 04-07-2013 | Dy. No. 22158 dated 07-06-2018 20000/- | 03-07-2023 | w.e.f 4-7-2018 to 3-7-2023. |
| xxiii. | **M/s. Panacea Pharmaceuticals, Plot # 4, St#S-6, National Industrial Zone, Rawat, Islamabad** | | | | | |
| 193. | 50172 | O-Lanz 10mg Tablet Each Tablet Contains: Olanzapine…10mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018 10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 194. | 50173 | Recam 7.5mg Tablet Each Tablet Contains: Meloxicam…7.5mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018 10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 195. | 50175 | O-Lanz 5mg Tablet Each Tablet Contains: Olanzapine…5mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018 10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 196. | 50177 | Lecetra 5mg Tablet/Le-Vox 5mg Tablet Each Tablet Contains: Levocetirizine as 2HCl…5mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018 10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 197. | 50178 | Moxilox 400mg Tablet Each Tablet Contains: Moxifloxacin (as HCl)…400mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018 10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 198. | 50179 | U-Fit 40mg Tablet Each Film Coated Tablet Contains: Famotidine…40mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018 10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 199. | 50180 | Na-Zole 150mg Capsule Each Capsule Contains: Fluconazole…150mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018 10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |

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| 200. | 50181 | Napum 550mg Tablet<br>Each Tablet Contains:<br>Naproxen Sodium…550mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018<br>10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 201. | 50182 | Ri-One 10mg Tablet<br>Each Tablet Contains:<br>Domperidone…10mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018<br>10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 202. | 50183 | Clap 75mg Tablet<br>Each Tablet Contains:<br>Clopidogrel as Bisulphate…75mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018<br>10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 203. | 50185 | Pasic 100mg Tablet<br>Each Tablet Contains:<br>Flurbiprofen…100mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018<br>10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 204. | 50186 | Fastec 120mg Tablet<br>Each Tablet Contains:<br>Fexofenadine as HCl…120mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018<br>10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 205. | 50187 | Fastec 60mg Tablet<br>Each Tablet Contains:<br>Fexofenadine as HCl…60mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018<br>10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| 206. | 50188 | U-Fit 60mg Tablet<br>Each Tablet Contains:<br>Famotidine…20mg | 23-07-2008 | Dy. No. 22654 dated 07-06-2018<br>10,000/- | 22-7-2023 | w.e.f. 23-07-2018 to 22-7-2023 |
| xxiv. | **M/s. Pharmatec Pakistan, D-86/A, S.I.T.E., Karachi** | | | | | |
| 207. | 004204-EX | Apocam 7.5mg Tablet<br>Each tablet contains:<br>Meloxicam…7.5mg | 20-07-2013 | Dy. No. 21548 dated 19-06-2018<br>10,000/- | 19-7-2023 | w.e.f. 20-7-2018 to 19-7-2023 |
| 208. | 004205-EX | Apocam 15mg Tablet<br>Each tablet contains:<br>Meloxicam…15mg | 20-07-2013 | Dy. No. 21548 dated 19-06-2018<br>10,000/- | 19-7-2023 | w.e.f. 20-7-2018 to 19-7-2023 |
| 209. | 004206-EX | Prepase Tablet<br>Each film coated tablet contains:<br>Losartan Potassium …….. …. 50mg | 20-07-2013 | Dy. No. 21548 dated 19-06-2018<br>10,000/- | 19-7-2023 | w.e.f. 20-7-2018 to 19-7-2023 |
| 210. | 004207-EX | Prepase H Tablet<br>Each film coated tablet contains:<br>Losartan Potassium …… …. 50mg<br>Hydrochlorothiazide ……12.5mg | 20-07-2013 | Dy. No. 21548 dated 19-06-2018<br>10,000/- | 19-7-2023 | w.e.f. 20-7-2018 to 19-7-2023 |
| 211. | 020341 | Alerid Syrup<br>Each 5ml contains:<br>Cetirizine Dihydrochloride …. 05mg | 31-10-1997<br>Change of brand name (Histex) dated: 18-08-1998 | Dy. No. 21548 dated 19-06-2018<br>10,000/- | 17-8-2023 | w.e.f. 18-8-2018 to 17-8-2023 |
| xxv. | **M/s Trison Research Laboratories (Pvt) Ltd, 27-A Punjab Small Industrial Estate Sargodha.** | | | | | |
| 212. | 075429 | Astadol Tablets<br>Each tablet contains:<br>Paracetamol……325mg<br>Tramadol HCl….37.50mg<br>(Trison Specs) | 23-05-2013 | Dy. No. 1722 dated 13-06-2018<br>10000 | 22-05-2023 | w.e.f.23-05-2018 to 22-05-2023 |

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| xxvi. | **M/s. Platinum Pharmaceuticals, A-20, North Western Industrial Zone, Bin Qasim, Karachi** | | | | | |
| 213. | 030202 | Seizunil SR Tablet 400mg<br>Each tablet contains:<br>Carbamazepine…400mg | 17-07-2003 | Dy. No. 21285<br>13-06-2018<br>10,000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 214. | 030208 | Losar Plus Tablet<br>Each tablet contains:<br>Losartan Potassium…50mg<br>Hydrochlorothiazide… 12.5mg | 17-07-2003 | Dy. No. 21285 dated<br>13-06-2018<br>10,000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 215. | 030204 | Apofer Syrup 50mg/5ml<br>Each 5ml contains:<br>Iron (III) Hydroxide Polymaltose Complex…50mg | 17-07-2003 | Dy. No. 21285 dated<br>13-06-2018<br>10,000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 216. | 030203 | Fastaid-R Dispersible Tablet 50mg<br>Each tablet contains:<br>Diclofenac Acid eq. to Diclofenac Sodium …50mg | 17-07-2003 | Dy. No. 21285 dated<br>13-06-2018<br>10,000/- | 16-7-2023 | w.e.f. 17-7-2018 to 16-7-2023 |
| 217. | 030911 | Topirama Tablet 25mg<br>Each tablet contains:<br>Topiramate…25mg | 26-07-2003 | Dy. No. 21285<br>13-06-2018<br>10,000/- | 25-7-2023 | w.e.f. 26-7-2018 to 25-7-2023 |
| 218. | 030835 | Topirama Tablet 100mg<br>Each tablet contains:<br>Topiramate…100mg | 26-07-2003 | Dy. No. 21285<br>13-06-2018<br>10,000/- | 25-7-2023 | w.e.f. 26-7-2018 to 25-7-2023 |
| 219. | 030906 | Lustral Tablet 50mg<br>Each tablet contains:<br>Sertraline HCl…50mg | 26-07-2003 | Dy. No. 21285 dated 13-06-2018<br>10,000/- | 25-7-2023 | w.e.f. 26-7-2018 to 25-7-2023 |
| 220. | 048537 | Gerdpill 20mg Capsule<br>Each capsule contains:<br>Enteric coated pellets of Esomeprazole Magnesium Trihydrate eq. to Esomerazole …. 20mg | 10-03-2008 | Dy. No. 21835 dated<br>22-06-2018<br>10,000/- | 09-3-2023 | w.e.f. 10-3-2018 to 09-3-2023 |
| 221. | 048538 | Gerdpill 40mg Capsule<br>Each capsule contains:<br>Enteric coated pellets of Esomeprazole Magnesium Trihydrate eq. to Esomerazole …. 40mg | 10-03-2008 | Dy. No. 21835 dated<br>22-06-2018<br>10,000/- | 09-3-2023 | w.e.f. 10-3-2018 to 09-3-2023 |
| xxvii. | **M/s P.D.H. Laboratories (Pvt) Ltd. 9.5-Km, Sheikhupura Road, (Khaki) Lahore** | | | | | |
| 222. | 030506 | Kuin Tablet 250mg<br>Each Tablet Contains:<br>Ciprofloxacin HCl eq. to Ciprofloxacin …250mg | 30-06-2003 | Dy. No. 20954 dated 11-06-2018<br>10000/- | 29-6-2023 | w.e.f. 30-6-2018 to 29-6-2023 |
| 223. | 030507 | Kuin Tablet 500mg<br>Each Tablet Contains:<br>Ciprofloxacin HCl eq. to Ciprofloxacin …500mg | 30-06-2003 | Dy. No. 20954 dated 11-06-2018<br>10000/- | 29-6-2023 | w.e.f. 30-6-2018 to 29-6-2023 |
| xxviii. | **M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.** | | | | | |
| 224. | 001006-EX | RTflox 500mg Tablets<br>Each tablet contains:<br>Levofloxacin as hemihydrate…500mg | 1-7-2008 | Dy. No. 21893 dated 22-6-2018 | 30-6-2023 | w.e.f.1-7-2018 to 30-6-2023 |

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| 225. | 001007-EX | Deprino 10mg Tablet<br>Each tablet contains:<br>Escitalopram as oxalate……..10mg | 1-7-2008 | Dy. No. 21893 dated 22-6-2018 | 30-6-2023 | w.e.f.1-7-2018 to 30-6-2023 |
| 226. | 001008-EX | Deprino 5mg Tablet<br>Each tablet contains:<br>Escitalopram as oxalate……..5mg | 1-7-2008 | Dy. No. 21893 dated 22-6-2018 | 30-6-2023 | w.e.f.1-7-2018 to 30-6-2023 |
| 227. | 001009-EX | RTflox 250mg Tablets<br>Each tablet contains:<br>Levofloxacin as hemihydrate…250mg | 1-7-2008 | Dy. No. 21893 dated 22-6-2018 | 30-6-2023 | w.e.f.1-7-2018 to 30-6-2023 |
| 228. | 001010-EX | Bonlife 70mg Tablets<br>Each tablet contains:<br>Alendronic acid as sodium alendronate….70mg | 1-7-2008 | Dy. No. 21893 dated 22-6-2018 | 30-6-2023 | w.e.f.1-7-2018 to 30-6-2023 |
| xxix. | **M/s. Synchro Pharmaceuticals, 77-Industrial Estate, Kot Lakhpat, Lahore** | | | | | |
| 229. | 076923 | Synklar Dry Suspension 125mg<br>Each 5ml Contains:<br>Clarithromycin...125mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 230. | 076924 | Fosfosyn Dry Suspension 250mg<br>Each 5ml Contains:<br>Fosfomycin Calcium eq. to Fosfomycin …250mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 231. | 076925 | Synocip Suspension 125mg<br>Each 5ml Contains:<br>Ciprofloxacin as HCl…125mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 232. | 076926 | Synfant Suspension<br>Each 5ml Contains:<br>Artemether…15mg<br>Lumefantrine…90mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 233. | 076927 | Synocip Suspension 250mg<br>Each 5ml Contains:<br>Ciprofloxacin as HCl ……250mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 234. | 076928 | Linlid Powder Suspension 100mg<br>Each 5ml Contains:<br>Linezolid……..100mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 235. | 076929 | Synkast Dry Suspension<br>Each 5ml Contains:<br>Montelukast Sodium eq. to Montelukast ……5mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 236. | 076930 | Syncon Suspension 50mg<br>Each 5ml Contains:<br>Fluconazole … 50mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 237. | 076931 | Venagro Tablet 100mg<br>Each tablet contains:<br>Iron (III) Hydroxide Polymaltose Complex | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |

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| | | eq. to Elemental Iron ……100mg | | | | |
| 238. | 076932 | Moflox Tablet 400mg<br>Each film coated tablet contains:<br>Moxifloxacin as HCl ……..…400mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 239. | 076933 | Synfant Tablet<br>Each tablet contains:<br>Artemether…40mg<br>Lumefantrine…240mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 240. | 076934 | Allerzin Tablet 10mg<br>Each tablet contains:<br>Cetirizine HCl…10mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 241. | 076935 | Synkast Tablet 10mg<br>Each tablet contains:<br>Montelukast Sodium ……10mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 242. | 076936 | Synocip Tablet 500mg<br>Each film coated tablet contains:<br>Ciprofloxacin as HCl ……500mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 243. | 076937 | Aclonac-K Tablet 50mg<br>Each tablet contains:<br>Diclofenac Potassium ……..…50mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 244. | 076938 | Synocip Tablet 250mg<br>Each film coated tablet contains:<br>Ciprofloxacin as HCl ……..…250mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 245. | 076939 | Linlid Tablet 600mg<br>Each tablet contains:<br>Linezolid…600mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 246. | 076940 | Camtrin Tablet 20mg<br>Each tablet contains:<br>Piroxicam Beta-Cyclodextrin eq to Piroxicam … 20mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 247. | 076941 | Comcin Capsule 500mg<br>Each capsule contains:<br>Lincomycin (as HCl) ……..…500mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 248. | 076942 | Syncon Oral Capsule 150mg<br>Each capsule contains:<br>Fluconazole … 150mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 249. | 076943 | Camtrin Capsule 20mg<br>Each capsule contains:<br>Piroxicam Beta-Cyclodextrin eq to Piroxicam … 20mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |
| 250. | 076944 | Venagro-F Capsule 100mg<br>Each capsule contains:<br>Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron…100mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | 24-6-2023 | w.e.f 25-6-2018 to 24-6-2023 |

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| | | Folic Acid…0.35mg | | | | |
| **xxx.** | **M/s. Schazoo Zaka, Kalawala, 20-KM, Lahore-Jaranwala Road, Dist: Sheikhupura** | | | | | |
| 251. | **044992** | Liverton 200mg Tablet<br>Each tablet contains:<br>Silymarin…200mg | 01-03-2007<br>Transfer of registration 28-06-2008 | 20-06-2018<br><br>10000/- | 27-06-2023 | w.e.f. 28-6-2018 to 27-06-2023 |
| 252. | 09933 | Rifapin 300mg Capsule<br>Each capsule contains:<br>Rifampicin…300mg | 15-09-1988<br>Transfer of registration dated 28-06-2008 | 20-06-2018<br><br>10000/- | 27-06-2023 | w.e.f. 28-6-2018 to 27-06-2023 |
| 253. | 028900 | Bizole 200mg Capsule<br>Each capsule contains:<br>Ribavirin…200mg | 21-08-2002<br>Transfer of registration dated 28-06-2008 | 20-06-2018<br><br>10000/- | 27-06-2023 | w.e.f. 28-6-2018 to 27-06-2023 |
| 254. | 025539 | Pyrazid Dry Syrup<br>Each 5ml contains:<br>Pyrazinamide…200mg | 01-02-2000<br>Transfer of registration dated 28-06-2008 | 20-06-2018<br><br>10000/- | 27-06-2023 | w.e.f. 28-6-2018 to 27-06-2023 |
| 255. | 06945 | Rifapin 150mg Capsule<br>Each capsule contains:<br>Rifampicin…150mg | 10-10-1983<br>Transfer of registration 28-06-2008 | 20-06-2018<br><br>10000/- | 27-06-2023 | w.e.f. 28-6-2018 to 27-06-2023 |
| 256. | 028901 | Bizole 400mg Capsule<br>Each capsule contains:<br>Ribavirin…400mg | 21-08-2002<br>Transfer of registration 28-06-2008 | 20-06-2018<br><br>10000/- | 27-06-2023 | w.e.f. 28-6-2018 to 27-06-2023 |
| 257. | 038124 | Tropizol Tablet<br>Each Tablet Contains:<br>Pantoprazole as Sodium Sesquihydrate…40mg | 06-05-2005<br>Transfer of registration dated 28-06-2008 | Dy. No. 20445 dated 06-06-2018<br><br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 258. | 046244 | Zetab Plus Tablet<br>Each Tablet Contains:<br>Ezetimibe…10mg<br>Atorvastatin…10mg | 03-05-2007<br>Transfer of registration 28-06-2008 | Dy. No. 20445 dated 06-06-2018<br><br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 259. | 020993 | Zoprol Capsule<br>Each Capsule Contains:<br>Omeprazole…20mg | 28-04-1998<br>Transfer of registration dated 28-06-2008 | Dy. No. 20445 dated 06-06-2018<br><br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 260. | 077006 | Rifa-3 Tablet<br>Each Film Coated Tablet Contains:<br>Rifampicin…150mg<br>Isoniazid…75mg<br>Ethambutol HCl…275mg | 24-10-2013 | Dy. No. 20444 dated 06-06-2018<br><br>10,000/- | 23-10-2023 | w.e.f.24-10-2018 to 23-10-2023 |
| 261. | 013082 | Rifapin Dry Syrup<br>Each 5ml Contains:<br>Rifampicin…100mg<br>Isoniazid…50mg | 12-12-1991<br>Transfer of registration dated 28-06-2008 | Dy. No. 20444 dated 06-06-2018<br><br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 262. | 027666 | Rifazol + Tablet<br>Each Tablet Contains:<br>Rifampicin…150mg<br>INH…75mg<br>Pyrazinamide…400mg | 07-05-2002<br>Transfer of registration dated 28-06-2008 | Dy. No. 20442 dated 06-06-2018<br><br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |

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| 263. | 008899 | Schazobutol 400mg Tablet<br>Contains:<br>Ethambutol HCl…400mg | 19-01-1986<br>Transfer of registration dated 28-06-2008 | Dy. No. 20442 dated 06-06-2018<br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 264. | 027667 | Schazobutol-H Tablet<br>Each Tablet Contains:<br>Ethambutol HCl…400mg<br>INH…150mg | 07-05-2002<br>Transfer of registration dated 28-06-2008 | Dy. No. 20442 dated 06-06-2018<br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 265. | 006946 | Rifapin 450mg Tablet<br>Contains:<br>Rifampicin…450mg | 10-10-1983<br>Transfer of registration dated 28-06-2008 | Dy. No. 20443 dated 06-06-2018<br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 266. | 013084 | Rifapin-H Dry Syrup<br>Each 5ml Contains:<br>Rifampicin…100mg<br>Isoniazid…50mg | 12-12-1991<br>Transfer of registration dated 28-06-2008 | Dy. No. 20443 dated 06-06-2018<br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 267. | 044706 | Rifapin-H Junior Sachet<br>Each Sachet Contains:<br>Rifampicin…60mg<br>Isoniazid…30mg | 07-11-2006<br>Transfer of registration dated 28-06-2008 | Dy. No. 20443 dated 06-06-2018<br>10,000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 268. | 045990 | Bone-Care 0.25mcg Tablet<br>Each tablet contains:<br>Alfacalcidol…0.25mcg | 12-02-2007<br>Transfer of registration dated 28-06-2008 | 20-06-2018<br>10000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 269. | 013594 | Rifapin H 150 Tablet<br>Each sugar coated tablet contains:<br>Rifampicin…150mg<br>Isoniazid…100mg | 25-07-1992<br>Transfer of registration dated 28-06-2008 | 06-06-2018<br>10000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 270. | 008357 | Rifapin H 300 Tablet<br>Each tablet contains:<br>Rifampicin…300mg<br>Isoniazid…150mg | 22-10-1985<br>Transfer of registration dated 28-06-2008 | 06-06-2018<br>10000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 271. | 013083 | Rifapin H 450 Tablet<br>Each sugar coated tablet contains:<br>Rifampicin…450mg<br>Isoniazid…300mg | 12-12-1991<br>Transfer of registration dated 28-06-2008 | 06-06-2018<br>10000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| 272. | 053618 | Calsup Tablet<br>Each chewable tablet contains:<br>Elemental Calcium …400mg<br>Vitamin D3 …2.5mcg (100U) | 04-12-2008 | 06-06-2018<br>10000/- | 03-12-2023 | w.e.f. 04-12-2018 to 03-12-2023 |
| 273. | 053619 | Piofit Plus 15/850mg Tablet<br>Each film coated tablet contains:<br>Pioglitazone as (HCl) …15mg<br>Metformin HCl…850mg | 04-12-2008 | 06-06-2018<br>10000/- | 03-12-2023 | w.e.f. 04-12-2018 to 03-12-2023 |

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| 274. | 077005 | Rifa-2 Tablet<br>Each film coated tablet contains:<br>Rifampicin…150mg<br>Isoniazid…75mg | 24-10-2013 | 06-06-2018<br><br><br><br>10000/- | 23-10-2023 | w.e.f. 24-12-2018 to 23-12-2023 |
| 275. | 030094 | Sontel 10mg Tablet<br>Each tablet contains:<br>Montelukast …10mg | 17-03-2003 | 06-06-2018<br><br>10000/- | 16-03-2023 | w.e.f.17-03-2018 to 16-03-2023 |
| xxxi. | **M/s. Sante (Pvt) Limited, 97-A, S.I.T.E. Super Highway, Karachi** | | | | | |
| 276. | 007501 | Optoflox Ophthalmic Solution<br>Each ml Contains:<br>Ofloxacin…3mg | 04-09-1997<br>Transfer of registration dated: 04-07-2013 | Dy. No. 2202 0 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 277. | 007784 | Levosan Solution<br>Each ml Contains:<br>Levobunolol HCl…5mg | 30-08-1997<br>Transfer of registration: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 278. | 011039 | Blink Fresh Solution<br>Each ml Contains:<br>Polyvinyl Alcohol…14mg<br>Povidone…6mg | 30-08-1997<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 279. | 021604 | Optolube Sterile Eye Ointment<br>Each gm Contains:<br>Paraffin Liquid…425mg<br>Lanolin Alcohol…20mg<br>White Petrolatum…549.75mg<br>Chlorobutanol as Preservative…..5.25mg | 20-05-1998<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 280. | 021605 | Santochlor Sterile Ophthalmic Solution<br>Contains:<br>Chloramphenicol ……..…0.5% | 20-05-1998<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 281. | 021608 | Optoflox Sterile Eye Ointment<br>Contains:<br>Ofloxacin…0.3% | 20-05-1998<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 282. | 021609 | Santochlor Sterile Eye Ointment<br>Contains:<br>Chloramphenicol ……0.1% | 20-05-1998<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 283. | 021610 | Betalol Sterile Eye Solution<br>Each ml Contains:<br>Timolol…5.0mg | 20-05-1998<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 284. | 022423 | Optofen Ophthalmic Solution<br>Contains:<br>Sodium Fluribiprofen ……..…0.03% | 14-12-1998<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br><br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 285. | 022424 | Ocuflur Ophthalmic Suspension<br>Contains: | 14-12-1998<br>Transfer of registration | Dy. No. 22020 dated 25-06-2018 | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |

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| | | Fluorometholone..0.1% | dated: 04-07-2013 | 10,000/- | | |
| 286. | 023325 | Santovir Ophthalmic Ointment<br>Each gm Contains:<br>Acyclovir…30mg | 16-04-1999 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 287. | 023326 | Oculerg Ophthalmic Solution<br>Each ml Contains:<br>Antazoline HCl…0.5mg<br>Tetrahyderzoline HCl …….0.4mg | 16-04-1999 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 288. | 023328 | Tropic Ophthalmic Solution<br>Each ml Contains:<br>Tropicamide…10mg | 16-04-1999 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 289. | 024659 | Natasan Ophthalmic Suspension<br>Each ml Contains:<br>Natamycin…50mg | 24-04-2002 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 290. | 025660 | Santirol Ophthalmic Suspension<br>Each 5ml Contains:<br>Neomycin (as Neomycin Sulfate)…3.5mg<br>Polymyxin B Sulfate…6000mg<br>Dexamethasone…1.0mg | 08-01-2001 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 291. | 026391 | Ketrosan 0.5% Sterile Ophthalmic Solution<br>Each ml Contains:<br>Ketrolac Tromethamine…5mg | 30-09-2000 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 292. | 026911 | Santobrex Ophthalmic Ointment<br>Each gm Contains:<br>Tobramycin…3.0mg | 12-05-2001 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 293. | 026912 | Santobrex Ophthalmic Solution<br>Each ml Contains:<br>Tobramycin…3.0mg | 12-05-2001 Transfer of registration 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 294. | 030354 | Ocuflur Forte Ophthalmic Suspension<br>Each ml Contains:<br>Fluorometholone ……2.5mg | 06-05-2003 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 295. | 030355 | Tears Forte Ophthalmic Solution<br>Each ml Contains:<br>Dextran…1.0mg<br>Hydroxy Propyl Methyl Cellulose…3.0mg | 06-05-2003 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 296. | 030360 | Fusigel viscous Eye Drops<br>Each ml Contains:<br>Fusidic Acid…10mg | 06-05-2003 Transfer of registration 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |

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| 297. | 030361 | Bakcin Ophthalmic Solution<br>Each ml Contains:<br>Ciprofloxacin (as Ciprofloxacin HCl…)…3mg | 06-05-2003<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 298. | 030362 | Salub Ophthalmic Solution 2%<br>Each ml Contains:<br>Sodium Chloride…20mg | 06-05-2003<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 299. | 032590 | Optoflox Plus Ophthalmic Solution<br>Each ml Contains:<br>Ofloxacin…3.0mg | 20-05-2004<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 300. | 032592 | Florozil Ophthalmic Suspension<br>Each ml Contains:<br>Fluorometholone (10% excess)…1.1mg<br>Sodium Cromoglycate…40mg | 20-05-2004<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 301. | 032593 | Ocuflur PN Ophthalmic Suspension<br>Each ml Contains:<br>Fluorometholone ……1.2mg<br>Polymyxin B Sulphate…5000Unit<br>Neomycin (as Neomycin Sulphate) …3.5mg | 20-05-2004<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 302. | 034768 | Co-Dorzal Ophthalmic Solution<br>Each ml Contains:<br>Dorzolamide HCl eq. to Dorzolamide…20mg<br>Timolol Maleate eq. to Timilol…5mg | 06-12-2004<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 303. | 037033 | Ocuflur Ophthalmic Ointment<br>Each 100gm Contains:<br>Flurometholone…1gm | 10-02-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 304. | 037034 | Santobet Ophthalmic Solution<br>Each ml Contains:<br>Betaxolol (as HCl)…5mg | 10-02-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 305. | 037037 | Salub Ophthalmic Solution 5%<br>Each ml Contains:<br>Sodium Chloride…50mg | 10-02-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 306. | 037041 | Santolev Ophthalmic Solution<br>Each ml Contains:<br>Levofloxacin eq. to Levofloxacin…5mg | 10-02-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |

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| 307. | 037900 | Hylosan Ophthalmic Solution 0.18%<br>Each ml Contains:<br>Sodium Hyaluronate…0.18% | 18-05-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 308. | 037921 | Trutears Liquigel 1% Ophthalmic Solution<br>Each gm Contains:<br>Carboxy Methyl Cellulose Sodium…10mg | 18-05-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 309. | 039283 | Ximer Ophthalmic Solution 0.3%<br>Each ml Contains:<br>Gatifloxacin…3.0mg | 06-12-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 310. | 039491 | Quixin Plus Ophthalmic Solution 1.5%<br>Each ml Contains:<br>Levofloxacin Hemihydrate 15.36mg eq. to Levofloxacin…15mg | 26-07-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 311. | 039492 | Kerovit A Ophthalmic Ointment<br>Each gm Contains:<br>Vitamin A (as Palmitate)…250IU | 26-07-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 312. | 042016 | Megamox Ophthalmic Solution 0.5% Sterile<br>Each ml Contains:<br>Moxifloxacin (as HCl)…5.0mg | 08-12-2005<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 313. | 048527 | Zyclat Ophthalmic Solution Sterile<br>Each ml Contains:<br>Latanoprost…50mcg(0.005%)<br>Timolol (as Timolol Maleate)…5mg(0.5%) | 07-03-2008<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 314. | 061775 | Xepat Ophthalmic Solution 0.1%<br>Each ml Contains:<br>Olopatadine as HCl…1mg | 02-08-2010<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 315. | 061776 | Brimolol Ophthalmic Solution<br>Each ml Contains:<br>Brimonidine Tartrate…2.0mg<br>Timolol as Maleate…5.0mg | 02-08-2010<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 316. | 067458 | Lotepred Forte Ophthalmic Suspension 0.5%<br>Each ml Contains:<br>Loteprednol Etabonate…5mg | 26-02-2011<br>Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018<br>10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 317. | 067459 | Lotepred Ophthalmic Suspension 0.2% | 26-02-2011<br>Transfer of | Dy. No. 22020 dated 25-06-2018 | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |

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| | | Each ml Contains: Loteprednol Etabonate…2mg | registration dated: 04-07-2013 | 10,000/- | | |
| 318. | 067460 | Xepat Forte Ophthalmic Solution 0.2% Each ml Contains: Olopatadine as HCl…2mg | 26-02-2011 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018 10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 319. | 067645 | Vislat Ophthalmic Solution Each ml Contains: Latanoprost…50mcg | 13-04-2011 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018 10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| 320. | 070515 | Lotepred-T Ophthalmic Suspension Each ml Contains: Tobramycin…3.0mg Loteprednol Etabonate…5.0mg | 28-04-2011 Transfer of registration dated: 04-07-2013 | Dy. No. 22020 dated 25-06-2018 10,000/- | 03-07-2023 | w.e.f. 04-07-2018 to 03-07-2023 |
| **xxxii. M/s S.J & G. Fazul Ellahie (Pvt) Ltd. E-46, S.I.T.E.Karachi** | | | | | | |
| 321. | 048802 | Nezkil 200mg Infusion Each ml contains: Linezolid…2mg | 21-07-2008 | 08-06-2018 10000/- | 20-07-2023 | w.e.f. 21-07-2018 to 20-07-2023 |
| 322. | 048803 | Nezkil 400mg Infusion: Each ml contains: Linezolid…2mg | 21-07-2008 | 08-06-2018 10000/- | 20-07-2023 | w.e.f. 21-07-2018 to 20-07-2023 |
| 323. | 048804 | Nezkil 600mg Infusion: Each ml contains: Linezolid…2mg | 21-07-2008 | 08-06-2018 10000/- | 20-07-2023 | w.e.f. 21-07-2018 to 20-07-2023 |
| 324. | 031101 | Motu 7.5mg Tablet Each tablet contains: Meloxicam…7.5mg | 26-08-2003 | 08-06-2018 10000/- | 25-08-2023 | w.e.f. 26-08-2018 to 25-08-2023 |
| 325. | 031102 | Motu 15mg Tablet Each tablet contains: Meloxicam…15mg | 26-08-2003 | 08-06-2018 10000/- | 25-08-2023 | w.e.f. 26-08-2018 to 25-08-2023 |
| 326. | 004160 | Droxryl Cream/Ointment 20gm Each gm contains: Bufexamac…50mg | 26-06-1978 | 08-06-2018 20000/- | 25-06-2023 | w.e.f. 26-06-2018 to 25-06-2023 |
| 327. | 004203-EX | Vervex Injection 1gm IM Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone…1.000gm | 02-07-2013 | 08-06-2018 10000/- | 01-07-2023 | w.e.f. 02-07-2018 to 01-07-2023 |
| xxxiii. **M/s Sanofi-Aventis Pakistan, Plot No. 22, Korangi Industrial Area, Karachi.** | | | | | | |
| 328. | 050375 | Aventriax 250mg IV Injection Each Vial Contains: Ceftriaxone (as Sodium) … 250mg | 05-08-2008 | Dy. No. 20431 dated 06-06-2018 10000/- | 04-08-2023 | w.e.f. 05-08-2018 to 04-08-2023 |
| 329. | 050376 | Aventriax 250mg IM Injection Each Vial Contains: Ceftriaxone (as Sodium) … 250mg | 05-08-2008 | Dy. No. 20432 dated 06-06-2018 10000/- | 04-08-2023 | w.e.f. 05-08-2018 to 04-08-2023 |
| 330. | 050377 | Aventriax 500mg IM Injection Each Vial Contains: | 05-08-2008 | Dy. No. 20434 dated 06-06-2018 | 04-08-2023 | w.e.f. 05-08-2018 to 04-08-2023 |

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| | | Ceftriaxone (as Sodium) … 500mg | | 10000/- | | |
| 331. | 050379 | Aventriax 1gm IV Injection<br>Each Vial Contains:<br>Ceftriaxone (as Sodium) … 1gm | 05-08-2008 | Dy. No. 20435 dated 06-06-2018<br><br>10000/- | 04-08-2023 | w.e.f. 05-08-2018 to 04-08-2023 |
| 332. | 050391 | Aventriax 500mg IV Injection<br>Each Vial Contains:<br>Ceftriaxone (as Sodium) … 500mg | 05-08-2008 | Dy. No. 20433 dated 06-06-2018<br><br>10000/- | 04-08-2023 | w.e.f. 05-08-2018 to 04-08-2023 |
| 333. | 050378 | Aventriax 1gm IM Injection<br>Each Vial Contains:<br>Ceftriaxone (as Sodium) … 1gm | 05-08-2008 | Dy. No. 20436 dated 06-06-2018<br><br>10000/- | 04-08-2023 | w.e.f. 05-08-2018 to 04-08-2023 |
| xxxiv. **M/s Servier Research & Pharmaceuticals Pakistan (Pvt) Ltd, Sheikhupura Road, Lahore** | | | | | | |
| 334. | 014911 | Stablon Tablets<br>Each coated tablet contains:<br>Tianeptine as sodium salt……..12.5mg | 09-02-1994<br>Import to local transfer approval dated: 27-09-2003 | Dy. No. 12213 dated 03-04-2018<br><br>10000 | 26-09-2023 | w.e.f 27-09-2018 to 26-09-2023 |
| 335. | 027918 | Vastarel MR Tablet<br>Each tablet contains:<br>Trimetazidine….35mg | 08-09-2008 (Re-registration of drug) | Dy. No. 12212 dated 03-04-2018<br><br>10000 | 07-09-2023 | w.e.f 08-09-2018 to 07-09-2023 |
| 336. | 014942 | Trivastal Retard 50mg Tablets<br>Each tablet contains:<br>Piribedil…..50mg | 08-09-2008 (Re-registration of drug) | Dy. No. 12210 dated 03-04-2018<br><br>10000 | 07-09-2023 | w.e.f 08-09-2018 to 07-09-2023 |
| xxxv. **M/s Shaheen Pharmaceuticals, 3-Km, Murghzar Road, Saidu Sharif, Swat.** | | | | | | |
| 337. | 077414 | Easyast 10mg Tablet<br>Each film coated tablet contains:<br>Montelukast Sodium eq. to Montelukast …. 10mg | 28-06-2013 | Dy. No. 21753 dated 21-06-2018<br><br>10000/- | 27-06-2023 | w.e.f. 28-06-2018 to 27-06-2023 |
| xxxvi. **M/s Shrooq Pharmaceuticals, 21-Km, Ferozepur Road, Lahore.** | | | | | | |
| 338. | 074341 | Bonpac Tablet<br>Each Film Coated Tablet Contains:<br>Ibandronate Sodium Monohydrate eq. to Ibandronic Acid…150mg | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| 339. | 074342 | BioArt-DS Dispersible Tablet<br>Each Tablet Contains:<br>Artemether…40mg<br>Lumefantrine…240mg | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| 340. | 074343 | Cebenz Tablet<br>Each Film Coated Tablet Contains:<br>Cyclobenzaprine HCl…10mg | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| 341. | 074344 | Clof Gel<br>Each gm Contains: | 12-04-2013 | Dy. No. 20629 dated 05-06-2018 | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |

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| | | Aceclofenac…1.5%w/w | | 20000/- | | |
| 342. | 074345 | BioArt-Forte Dispersible Tablet<br>Each Tablet Contains:<br>Artemether…80mg<br>Lumefantrine…480mg | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| 343. | 074346 | Natifin Cream<br>Each gm Contains:<br>Naftifine (as HCl)…1%w/w | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 with label calim as per innovator i.e. Naftifine hydrochloride. |
| 344. | 074347 | Benipro Tablet<br>Each Film Coated Tablet Contains:<br>Probenecid…500mg | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| 345. | 074348 | Cebenz Tablet<br>Each Film Coated Tablet Contains:<br>Cyclobenzaprine HCl…5mg | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| 346. | 074349 | Termi Gel<br>Each 100gm Contains:<br>Terbinafine HCl…1.0%w/w | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| 347. | 074350 | BioArt Dispersible Tablet<br>Each Tablet Contains:<br>Artemether…20mg<br>Lumefantrine…120mg | 12-04-2013 | Dy. No. 20629 dated 05-06-2018<br>20000/- | 11-04-2023 | w.e.f. 12-4-2018 to 11-04-2023 |
| xxxvii. **M/s Standpharm Pakistan, 20-Km, Ferozepur Road, Lahore** | | | | | | |
| 348. | 049938 | Simib Tablet<br>Each film coated tablet contains:<br>Simvastatin…10mg<br>Ezitimibe…10mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 349. | 049942 | Cephinol Tablet 100mg<br>Each film coated tablet contains:<br>Pyritinol HCl…100mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 350. | 049943 | Simib Forte Tablet<br>Each film coated tablet contains:<br>Simvastatin…20mg<br>Ezitimibe…10mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 351. | 049944 | Cephinol Liquid<br>Each 5ml contains:<br>Pyritinol HCl…80.5mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 352. | 049945 | A-Mal Injection<br>Each ampoule contains:<br>Artemether…80mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 353. | 049946 | Kolex Tablet 10mg<br>Each tablet contains:<br>Simvastatin…10mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 354. | 049947 | Kolex Tablet 20mg<br>Each tablet contains:<br>Simvastatin…20mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 355. | 049948 | Kolex Tablet 40mg<br>Each tablet contains: | 17-07-2008 | Dy. No. 22021 dated 25-06-2018 | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |

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| | | Simvastatin…40mg | | 10000/- | | |
| 356. | 049949 | Sapride Tablet 25mg<br>Each tablet contains:<br>Levosulpiride…25mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 357. | 049950 | Sapride Tablet 50mg<br>Each tablet contains:<br>Levosulpiride…50mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 358. | 049951 | Sapride Tablet 100mg<br>Each tablet contains:<br>Levosulpiride…100mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 359. | 049953 | Patin Tablet 20mg<br>Each tablet contains:<br>Paroxetine as HCl…20mg | 17-07-2008<br>Change of brand name dated: 02-10-2009 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 360. | 049954 | Nervex Tablet 300mg<br>Each tablet contains:<br>Gabapentin…300mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 361. | 049955 | Bronkeez Chewable Tablet 4mg<br>Each tablet contains:<br>Montelukast (as Sodium)…4mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 362. | 049956 | Ophen Tablet<br>Each tablet contains:<br>Aceclofenac…100mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 363. | 049958 | Tromit Injection 30mg/ml<br>Each 1ml ampoule contains:<br>Ketorolac Tromethamine …30mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 364. | 049961 | Amlotin 10mg Tablet<br>Contains:<br>Amlodipine Besylate eq. to Amlodipine…10mg<br>Atorvastatin Calcium eq. to Atorvastatin…10mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 365. | 049962 | Amlotin Forte Tablet<br>Contains:<br>Amlodipine Besylate eq. to Amlodipine…10mg<br>Atorvastatin Calcium eq. to Atorvastatin…20mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| 366. | 049963 | Megnil Tablet<br>Each film coated tablet contains:<br>Zolmitriptan…2.5mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| xxxviii. **M/s Swat Pharmaceuticals, Saidu Sharif Road Amankot Swat.** | | | | | | |
| 367. | 021628 | Panaset Tablet<br>Each Tablet Contains:<br>Paracetamol…500mg<br>Caffeine…65mg | 20-05-1998 | Dy. No. 20946 dated 11-06-2018<br>20000/- | 19-05-2023 | w.e.f 20-05-2018 to 19-05-2023 |
| xxxix. **M/s. Tabros Pharma, L-20/B, Sector-22, F. B. Industrial Area, Karachi** | | | | | | |
| 368. | 075990 | E-Clar XL 500mg Tablet<br>Each Extended Release Film Coated Tablet | 30-08-2013 | Dy. No. 20288 dated 05-06-2018<br>10,000/- | 29-08-2023 | w.e.f. 30-8-2018 to 29-8-2023 |

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| | | Contains: Clarithromycin…500mg | | | | |
| 369. | 030985 | Fusil-B Cream Each gm contains: Fusidic Acid…20mg | 18-09-2003 | Dy. No. 22734 dated 29-06-2018 10,000/- | 17-9-2023 | w.e.f. 18-9-2018 to 17-9-2023 |
| 370. | 030986 | Fusil-HC Cream Each gm contains: Fusidic Acid…20mg Hydrocortisone Acetate…10mg | 18-09-2003 | Dy. No. 22734 dated 29-06-2018 10,000/- | 17-9-2023 | w.e.f. 18-9-2018 to 17-9-2023 |
| 371. | 030987 | Nixim Tablet Each tablet contains: Nimesulide…100mg | 18-09-2003 | Dy. No. 22734 dated 29-06-2018 10,000/- | 17-9-2023 | w.e.f. 18-9-2018 to 17-9-2023 |
| 372. | 076015 | Uraxat 40mg Tablet Each film coated tablet contains: Febuxostat…40mg | 19-09-2013 | Dy. No. 22735 dated 29-06-2018 10,000/- | 18-9-2023 | w.e.f. 19-9-2018 to 18-9-2023 |
| 373. | 076016 | Valtec AMH 5/160/12.5mg Tablet Each film coated tablet contains: Amlodipine Besylate eq. to Amlodipine…5mg Valsartan…160mg Hydrochlorothiazide ……12.5mg | 19-09-2013 | Dy. No. 22735 dated 29-06-2018 10,000/- | 18-9-2023 | w.e.f. 19-9-2018 to 18-9-2023 |
| 374. | 076017 | Bisheart 2.5mg Tablet Each film coated tablet contains: Bisoprolol Fumarate eq. to Bisoprolol…2.5mg | 19-09-2013 | Dy. No. 22735 dated 29-06-2018 10,000/- | 18-9-2023 | w.e.f. 19-9-2018 to 18-9-2023 |
| xl. | **M/s. Venus Pharma, 23 KM, Multan Road, Lahore** | | | | | |
| 375. | 030227 | Oxynin Tablet Each tablet contains: Oxybutynin HCl...3mg | 16-06-2003 | Dy. No. 20623 dated 07-06-2018 10,000/- | 15-06-2023 | W.e.f. 16-6-2018 to 15-6-2023 |
| 376. | 030228 | Metrolone Tablet Each tablet contains: Metronidazole Benzoate…321.60mg Di-Iodohydroxyquinolone…325mg | 16-06-2003 | Dy. No. 20623 dated 07-06-2018 10,000/- | 15-06-2023 | W.e.f. 16-6-2018 to 15-6-2023 |
| 377. | 030229 | Lipinil-10 Tablet Each tablet contains: Simvastatin…10mg | 16-06-2003 | Dy. No. 20623 dated 07-06-2018 10,000/- | 15-06-2023 | W.e.f. 16-6-2018 to 15-6-2023 |
| 378. | 030230 | Lipinil-20 Tablet Each tablet contains: Simvastatin…20mg | 16-06-2003 | Dy. No. 20623 dated 07-06-2018 10,000/- | 15-06-2023 | W.e.f. 16-6-2018 to 15-6-2023 |
| 379. | 030231 | Vio-Chlor Tablet Each tablet contains: Chloroquine Phosphate 250mg eq. to Chloroquine Base…150mg | 16-06-2003 | Dy. No. 20623 dated 07-06-2018 10,000/- | 15-06-2023 | W.e.f. 16-6-2018 to 15-6-2023 |
| 380. | 030232 | Vio-Cobal Injection Each ml contains: Mecobalamine..500mcg | 16-06-2003 | Dy. No. 20623 dated 07-06-2018 10,000/- | 15-06-2023 | W.e.f. 16-6-2018 to 15-6-2023 |
| 381. | 030233 | Vio-Aqua Injection Each 5ml contains: Water for | 16-06-2003 | Dy. No. 20623 dated 07-06-2018 | 15-06-2023 | W.e.f. 16-6-2018 to 15-6-2023 |

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| | | Injection…5ml | | 10,000/- | | |
| xli. | **M/s Wilson's Pharmaceuticals, 387-388, I-9, Industrial Area, Islamabad.** | | | | | |
| 382. | 072840 | Sofvasc-Telm Tablet 5/40mg<br>Each tablet contains:<br>Amlodipine Besylate…5mg<br>Telmisartan…40mg | 18-08-2011<br>Change of brand name dated 25-6-2013 | Dy. No. 21284 dated 13-06-2018<br>10000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 383. | 072841 | Sofvasc-Telm Tablet 5/80mg<br>Each tablet contains:<br>Amlodipine Besylate…5mg<br>Telmisartan…80mg | 18-08-2011<br>Change of brand name dated 25-6-2013 | Dy. No. 21284 dated 13-06-2018<br>10000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| 384. | 072842 | Sofvasc-Telm Tablet 10/40mg<br>Each tablet contains:<br>Amlodipine Besylate…10mg<br>Telmisartan…40mg | 18-08-2011<br>Change of brand name dated 25-6-2013 | Dy. No. 21284 dated 13-06-2018<br>10000/- | 24-6-2023 | w.e.f. 25-6-2018 to 24-6-2023 |
| xlii. | **M/s Xenon Pharmaceuticals, 9.5-Km, Sheikhupura Road, Lahore.** | | | | | |
| 385. | 021205 | Dermistat Cream<br>Contains:<br>Miconazole Nitrate…2% | 25-04-1998 | Dy. No. 21880 dated 22-06-2018<br>20000/- | 24-4-2023 | w.e.f 25-4-2018 to 24-4-2023 |
| 386. | 053602 | Yoxi 400mg Tablet<br>Each tablet contains:<br>Moxifloxacin…400mg | 04-12-2008 | Dy. No. 21881 dated 22-06-2018<br>10000/- | 03-12-2023 | w.e.f 04-12-2018 to 03-12-2023 |
| 387. | 053614 | Fervol Tablet<br>Each tablet contains;<br>Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron…100mg<br>Folic Acid…0.35mg | 04-12-2008 | Dy. No. 21882 dated 22-06-2018<br>10000/- | 03-12-2023 | w.e.f 04-12-2018 to 03-12-2023 |
| 388. | 053613 | ASP Tablet<br>Each tablet contains:<br>Aspirin…75mg | 04-12-2008 | Dy. No. 21883 dated 22-06-2018<br>10000/- | 03-12-2023 | w.e.f 04-12-2018 to 03-12-2023 |
| 389. | 053600 | Profox 250mg Tablet<br>Each tablet contains:<br>Ciprofloxacin…250mg | 04-12-2008 | Dy. No. 21885 dated 22-06-2018<br>10000/- | 03-12-2023 | w.e.f 04-12-2018 to 03-12-2023 |
| 390. | 053601 | Profox 500mg Tablet<br>Each tablet contains:<br>Ciprofloxacin…500mg | 04-12-2008 | Dy. No. 21886 dated 22-06-2018<br>10000/- | 03-12-2023 | w.e.f 04-12-2018 to 03-12-2023 |
| 391. | 030998 | Zepitor 10mg Tablet<br>Each tablet contains:<br>Atorvastatin (as Calcium)…10mg | 30-10-2003 | Dy. No. 21887 dated 22-06-2018<br>10000/- | 29-10-2023 | w.e.f. 30-10-2018 to 29-10-2023 |
| 392. | 030999 | Zepitor 20mg Tablet<br>Each tablet contains:<br>Atorvastatin (as Calcium)…20mg | 30-10-2003 | Dy. No. 21888 dated 22-06-2018<br>10000/- | w.e.f. 30-10-2018 to 29-10-2023 | w.e.f. 30-10-2018 to 29-10-2023 |
| 393. | 030403 | Febricod-15 Tablet<br>Each tablet contains:<br>Paracetamol…500mg<br>Codeine…15mg | 05-07-2003 | Dy. No. 21889 dated 22-06-2018<br>10000/- | 04-07-2023 | w.e.f. 05-07-2018 to 04-07-2023 |
| 394. | 030404 | Febricod-30 Tablet<br>Each tablet contains:<br>Paracetamol…500mg | 05-07-2003 | Dy. No. 21890 dated 22-06-2018<br>10000/- | 04-07-2023 | w.e.f. 05-07-2018 to 04-07-2023 |

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| | | Codeine…30mg | | | | |
| 395. | 030405 | Febricod-C Tablet<br>Each tablet contains:<br>Paracetamol…500mg<br>Codeine…15mg<br>Caffeine…15mg | 05-07-2003 | Dy. No. 21891 dated 22-06-2018 10000/- | 04-07-2023 | w.e.f. 05-07-2018 to 04-07-2023 |

**b. Locally Manufactured Registered Drugs (Veterinary)**

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

| Sr. No | Reg. No. | Brand Name, Composition & Specification | Initial date of Registration | Date of application (R&I) Fee submitted | Renewal validity | Decision |
|---|---|---|---|---|---|---|
| **xliii.** | **M/s Elegance Pharmaceuticals, Chak Belli, Pandori Road, District Rawalpindi.** | | | | | |
| 396. | 049793 | Enrotin Solution<br>Each 100ml Contains:<br>Enrofloxacin…10gm<br>Colistin Sulphate…50MIU | Transfer of registration dated 27-06-2013 | Dy. No. 22013 dated 25-06-2018 10000/- | 26-06-2023 | w.e.f. 27-06-2018 to 26-06-2023 |
| xliv. | **M/s Elko Organization, Plot# 27 & 28, Sector 12/B, North Karachi, Industrial Area, Karachi.** | | | | | |
| 397. | 075648 | Levanil 13.65% Injection<br>Each ml Contains:<br>Levamisole HCl…13.65% | 03-06-2013 | Dy. No. 20016 dated 04-06-2018 10000/- | 02-06-2023 | w.e.f. 03-06-2018 to 02-06-2023 |
| 398. | 075649 | Clant Oral Suspension<br>Each ml Contains:<br>Closantel…50mg | 03-06-2013 | Dy. No. 20016 dated 04-06-2018 10000/- | 02-06-2023 | w.e.f. 03-06-2018 to 02-06-2023 |
| 399. | 075650 | Fe-Zole 5% Oral Suspension<br>Each gm Contains:<br>Fenbendazole…5% | 03-06-2013 | Dy. No. 20016 dated 04-06-2018 10000/- | 02-06-2023 | w.e.f. 03-06-2018 to 02-06-2023 |
| 400. | 075651 | Fe-Zole 10% Oral Suspension<br>Each gm Contains:<br>Fenbendazole…10% | 03-06-2013 | Dy. No. 20016 dated 04-06-2018 10000/- | 02-06-2023 | w.e.f. 03-06-2018 to 02-06-2023 |
| xlv. | **M/s Nawan Laboratories (Pvt) Ltd. 136, Sector 15, Korangi Industrial Area, Karachi.** | | | | | |
| 401. | 049514 | Naflor Oral Solution<br>Each ml Contains:<br>Florfenicol… 100mg | 22-07-2008 | Dy. No. 22294 dated 26-06-2018 10000/- | 21-07-2023 | w.e.f 22-07-2018 to 21-07-2023 |
| 402. | 049512 | Multina Injection<br>Each ml Contains;<br>Vitamin A…15,000IU<br>Vitamin D3…1,000IU<br>Vitamin E…20mg<br>Vitamin B1…10mg<br>Vitamin B2…5mg<br>Vitamin B6…3mg<br>Nicotinamide…35mg<br>D-Pantothenol…25mg<br>Vitamin B12…5mcgc | 22-07-2008 | Dy. No. 22293 dated 26-06-2018<br><br>10000/- | 21-07-2023 | w.e.f 22-07-2018 to 21-07-2023 |
| xlvi. | **M/s Evergreen Pharmaceuticals (Vet. Division) 69-70 / B, Glaxo Town Industrial Estate, 20-Km F/Pur Road, Lahore.** | | | | | |
| 403. | 074071 | EG Supertonic Solution<br>Each ml contains:<br>Vitamin E…200mg | 07-05-2013 | Dy. No. 20625 dated 07-06-2018 | 06-05-2023 | w.e.f. 07-05-2018 to 06-05-2023 |

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| | | Sorbitol…50mg<br>Choline Chloride…50mg | | 20000/- | | |
| xlvii. | **M/s A & K Pharmaceuticals, 94-A, Punjab Small Industries Estate, Sargodha Road, Faisalabad.** | | | | | |
| 404. | 048217 | En-Col Liquid<br>Each 100ml Contains:<br>Enrofloxacin HCl…20gm<br>Colistin Sulphate…50,000,000IU | 19-07-2008 | Dy. No. 21840 dated 22-06-2018 10000/- | 18-07-2023 | w.e.f. 19-07-2018 to 18-07-2023 |
| 405. | 048216 | Enroak Liquid<br>Each 100ml Contains:<br>Enrofloxacin HCl…20gm | 19-07-2008 | Dy. No. 21843 dated 22-06-2018 10000/- | 18-07-2023 | w.e.f. 19-07-2018 to 18-07-2023 |
| xlviii. | **M/s Intervac (Pvt) Ltd., 18-KM, Lahore Sheikhupura Road, Sheikhupura** | | | | | |
| 406. | 048245 | Enro-C Liquid<br>Each 100ml Contains:<br>Enrofloxacin HCl…10gm<br>Colistin Sulphate ……5,000,000IU | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 407. | 048246 | Enrofas-C Oral Powder<br>Each 100gm Contains:<br>Enrofloxacin HCl…20,000mg<br>Colistin Sulphate …4,500,000IU | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 408. | 048248 | Oxytet 200 Powder<br>Each Kg Contains:<br>Oxytetracyclin HCl 200gm eq. to Oxytetracyclin …185gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 409. | 048249 | Lincol Water Soluble Powder<br>Each gm Contains:<br>Lincomycin HCl…100mg<br>Colistin Sulfate ……..…800,000IU | 02-09-2008 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 01-09-2023 | w.e.f. 02-09-2018 to 01-09-2023 |
| 410. | 048251 | Leva-C Oral Suspension<br>Each ml Contains:<br>Levamisole HCl…100mg<br>Closantai…100mg | 30-07-2008 | Dy. No. 21578 dated 19-06-2018 10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 411. | 048252 | Intermectin Oral Solution<br>Each 100ml Contains:<br>Ivermectin…1gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018 10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 412. | 048253 | NCC-154 Powder<br>Each Kg Contains:<br>Colistin Sulphate…4.0gm<br>Chlortetracycline HCl…80.0gm<br>Neomycin Sulphate…70.0gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 413. | 048254 | Novafas Liquid<br>Each ml Contains:<br>Novaminsulfon…40mg<br>Etilefrin…0.2mg<br>Calcium Gluconate…110mg<br>Magnesium Gluconate…10mg<br>Sodium Salicylate…7mg<br>Nicotinamide…0.3mg | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |

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| | | Caffeine…10mg<br>Boric Acid…10mg | | | | |
| 414. | 048255 | Neo-Oxy-E Powder<br>Each 100gm Contains:<br>Erythromycin (Thiocyanate)…10gm<br>Neomycin Sulphate…10gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 415. | 048256 | Niclovit Powder<br>Each 100gm Contains:<br>Niclosamide…40gm<br>Levamisole HCl…10gm<br>Vitamin A…15,000IU | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 416. | 048257 | Erythrofas Plus Powder<br>Each 100gm Contains:<br>Erythromycin Thiocyanate…10gm<br>Sulphadiazine Sodium…10gm<br>Trimethoprim…2.0gm<br>Bromhexine HCl…2.50gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 417. | 048258 | Chlorofura-N Water Soluble Powder<br>Each 100gm Contains:<br>Chlortetracycline HCl Vet…10gm<br>Neomycin Sulphate…3.0gm<br>Furaltadone Vet…7.5gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 418. | 048259 | Albasol CS Suspension<br>Each 100ml Contains:<br>Albendazole…2.5gm<br>Cobalt Chloride…0.075gm<br>Sodium Selenite…0.035gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 419. | 048260 | Clozanide-CS Drench<br>Each 100ml Contains:<br>Oxyclozanide…4.5gm<br>Cobalt Sulphate…0.382gm<br>Sodium Selenite…50mg | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 420. | 048262 | Levacol Plus Oral Suspension<br>Each 100ml Contains:<br>Levamisole HCl…1.50gm<br>Oxyclozanide…3.0gm<br>Cobalt Sulphate…0.380gm<br>Selenium…0.035gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 421. | 048263 | Oxafas CS Liquid<br>Each 100ml Contains:<br>Oxfendazole…2.265gm<br>Cobalt…0.200gm<br>Selenium…0.050gm | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 422. | 048264 | Cinafas Oral Suspension<br>Each 100ml Contains:<br>Trimethoprim…2500mg<br>Sulphamethazine…5000mg<br>Sulphamethoxypyridazine …7500mg<br>Enrofloxacin…7500mg | 30-07-2008 | Dy. No. 21578 dated 19-06-2018<br><br>10,000/- | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |
| 423. | 048265 | Poulcocx Super Oral Suspension<br>Each ml Contains: | 30-07-2008 | Dy. No. 21578 dated 19-06-2018 | 29-07-2023 | w.e.f. 30-07-2018 to 29-07-2023 |

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| | | Slulphadiazine…35.50mg<br>Sulphadimidine…28.4mg<br>Neomycin<br>Sulphate…1.8mg<br>Hyoscine<br>Methylbromide…0.04mg<br>Pectin…7.1mg<br>Kaolin…103.3mg<br>Vitamin B1…0.15mg<br>Vitamin B2…0.2mg | | 10,000/- | | |
| 424. | 075733 | Tricla Plus Drench<br>Each 100ml Contains:<br>Triclabendazole…5gm<br>Levamisole HCl…3.75gm | 19-06-2013 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 18-06-2023 | w.e.f. 19-06-2018 to 18-06-2023 |
| 425. | 075734 | Naflosol Oral Solution<br>Each 1 Liter Contains:<br>Florfenicol…230mg | 19-06-2013 | Dy. No. 21578 dated 19-06-2018<br>10,000/- | 18-06-2023 | w.e.f. 19-06-2018 to 18-06-2023 |
| xlix. | **M/s Noa Hemis Pharmaceuticals, Plot No. 154 Sector 23 Korangi Industrial Area Karachi** | | | | | |
| 426. | 048204 | Tylodoxin Water Soluble Powder<br>Each 1000g Contains:<br>Tylosin Tartrate…100gm<br>Doxycycline HCl…210gm | 17-07-2008 | Dy. No. 22405 dated 07-06-2018<br>10000/- | 16-07-2023 | w.e.f. 17-07-2018 to 16-07-2023 |
| l. | **M/s SJ&G Fazul Ellahie, Karachi** | | | | | |
| 427. | 048153 | Enflox-20 Injection<br>Each ml contains:<br>Enrofloxacin…200mg | 02-07-2008 | 08-06-2018<br>10000/- | 01-07-2023 | w.e.f. 02-07-2018 to 01-07-2023 |
| 428. | 048295 | Rexa-Plus Injection<br>Each ml contains:<br>Florefenicol…300mg | 31-07-2008 | 08-06-2018<br>10000/- | 30-07-2023 | w.e.f. 31-07-2018 to 30-07-2023 |
| 429. | 048296 | Flukazole Suspension 8.75%<br>Each ml contains:<br>Triclabendazole…50mg<br>Levamisole HCl…37.5mg | 31-07-2008 | 08-06-2018<br>10000/- | 30-07-2023 | w.e.f. 31-07-2018 to 30-07-2023 |
| 430. | 048297 | Flukazole Suspension 19.5%<br>Each ml contains:<br>Triclabendazole…120mg<br>Levamisole HCl…75mg | 31-07-2008 | 08-06-2018<br>10000/- | 30-07-2023 | w.e.f. 31-07-2018 to 30-07-2023 |

**c. Pending cases**

Below mentioned products of various firms were submitted in period of January 2018 to May, 2018 which evaluated previously but were incomplete on the part of firm due various shortcoming. After completion of application by the firms the same are placed before Registration Board for consideration. The decision is mentioned in the last column below:

| Sr. No. | Reg. No. | Brand Name, Composition | Initial date of Registration | Date of application (R&I) Fee submitted | Renewal validity | Decision |
|---|---|---|---|---|---|---|
| **li.** | **M/s. Martin Dow Marker Ltd., 7, Jail Road, Quetta.** | | | | | |
| 431. | 017582 | Pcam 10mg Capsules<br>Each capsule contains:<br>Piroxicam …..10mg | 13-05-1997<br>Transfer of registration dated: 03-3-2008 and 21-3-2018 | Dy. No. 6599 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 432. | 010194 | Concor Tablet 5mg<br>Each film coated tablet contains:<br>Bisoprolol Hemifumarate..5mg | 05-12-1989<br>Transfer of registration dated 03-03-2008 and 21-03-2018 | Dy. No. 6522 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 433. | 004158 | Multibionta for Infusion<br>Each 10ml contains:<br>Vitamin A (Palmitate) … 10,000 I.U<br>Vitamin B1 (Thiamine HCl) … 50mg<br>Riboflavin 5 (Phosphate Sodium)… 10mg<br>Vitamin B6 (Pyridoxine HCl)… 15mg<br>Nicotinamide… 100mg<br>Dexpanthenol … 25mg<br>Vitamin C (Ascorbic Acid) …500mg<br>Vitamin E (dl-Alpha Tocopheryl Acetate) … 5mg | 11-06-1978<br>Transfer of registration dated 03-03-2008 and 21-03-2018 | Dy. No. 6569 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 434. | 026855 | Lodopin 10mg Tablet<br>Each film coated tablet contain:<br>Amlodipine Besylate eq. to Amlodipine …10mg | 12-05-2001<br>Change of brand name dated 22-01-2002<br>Transfer of registration dated: 03-3-2008 and 21-03-2018 | Dy. No. 6557 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 435. | 025485 | Ranulcid Tablet 300mg<br>Each film coated tablet contain:<br>Ranitidine HCl eq. to Ranitidine … 300mg | 17-11-1999<br>Change of brand name dated 15-02-2000<br>Transfer of registration dated 03-03-2008 and 21-03-2018 | Dy. No. 6613 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 436. | 025486 | Ranulcid Tablet 150mg<br>Each film coated tablet contains:<br>Ranitidine HCl eq. to Ranitidine … 150mg | 17-11-1999<br>Change of brand name dated 15-02-2000 | Dy. No. 6612 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |

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| | | | Transfer of registration dated: 03-3-2008 and 21-03-2018 | | | |
| 437. | 007434 | Sangobion Syrup<br>Each 5ml contains:<br>Ferrous Gluconate … 129.5mg<br>Vitamin B1 (Thiamine HCI) … 1mg<br>Vitamin B2 (Riboflavin)… 1mg<br>Vitamin B6 (Pyridoxine HCI)… 1.5mg<br>Nicotinamide… 15mg<br>Biotin … 0.3mg | 27-05-1984<br>Transfer of registration dated 03-03-2008 and 21-03-2018 | Dy. No. 6619 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 438. | 018032 | Optifam Tablet 20mg<br>Each film coated tablet contains:<br>Famotidine … 20mg | 05-10-1995<br>Change of brand name dated 04-03-1996<br>Transfer of registration dated 03-03-2008 and 21-03-2018 | Dy. No. 6596 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 439. | 037634 | Mercip Tablets 750 mg<br>Each Film Coated Tablet contains:<br>Ciprofloxacin Hydrochloride, USP equivalent to Ciprofloxacin …750mg | 07-03-2005<br>Transfer of registration dated 03-03-2008 and 07-06-2018 | Dy. No. 6563 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 440. | 018040 | Pcam 20mg Capsules<br>Each capsule contains:<br>Piroxicam …..20mg | 13-05-1997<br>Transfer of registration dated 03-03-2008 and 21-03-2018 | Dy. No. 6600 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 441. | 018039 | Teril 200mg Tablet<br>Each tablet contain:<br>Carbamazepine … 200mg | 15-10-1995<br>Transfer of registration dated 03-03-2008 and 21-03-2018 | Dy. No. 6625 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 442. | 006472 | Refobacin Injection 40 mg<br>Each 1 ml contains:<br>Gentamicin sulfate USP equivalent to Gentamicin …….40 mg | 11-07-1982<br>Transfer of registration dated 03-03-2008 and 07-06-2018 | Dy. No. 6616 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 443. | 023375 | Refobacin Injection 20 mg<br>Each 1 ml contains:<br>Gentamicin sulfate USP equivalent to Gentamicin ….20 mg | 19-04-199<br>Transfer of registration dated 03-03-2008 and 07-06-2018 | Dy. No. 6615 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 444. | 045345 | Neurogabin-M Capsule 100mg<br>Each capsule contains:<br>Gabapentin … 100mg | 11-05-2007<br>Change of brand name and transfer dated 15-03-2008<br>Transfer of registration dated **21-03-2018** | Dy. No. 6591 Dated21-02-2018<br><br>10000/- | 14-03-2023 | w.e.f. 15-03-2018 to 14-03-2023 |
| 445. | 045346 | Neurogabin-M Capsule 300mg<br><br>Each Capsule Contains:<br>Gabapentin … 300mg | 11-05-2007<br>Change of brand name dated 31-12-2007 | Dy. No. 6592 dated 21-02-2018 | 14-03-2023 | w.e.f. 15-03-2018 to 14-03-2023 |

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| | | | Change of brand name and transfer dated 15-03-2008<br><br>Transfer of registration dated 21-03-2018 | 10000/- | | |
| 446. | 025583 | Lodoz Tablets<br>Each Film coated Tablet contains:<br>Bisoprolol Hemifumarate ... 2.5 mg<br>Hydrochlorothiazide ... 6.25 mg | 24-03-2000<br>Transfer of registration dated 03-03-2008 and 07-06-2018 | Dy. No. 6562 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 447. | 001492 | Polybion Forte C Tablets<br>Each Film Coated Tablet contains:<br>Vitamin B1 (Thiamine Mononitrate) …..15 mg<br>Vitamin B2 (Riboflavin) ….15 mg<br>Nicotinamide …. 50 mg,<br>Vitamin B6 (Pyridoxine Hydrochloride)… 10 mg<br>Calcium D-Pantothenate……25 mg<br>Vitamin B12 (Cyanocobalamin) …..10 mcg<br>Vitamin C (Ascorbic Acid) ……. 300 mg | 15-08-1976<br><br>Transfer of registration dated:<br>03-03-2008<br><br>Transfer of registration dated:<br>07-06-2018 | Dy. No. 6605 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 448. | 000719 | Polybion Strong Tablets<br>Each Film coated Tablet contains:<br>Vitamin B1 (Thiamine Hydrochloride)…..15 mg,<br>Vitamin B2 (Riboflavin)….4 mg<br>Vitamin B6 (Pyridoxine Hydrochloride)…… 10 mg<br>Vitamin B12 (Cyanocobalamin)…10 mcg<br>Nicotinamide…..50 mg,<br>Calcium D-Pentothenate….6mg | 30-11-1976<br><br>Transfer of registration dated:<br>03-03-2008<br><br>Transfer of registration dated:<br>07-06-2018 | Dy. No. 6609 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 449. | 017581 | Pcam 20mg Tablets (Dispersible)<br><br>Each tablet contains:<br>Piroxicam USP … 20mg | 13-05-1997<br><br>Transfer of registration dated:<br>03-03-2008<br><br>Transfer of registration dated: 21-03-2018 | Dy. No. 6603 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 450. | 001465 | Bisolvon 8 mg Tablets<br>Each Tablets Contains:<br>Bromhexine Hydrochloride ... | 15-08-1976<br><br>Transfer of | Dy. No. 6629 dated | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |

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| | | 8mg | registration dated: 03-3-2008 Transfer of registration dated: 07-6-2018 | 21-02-2018 10000/- | | |
| 451. | 024601 | Mercip Tablet 250mg<br>Each film coated tablet contains:<br>Ciprofloxacin HCl eq. to Ciprofloxacin …250mg | 21-03-2002 Transfer of registration dated: 03-3-2008 Transfer of registration dated: 21-3-2018 | Dy. No. 6564 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 452. | 020741 | Sterile Water for Injection<br>Each ampoule contains:<br>Sterile water….. 5 ml | 23-12-1997 Transfer of registration dated: 03-3-2008 Transfer of registration dated: 07-6-2018 | Dy. No. 6623 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 453. | 014786 | Polybion-N-Drops<br>Each 2 ml contains:<br>Thiamine Hydrochloride...5mg<br>Riboflavin 5'-Phosphate….2 mg<br>Pyridoxine Hydrochloride …..…2 mg<br>Biotin…… 2 mg<br>Nicotinamide…..20 mg<br>Dexpanthenol ….250 mcg | 05-12-1993 Transfer of registration dated: 03-3-2008 Transfer of registration dated: 07-6-2018 | Dy. No. 6610 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 454. | 017580 | Pcam 10mg Tablets<br>Each dispersible tablet contains:<br>Piroxicam USP … 10mg | 13-05-1997 Transfer of registration dated: 03-3-2008 Transfer of registration dated: 21-3-2018 | Dy. No. 6602 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 455. | 025487 | Ranulcid Injection<br>Each 2ml contains:<br>Ranitidine HCI as base ……50mg | 17-11-1999 Change of Brand Name 15-2-2000 Transfer of registration dated: 03-3-2008 Transfer of registration dated:21-3-2018 | Dy. No. 6611 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 456. | 013911 | Neurofenac Injection<br>Each 3ml contains:<br>Diclofenac Sodium … 75mg | 16-01-1993 Change of title of firm dated 03-03-2008 Transfer of registration dated: 21-3-2018 | Dy. No. 6586 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 457. | 004169 | Polybion Forte Syrup<br>Vitamin B1 (Thiamine HCI) … 5mg<br>Vitamin B6 (Pyridoxine HCI)… 2.5mg<br>Nicotinamide … 20mg<br>Riboflavin 5 (Phosphate Sodium) … 2.5mg<br>Dexpanthenol … 3mg | 11-06-1978 Change of title of firm dated 03-3-2008 Transfer of registration dated:21-3-2018 | Dy. No. 6607 dated 21-02-2018 10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |

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| | | Vitamin B12 (Cyanocobalamin) … 3mcg | | | | |
| 458. | 048580 | Psyper Tablets 4 mg<br><br>Each Film coated Tablet contains:<br>Risperidone……..4 mg | 03-05-2008<br><br>Transfer of registration dated: 07-06-2018 | Dy. No. 14426 dated 18-04-2018<br><br>10000/- | 02-05-2023 | w.e.f. 03-05-2018 to 02-05-2023 |
| 459. | 017583 | Cosome Cough Syrup<br>Each 5ml Contains:<br>Dextromethorphan Hydrobromide…..10mg<br>Pseudoephedrine Hydrochloride……30mg<br>Chlorpheniramine Maleate……2mg | 10-07-1995<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6524 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 460. | 024603 | Klaribact 250mg Tablet<br><br>Each Tablet Contains:<br>Clarithromycin…… 250mg | 21-03-2002<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6553 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 461. | 030010 | Glucovance Tab<br><br>Each Tablet Contains:<br>250mg/1.25mg<br>Metformin Hydrochloride … 250mg<br>Glibenclamide ... 1.25mg | 21-02-2003<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6539 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 462. | 020245 | Depex Capsule<br><br>Each Capsule Contains:<br>Fluoxetine HCI eq. to Fluoxetine … 20mg | 14-10-1997<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6527 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 463. | 028000 | Concor Tablet 2.5mg<br>Each Tablet Contains:<br>Bisoprolol Hemi fumarate …..2.5mg | 14-06-2002<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6521 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 464. | 020990 | Neuromet Injection<br>Each 1ml contains:<br>Mecobalamin…..500mcg | 25-04-1998<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6589 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 465. | 037355 | Levomerc 500mg Tablet<br>Each film coated tablet Contains:<br>Levofloxacin Hemihydrate eq. to Levofloxacin … 500mg | 23-02-2005<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6556 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |

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| 466. | 037354 | Levomerc 250mg Tablet<br>Each Film Coated Contains:<br>Levofloxacin Hemihydrate eq. to Levofloxacin …250mg | 23-02-2005<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-03-2018 | Dy. No. 6555 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 467. | 020241 | Multibionta Syrup<br>Each 5ml Contains:<br>Vitamin A (Palmitate) USP…….3000 I.U<br>Vitamin D (Cholecalciferol) USP….400 I.U<br>Vitamin B1 (Thiamine Hydrochloride) USP… 1.5mg<br>Riboflavin 5 Phosphate sodium…..... 1.2mg<br>Vitamin B6 (Pyridoxine HCl) USP……1mg<br>Vitamin B12 (cyanocobalamin) USP… 3mcg<br>Vitamin C (Ascorbic acid) USP…… 50mg<br>Nicotinamide USP… 10mg | 14-10-1997<br><br>Transfer of registration dated: 03-03-2008<br><br>Transfer of registration dated 21-3-2018 | Dy. No. 6567 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 468. | 001501 | Wintogeno Balm<br>Each 50gm Balm Contains:<br>Methyl Salicylate … 12.17% w/w | 25-10-1976<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6628 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 469. | 017573 | Nidonil Tablet<br><br>Each Tablet Contains:<br>Gilclazide … 80mg | 10-07-1995<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6594 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 470. | 047263 | Exigentin Syrup<br>Each 5ml Contains:<br>Loratadine … 5mg | 24-11-2007<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6534 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 471. | 001062 | Encephabol Liquid<br>Each 5ml contains:<br>Pyritinol Eq. to Pyritinol Hydrochloride Monohydrate…… 80.5mg | 23-10-1988<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6531 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 472. | 027809 | Merstatin Tablets 20mg<br>Each Tablet contains:<br>Simvastatin..…20 mg | 07-05-2002<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 07-06-2018 | Dy. No. 6580 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |

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| 473. | 032062 | Ibusoft Gel<br>Each 1gm contains:<br>Ibuprofen ….100 mg | 24-01-2004<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 07-06-2018 | Dy. No. 6551 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 474. | 047220 | Cosome –E Cough Syrup<br>Ammonium Chloride … 30mg<br>Diphenhydramine HCI … 8mg<br>Aminophylline …32mg | 13-11-2007<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6525 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 475. | 024605 | Klaribact Dry Suspension<br><br>Each 5ml Contains:<br>Clarithromycin…..125mg | 21-03-2002<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6552 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 476. | 030008 | Glucovance Tablet 500mg/5mg<br>Each film coated tablet contains:<br>Metformin Hydrochloride …….500mg<br>Glibenclamide ... 5mg | 21-02-2003<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6541 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 477. | 030009 | Glucovance Tablet 500mg/2.5mg<br>Each film coated tablet contains:<br>Metformin Hydrochloride …….. 500mg<br>Glibenclamide ... 2.5mg | 21-02-2003<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6540 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 478. | 045347 | Neurogabin-M Capsule 400mg<br><br>Each Capsule Contains:<br>Gabapentin…….400mg | 11-05-2007<br>Change of brand name 31-12-2007 and 15-03-2008<br>Transfer of registration dated 15-03-2008 and 21-3-2018 | Dy. No. 6593 dated 21-02-2018<br><br>10000/- | 14-03-2023 | w.e.f. 15-03-2018 to 14-03-2023 |
| 479. | 010195 | Concor Tablet 10mg<br><br>Each Film Coated Tablet Contains:<br>Bisoprolol Hemifumarate … 10mg | 05-12-1989<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6523 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 480. | 000552 | Glucophage Tab 500mg<br><br>Each Film Coated Tablet Contains:<br>Metformin Hydrochloride … 500mg | 21-10-1987<br>Transfer of registration dated:03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6536 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 481. | 001486 | Neurobion Tablet<br>Each Film Coated Tablet Contains: | 15-08-1976<br>Transfer of registration | Dy. No. 6584 dated | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |

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| | | Vitamin B1 (Thiamine Mononitrate) … 100mg<br>Vitamin B6 (Pyridoxine HCI)… 200mg<br>Vitamin B12 (Cyanocobalamin) … 200mcg | dated: 03-03-2008<br><br>Transfer of registration dated 21-3-2018 | 21-02-2018<br><br>10000/- | | |
| 482. | 024604 | Klaribact Tablet500mg<br><br>Each Film Coated Tablet Contains:<br>Clarithromycin … 500mg | 21-03-2002<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6554 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 483. | 013365 | Glucophage Tablet 250mg<br>Each film coated tablet contains:<br>Metformin Hydrochloride … 250mg | 25-05-1992<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6535 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 484. | 032061 | Ibusoft Suspension<br><br>Each 5 ml contains:<br>Ibuprofen .....100mg | 24-01-2004<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 07-06-2018 | Dy. No. 6550 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 485. | 001063 | Encephabol Tablet<br><br>Each film coated tablet contains:<br>Pyritinol Dihydrochloride Mononitrate ...100mg | 14-07-1976<br>Transfer from import to local 4-12-1986<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6532 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 486. | 027808 | Merstatin Tablets 10mg<br><br>Each Tablet contains:<br>Simvastatin …10 mg | 07-05-2002<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 07-06-2018 | Dy. No. 6579 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 487. | 024602 | Mercip Tablet500mg<br><br>Each Film Coated Tablet Contains:<br>Ciprofloxacin HCL eq. Ciprofloxacin … 500mg | 21-03-2002<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6565 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 488. | 001485 | Neurobion Injection<br>Each 3ml contains:<br>Vitamin B1 (Thiamine HCI) … 100mg<br>Vitamin B6 (Pyridoxine HCI)… 100mg<br>Vitamin B12 (Cyanocobalamin)… 1000mcg | 15-08-1976<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6583 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |

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| 489. | 047264 | Exigentin Tablet<br>Each Film Coated Tablet Contains:<br>Loratadine …10mg | 24-11-2007<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6533 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 490. | 018749 | Delax Tablet<br><br>Each sugar enteric coated tablet contains:<br>Bisacodyl … 5mg | 03-04-1996<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 22-3-2018 | Dy. No. 6526 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 491. | 025488 | Glucophage Tablet 1g<br><br>Each Film Coated Tablet Contains:<br>Metformin Hydrochloride … 1g | 11-05-2000<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6590 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 492. | 011875 | Glucophage Tablet 850mg<br><br>Each film coated Tablet Contains:<br>Metformin Hydrochloride … 850mg | 29-12-1990<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6537 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 493. | 020991 | Neuromet Tablet<br><br>Each Sugar Coated Tablet Contains:<br>Mecobalamin…….500mcg | 25-04-1998<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6590 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| 494. | 017585 | Neoprox 500mg Tablet<br><br>Each film coated Tablet Contains:<br>Naproxen … 500mg | 10-07-1995<br>Transfer of registration dated: 03-3-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6582 dated 21-02-2018<br><br>10000/- | 02-03-2023 | w.e.f. 03-03-2018 to 02-03-2023 |
| lii. | **M/s. Welwrd Pharmaceuticals, Plot No. 3, Block A, Phase I-II, Industrial Estate Hattar-Pakistan** | | | | | |
| 495. | 040344 | Safbal Injection<br>Each ml Contains:<br>Mecobalamine…500mcg | 08-04-2013<br>Change of Brand Name | Dy. No. 10390 20-03-2018 10000/- | 07-04-2023 | w.e.f. 08-04-2018 to 07-04-2023 |
| 496. | 076811 | Wrd-D Injection<br>Each 1ml Contains;<br>Cholecalciferol…5mg (200,000 IU) | 08-04-2013 | Dy. No. 10390 dated 20-03-2018 10000/- | 07-04-2023 | w.e.f. 08-04-2018 to 07-04-2023 |
| 497. | 076812 | Pyrostig Injection<br>Each 1ml Contains:<br>Neostigmine…2.5mg<br>Glycopyrolate…0.5mg | 08-04-2013 | Dy. No. 10390 20-03-2018 10000/- | 07-04-2023 | w.e.f. 08-04-2018 to 07-04-2023 |
| 498. | 076813 | Dexwel Tablet<br>Each Film Coated Tablet Contains:<br>Dexibuprofen…400mg | 08-04-2013 | Dy. No. 10390 20-03-2018 10000/- | 07-04-2023 | w.e.f. 08-04-2018 to 07-04-2023 |

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| 499. | 076814 | Brtil Tablet<br>Each Tablet Contains:<br>Bromocriptine (as Mesylate)…2.5mg | 08-04-2013 | Dy. No. 10390 20-03-2018 10000/- | 07-04-2023 | w.e.f. 08-04-2018 to 07-04-2023 |
| 500. | 076815 | Duloxwrd 30mg Capsule<br>Each Capsule Delayed Release Contains:<br>Enteric-Coated Pellets of Duloxetine HCl eq. to Duloxetine…30mg<br><br>M/s Vision Pharmaceuticals Islamabad. | 10-04-2013 | Dy. No. 10390 dated 20-03-2018 10000/- | 09-04-2023 | w.e.f. 10-04-2018 to 09-04-2023 |
| 501. | 075551 | Moxiwrd 400mg Tablet<br>Each Film Coated Tablet Contains:<br>Moxifloxacin (as HCl)…400mg | 24-01-2013 | Dy.# 10390 20-03-2018 10000/- Differential fee of Rs. 10,000/- submitted on 30-01-2019 | 23-01-2023 | w.e.f.24-01-2018 to 23-01-2023 |
| 502. | 075517 | Paroxiwel 20mg Tablet<br>Each Film Coated Tablet Contains:<br>Paroxetine (as HCl)…20mg | 04-01-2013 | Dy.10390 dated 20-03-2018 30000/- | 03-01-2023 | w.e.f. 04-01-2018 to 03-01-2023 |
| 503. | 049373 | Narbip Injection<br>Each ml Contains:<br>Buprenorphine as HCl…0.3mg | 12-07-2008 | Dy. 10390 dated 20-03-2018 10000/- | 11-07-2023 | w.e.f. 12-07-2018 to 11-07-2023 |
| 504. | 049374 | Nalbowin Injection<br>Each ml Contains:<br>Nalbuphene HCl…10mg | 12-07-2008 | Dy. 10390 dated 20-03-2018 10000/- | 11-07-2023 | w.e.f. 12-07-2018 to 11-07-2023 |
| 505. | 049375 | Pintaz Injection<br>Each ml Contains:<br>Pantazocine as Lactate…30mg | 12-07-2008 | Dy. 10390 dated 20-03-2018 10000/- | 11-07-2023 | w.e.f. 12-07-2018 to 11-07-2023 |
| 506. | 075518 | Montiwel 4mg Sachet<br>Each Sachet Contains:<br>Montelukast (as Sodium) Granules…4mg | 04-01-2013 | Dy. 10532 dated 21-03-2018 30000/- | 03-01-2023 | w.e.f. 04-01-2018 to 03-01-2023 |

## INCOMPLETE CASES

### a. Locally manufactured registered drugs (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

| Sr. No | Reg. No. | Brand Name, Composition & Specification | Initial date of Registration | Date of application (R&I) Fee submitted | Validity | Decision |
|---|---|---|---|---|---|---|
| **liii.** | **M/s Leads Pharma Pvt Ltd, Plot No .81-A, Street No.6, I-10/3. Islamabad.** | | | | | |
| 507. | 035886 | Leceph 500mg Injection<br>Each ml contains:<br>Cephradine…500mg | 10-01-2005<br><br>Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018<br><br>10,000/- | | Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. |
| liv. | **M/s Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad** | | | | | |
| 508. | 21859 | Fertin Tablet<br>Each Tablet Contains:<br>Vitamin A…30,000IU<br>Vitamin E…70mg | 09-06-1998 | Dy. No. 20293 dated 05-06-2018<br><br>10,000/- | 08-06-2023 | Deferred for latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status. |
| 509. | 21860 | Healet Tablet 200mg<br>Each Tablet Contains:<br>Cimetidine…200mg | 11-07-1998 | Dy. No. 20293 dated 05-06-2018<br><br>10,000/- | 10-7-2023 | Deferred for latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status. |
| 510. | 21862 | Healet Tablet 400mg<br>Each Tablet Contains:<br>Cimetidine…400mg | 11-07-1998 | Dy. No. 20293 dated 05-06-2018<br><br>10,000/- | 10-7-2023 | Deferred for latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status. |
| 511. | 021862 | Vitalet-M Tablet<br>Each Tablet Contains:<br>Vitamin A…5500IU<br>Vitamin E…30IU<br>Vitamin D…400IU<br>Vitamin B1…3.0mg<br>Riboflavin…3.4mg<br>Pyrodoxine HCl…3.0mg<br>Cyanocobalamine …9.0mg<br>Nicotinamide…30mg<br>Pantothenic Acid …10mg<br>Ascorblic Acid…120mg<br>Folic Acid…0.4mg<br>Magnesium…100mg<br>Calcium…40mg<br>Zinc..15mg<br>Manganese...5mg<br>Iron...27mg<br>Copper...2mg<br>Chloride...7.5mg<br>Potassium...7.5mg<br>Iodine...150mcg | 09-06-1998 | Dy. No. 20293 dated 05-06-2018<br><br>10,000/- | 08-06-2023 | Deferred for latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status. |

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| | | Molybdenum...15mcg<br>Biotin...15mcg<br>Chromium...15mcg<br>Selenium...10mcg | | | | |
| 512. | 021863 | Vitalet-H Tablet<br>Each Tablet Contains:<br>Vitamin A Acetate…8.333IU<br>Vitamin E…5.0IU<br>Vitamin D…133IU<br>Thiamine Monohydrate…3.3mg<br>Riboflavin…3.3mg<br>Cynocobalamine …50mcg<br>Nicotinamide…33.3mg<br>Calcium Pantothenate…11.7mg<br>Ascorbic Acid…100mg<br>Folic Acid…0.33mg<br>Magnesium…41.7mg<br>Iron…66.7mg<br>Copper…0.67mg | 09-06-1998 | Dy. No. 20293 dated 05-06-2018<br><br>10,000/- | 08-06-2023 | Deferred for latest inspection report declaring GMP compliant status, since submitted report does not conclude GMP compliant status. |
| lv. | **M/s. AGP Limited, B-23-C, S.I.T.E., Karachi.** | | | | | |
| 513. | 024881 | Novafol 250mg Capsules<br>Each capsule contains:<br>Cephradine……250mg | 23-06-1999<br><br>Transfer of registration dated 17-07-2008 | Dy. No. 21874 dated 22.6.2018 10000/- | s | Registration Board decided to defer the case for the opinion from legal Affair Division and clarification from the firm regarding the matter related to dedicated section of Cephalosporin under Schedule B Section I (5.2).**Dedicated Facilities for Production of** Drug Act 1976. Whether firm is legally authorize to hold the registration of such product for which they do not have dedicated section currently. According to the firm, they have approved area for the production of Cephalosporin at the time of Registration later the firm discontinued the production of Cephalosporin and the firm do not have approval of Cephalosporin section vide letter no. F.2-3/92-Lic (Vol-II) Dated 28th April, 2016 of Licensing Division. |
| 514. | 024882 | Novafol 500mg Capsules<br>Each capsule contains:<br>Cephradine……500mg | 23-06-1999 Transfer of registration 17-7-2008 | Dy. No. 21875 dated 22.6.2018 10000/- | | -do- |
| 515. | 024884 | Novafol 250mg Suspension<br>Each 5ml contains:<br>Cephradine……250mg | 23-06-1999 Transfer of registration 17-7-2008 | Dy. No. 21873 dated 22.6.2018 10000/- | | -do- |
| 516. | 024878 | Novafol 250mg Injection (IM/IV) | 23-06-1999 | Dy. No. 21876 dated | | -do- |

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| | | Each vial contains:<br>Cephradine…..250mg | Transfer of registration 17-7-2008 | 22.6.2018<br><br>10000/- | | |
| 517. | 024949 | Tecadin Injection 250mg IM/IV<br>Each vial contains:<br>Cefoperazone..250mg | 23-06-1999<br>Transfer of registration dated 17-7-2008 | Dy. No. 21863 dated 22-6-2008<br>10000/- | | -do- |
| 518. | 018070 | Kefadim 1gm Injection<br>Each vial contains:<br>Ceftazidime Sterile…..1.00gm | 24-09-1995<br>Transfer of registration dated 13-10-2003 | Dy. No. 21868 dated 22.6.2018<br><br>10000/- | | Registration Board decided to defer the case for the clarification of status of Application of year 2011 for the extension in contract manufacturing from the concerned section. As the firm submitted permission dated 15-7-2008 of contract manufacturing from M/s PharmEvo Pvt Limited Karachi for three years. The firm also informed that they had applied for extension in 2011 from same facility for five years but no evidence of approval of extension is provided. They further stated that product is discontinued. |
| 519. | 018069 | Kefadim 500mg Injection<br>Each vial contains:<br>Ceftazidime Sterile…….500mg | 24-09-1995<br>Transfer of registration dated 13-10-2003 | Dy. No. 21868 dated 22.6.2018<br><br>10000/- | | -do- |
| 520. | 036178 | Kefadim 250mg Injection<br>Each vial contains:<br>Ceftazidime Pentahydrate eq. to Ceftazidime…..250mg | 10-01-2005 | Dy. No. 21866 dated 22-6-2008<br><br>10000/- | | . –do- |
| 521. | 021640 | Phyllocontin 100mg Tablet<br>Each tablet contains:<br>Aminophylline Hydrate……100mg | 20-05-1998<br>Transfer of registration dated 17-7-2008 | Dy. No. 21852 dated 22.6.2018<br><br>10000/- | | As the product was initially registered with the brand name Phyllocontin Continus Tablet. The transfer of registration also bears the same name. However the transfer letter dated 17-7-2008 bears only "Phyllocontin" when the was inquired about the evidence of change of brand name, they informed that:<br>"*The full brand name is Phyllocontin Continus Tablet, sometimes it is mentioned in short form as Phyllocontin 100mg Tablet"*<br>**Registration Board decided to defer the case for the clarification from the firm regarding the change of brand name if any.** |

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| 522. | 016418 | Nebcin Injection 80mg<br>Each vial contains:<br>Tobramycin Sulphate….. 80mg | 21-11-1994<br><br>Change of brand name dated 30-8-2003 | Dy. No. 21857 dated 22-6-2008<br><br>10000/- | | Registration Board decided to defer the case for the clarification of transfer of registration in the name of M/s. AGP Limited, Karachi from the concerned section. |
| 523. | 024951 | Tecadin Injection 1gm IM/IV<br>Each vial contains:<br>Cefoperazone…..1gm | 23-06-1999<br><br>Transfer of registration dated 17-7-2008 | Dy. No. 21865 dated 22-6-2008<br><br>10000/- | | Registration Board decided to defer the case for the opinion from legal Affair Division and clarification from the firm regarding the matter related to dedicated section of Cephalosporin under Schedule B Section I (5.2).**Dedicated Facilities for Production of** Drug Act 1976. Whether firm is legally authorize to hold the registration of such product for which they do not have dedicated section currently. According to the firm, they have approved area for the production of Cephalosporin at the time of Registration later the firm discontinued the production of Cephalosporin and the firm do not have approval of Cephalosporin section vide letter no. F.2-3/92-Lic (Vol-II) Dated 28th April, 2016 of Licensing Division. |
| 524. | 024883 | Novafol Suspension<br>Each 5ml Contains:<br>Cephradine…..125mg | 23-06-1999<br>Transfer of registration dated 17-7-2008 | Dy. No. 21872 dated 22-6-2008<br><br>10000/- | | -do- |
| 525. | 024880 | Novafol Injection IM/IV<br>Each vial contains:<br>Cephradine…..1gm | 23-06-1999<br>Transfer of registration dated 17-7-2008 | Dy. No. 21878 dated 22-6-2008<br><br>10000/- | | -do- |
| 526. | 024950 | Tecadin Injection 500mg IM/IV<br>Each vial contains:<br>Cefoperazone….500mg | 23-06-1999<br>Transfer of registration dated 17-7-2008 | Dy. No. 21864 dated 22-6-2008<br><br>10000/- | | -do- |
| 527. | 024879 | Novafol Injection IM/IV<br>Each vial contains:<br>Cephradine…..500mg | 23-06-1999<br>Transfer of registration 17-07-2008 | Dy. No. 21877 dated 22-6-2008<br>10000/- | | -do- |
| 528. | 016908 | Tojina 6.0mg Tablet<br>Each tablet contains:<br>Bromazepam…..6mg | Transfer of registration dated:<br>02-07-1999<br><br>Change of brand name 30-08-2003 | Dy. No. 21862 dated 22-6-2008<br><br>10000/- | | Defer for following:<br>i. Opinion from Legal Affair Division regarding those firms where at the time of registration there is no requirement for approval of Psychotropic section but later on it is mandatory to do so, in the light of decision of Central |

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| | | | | | | Licensing Board in its 233rd meeting i.e. as follows:<br>After thorough deliberations and keeping in view the directions of Policy Board, recommendations of DRAP Authority, recommendations of Committee for Allocation of Controlled Substances / Drugs (Inter-Ministerial Committee), views of honorable members, previous decisions of Central Licensing Board on the said issue, and ensuring adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes as highlighted by INCB, the Central Licensing Board decided: -<br>□ To continue the previous policy / decisions of Central Licensing Board of segregated facility for manufacturing of Psychotropic / Narcotic Drugs.<br>□ To process all pending layout plans / applications accordingly in the light of above decision.<br>□ To carryout fresh panel inspections of sections / areas of Psychotropic / Narcotic Drugs considered and deferred in 227th meeting of CLB.<br>ii. Clarification from the firm regarding transfer of registration in name of M/s AGP Pvt Limited from the firm. |
| 529. | 016907 | Tojina 3.0mg Tablet<br>Each tablet contains:<br>Bromazepam…..3mg | Transfer of registration dated: 02-07-1999<br>Change of brand name : 30-8-2003 | Dy. No. 21861 dated 22-6-2008<br><br>10000/- | | -do- |
| lvi. | **M/s Amson Vaccines & Pharma, 154, Industrial Triangle, Kahuta Road, Islamabad** | | | | | |
| 530. | 029052 | Cepham 125mg Suspension<br>Each 5ml Contains:<br>Cephalexin Monohydrate eq. to Cephalexin…125mg | 31-12-2002 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | Registration Board decided to defer the case for clairfaction regarding the approval of manufacturing facility from licensing division. |
| 531. | 029053 | Cepham 250mg Suspension<br>Each 5ml Contains:<br>Cephalexin Monohydrate eq. to Cephalexin…250mg | 31-12-2002 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | -do- |

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| 532. | 029054 | Cepham 250mg Capsule<br>Each Capsule Contains:<br>Cephalexin Monohydrate eq. to Cephalexin…250mg | 31-12-2002 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | -do- |
| 533. | 029055 | Cepham 500mg Capsule<br>Each Capsule Contains:<br>Cephalexin Monohydrate eq. to Cephalexin…500mg | 31-12-2002 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | -do- |
| 534. | 029056 | Curoxime 250mg Injection<br>Each Vial Contains:<br>Cefuroxime Sodium eq. to Cefuroxime…250mg | 31-12-2002 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | -do- |
| 535. | 029057 | Curoxime 750mg Injection<br>Each Vial Contains:<br>Cefuroxime Sodium eq. to Cefuroxime…750mg | 31-12-2002 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | -do- |
| 536. | 029058 | Curoxime 1.5g Injection<br>Each Vial Contains:<br>Cefuroxime Sodium eq. to Cefuroxime…1.5g | 31-12-2002 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | -do- |
| 537. | 052403 | Cesod 2gm IV Injection<br>Each Vial Contains:<br>Ceftriaxone (as Sodium)…2gm | 11-09-2008 | Dy. No. 20961 dated 11-06-2018<br><br>10000/- | | -do- |
| 538. | 052404 | Cesod 2gm IM Injection<br>Each Vial Contains:<br>Ceftriaxone (as Sodium)…2gm | 11-09-2008 | Dy. No. 20961 dated 11-06-2018<br>10000/- | | -do- |
| lvii. | **M/s. Bio Fine Pharmaceuticals, 74-Industrial Estate, Multan-Pakistan** | | | | | |
| 539. | 30411 | Tricaine Suspension<br>Each 5ml contains:<br>Dried Aluminum Hydroxide Gel..291mg<br>Magnesium Hydroxide …..…98mg<br>Oxethazine…10mg | 30-06-2003 | Dy. No. 20956 dated 11-06-2018<br><br>10,000/- | | Defer for the issuance of final reminder for rectifcation of shortcomings communicated vide letter No. 1-65/2018 dated 15-1-2019. |
| 540. | 30412 | S-Pram Tablet<br>Each Tablet Contains:<br>Citalopram Hydrobromide eq. to Citalopram…20mg | 30-06-2003 | Dy. No. 20956 dated 11-06-2018<br><br>10,000/- | | -do- |
| lviii. | **M/s Ferroza International Pharmaceuticals, 33-Km, Ferozpur Road, Lahore.** | | | | | |
| 541. | 049826 | Welfam Tablet 40mg<br>Each Tablet Contains:<br>Famotidine…40mg | 16-07-2008 | Dy. 20737 08-06-2018 10000/- | | Defer of the status of GMP from QA&LT Divison. |
| 542. | 049830 | Montefer 5mg Tablet<br>Each Film Coated Tablet Contains:<br>Montelukast (as Sodium)…5mg | 16-07-2008 | Dy. 20737 08-06-2018 10000/- | | -do- |

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| 543. | 049831 | Montefer 10mg Tablet<br>Each Film Coated Tablet Contains:<br>Montelukast (as Sodium)…10mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| 544. | 049832 | Cipromax 250mg Tablet<br>Each Tablet Contains:<br>Ciprofloxacin HCl …….250mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| 545. | 049833 | Cipromax 500mg Tablet<br>Each Tablet Contains:<br>Ciprofloxacin HCl …….500mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| 546. | 049834 | Sparmax 100mg Tablet<br>Each Film Coated Tablet Contains:<br>Sparfloxacin…100mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| 547. | 049835 | Sparmax 200mg Tablet<br>Each Film Coated Tablet Contains:<br>Sparfloxacin…200mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| 548. | 049836 | Maxzole 20mg Capsule<br>Each Capsule Contains:<br>Esomeprazole as Enteric Coated Pellets…20mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| 549. | 049837 | Ferolax Tablet 10mg<br>Each Tablet Contains:<br>Escitalopram…10mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| 550. | 049839 | D-K Tablet 75mg<br>Each Tablet Contains:<br>Diclofenac Potassium…75mg | 16-07-2008 | Dy. No. 20737 dated 08-06-2018<br>10000/- | | -do- |
| lix. | **M/s. Delux Chemical Industries, LT, 26 A-1, Landhi Industrial Area, Karachi** | | | | | |
| 551. | 030342 | Lactolac Syrup<br>Each 100ml Contains:<br>Lactulose…67gm<br><br>Source:<br>M/s Biofac Denmark | 12-06-2003 | Dy. No. 20732 dated 08-06-2018<br><br>10,000/- | | Deferred for following:<br>i. GMP and status of renewal of Licence from QA&LT and Licensing Division respecetively.<br>ii. Submission of 10000/- differential fee by the firm. |
| 552. | 030343 | Rosaced Tablet<br>Each tablet contains:<br>Metronidazole Benzoate 321.6mg eq. to Metronidazole …200mg | 12-06-2003 | Dy. No. 20732 dated 08-06-2018<br><br>10,000/- | | Deferred for GMP and status of renewal of Licence from QA&LT and Licensing Division respecetively. |
| 553. | 030344 | Rosaced Suspension<br>Each 5ml contains:<br>Metronidazole Benzoate 321.6mg eq. to Metronidazole …200mg | 12-06-2003 | Dy. No. 20732 dated 08-06-2018<br><br>10,000/- | | -do- |
| 554. | 030345 | Rosaced-Forte Suspension<br>Each 5ml contains:<br>Metronidazole | 12-06-2003 | Dy. No. 20732 dated 08-06-2018 | | -do- |

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| | | Benzoate 321.6mg eq. to Metronidazole …200mg Di-Iodohydroquinolone ……200mg | | 10,000/- | | |
| 555. | 030995 | Deemac Forte Tablet Each tablet contains: Mefenamic Acid…500mg | 21-10-2003 | Dy. No. 21609 dated 20-06-2018 10,000/- | | -do- |
| 556. | 030996 | Deenopan Tablet Each Tablet Contains: Hyoscine N-Butylbromide…10mg | 21-10-2003 | Dy. No. 21609 dated 20-06-2018 10,000/- | | -do- |
| 557. | 030997 | Deloquin Syrup Each 5ml contains: Chloroquine Phosphate 81mg eq. to Chloroquine Base …50mg | 21-10-2003 | Dy. No. 21609 dated 20-06-2018 10,000/- | | -do- |
| lx. | **M/s Hassan Pharmaceuticals, 99-A, Industrial Estate Hayatabad, Peshawar** | | | | | |
| 558. | 030606 | Betacef Dry Suspension Each 5ml Contains: Cefixime…100mg | 29-06-2003 | Dy. No. 22019 dated 25-06-2018 10000/- | | Deferred for clarification regarding the last renewal as there is no statistical endorsement and R&I receiving on evidence of renewal of 2013 provided by the firm. |
| 559. | 030607 | Betacef Capsule 400mg Each Capsule Contains: Cefixime…400mg | 29-06-2003 | Dy. No. 22019 dated 25-06-2018 10000/- | | -do- |
| 560. | 030608 | Hifenac Capsule 50mg Each Capsule Contains: Diclofenac Sodium…50mg | 29-06-2003 | Dy. No. 22019 dated 25-06-2018 10000/- | | Deferred for following:<br>i. Deferred for clarification regarding the last renewal as there is no statistical endorsement and R&I receiving on evidence of renewal of 2013 provided by the firm.<br>ii. Source of pellets is not provided by the firm |
| lxi. | **M/s IPP Pharma Products Manufacturer,** | | | | | |
| 561. | 021388 | Coral-T Tablet Each tablet contains: Nifedipine…30mg | 20-06-1998 | Dy. No. 21604 dated 20-06-2018 10000/- | | Deferred for issuance of final reminder for rectification of shortcomings communicated vide letter No. No. 1-65/2018 dated 31-1-2019. |
| lxii. | **M/s. Leads Pharma, Plot # 81-A, Street # 6, I-10/3, Islamabad** | | | | | |
| 562. | 035884 | Leceph 125mg Suspension Each 5ml contains: Cephradine…125mg | 10-01-2005 Transfer of registration dated 08-07-2008 | Dy. No. 21286 dated 13-06-2018 10,000/- | | Deferred for clarification from the firm as the Formulation is not approved by RRA |
| 563. | 036303 | Temerol 20mg Capsule Each capsule contains: Omeprazole…20mg | 10-01-2005 Brand name change dated:24-06-2006 Transfer of registration 25-6-2008 | Dy. No. 21286 dated 13-06-2018 10,000/- | | Deferred for confirmation of source of pellets and in case of imported pellets the requisite fee thereof. |

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| lxiii. | **M/s Metro Pharmaceutical, Plot 14, Street No. SS-2, National Industrial Zone, RCCI, Rawat, Islamabad** | | | | | |
| 564. | 075247 | Wencin-250 Capsule Each capsule contains: Ciprofloxacin as Hcl … 250mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| 565. | 75248 | Wencin-500 Capsule Each capsule contains: Ciprofloxacin as Hcl … 500mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| 566. | 075249 | Myso-20 Capsule Each capsule contains: Isotretinoin …. 20mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| 567. | 75263 | Melcin-125 Dry Suspension Each 5ml Contains: Levofloxacin as Hemihydrate…125mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| 568. | 75264 | Melcin-250 Dry Suspension Each 5ml Contains: Levofloxacin as Hemihydrate…250mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| 569. | 75265 | Wencin-125 Dry Suspension Each 5ml Contains: Ciprofloxacin as Hcl … 125mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| 570. | 75266 | Wencin-250 Dry Suspension Each 5ml Contains: Ciprofloxacin as Hcl … 250mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| 571. | 75274 | Mepzol 20mg Sachet Each sachet contains: Omeprazole…20mg | 02-04-2013 | Dy. No. 20018 dated 01-06-2018 20000/- | | Deferred for clarification from the firm as the Formulation is not approved in reference agencies |
| lxiv. | **M/s Nawabsons Laboratories, Jia Bagga Off Raiwind Road, Lahore** | | | | | |
| 572. | 030320 | Hemasol Syrup Each 5ml Contains: Ferrous Sulphate…100mg Ascorbic Acid…5mg | 30-06-2003 | Dy. No. 20289 dated 05-06-2018 10000/- | | Deferred for clarification of following:<br>i. Reference formulation of BPC is provided which is 30g/1000ml i.e. 150mg/5ml.<br>ii. Section approval letter. |
| **lxv.** | **M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi** | | | | | |
| 573. | 039557 | Nettle Capsules 250mg Each capsule contains: Cefaclor…..250mg | 31-08-2005 | Dy. No. dated 28-06-2018 10,000/- | | Deferred for clarification of following from concerned section:<br>The product was initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However |

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| | | | | | | the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Noor Capsule 250mg to Nettle Capsules 250mg vide approval dated 8-11-2008 by Registration Division in name of M/s Nexus Pvt Limited. |
| 574. | 039558 | Nettle capsules 500mg<br>Each capsule contains:<br>Cefaclor……500mg | 31-08-2005 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for clarification of following from concerned section:<br>The product initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Noor Capsule 500mg to Nettle Capsules 500mg vide approval dated 8-11-2008 by Registration Division in name of M/s Nexus Pvt Limited. |
| 575. | 039561 | Nitaxim 250mg Injection<br>Each vial contains:<br>Cefotaxime (as Sodium)….250mg | 31-08-2005 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for clarification of following from concerned section:<br>The product initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Noortax Injection to Nitaxim Injection vide approval dated 8-11-2008 by Registration Division in name of M/s Nexus Pvt Limited. |
| 576. | 039529 | Flur Tablet 100mg<br>Each tablet contains:<br>Flurbiprofen …..100mg | 31-08-2005 | Dy. No. dated 28-06-2018 | | Deferred for clarification of following from concerned section: |

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| | | | | 10,000/- | | The product initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Purnoor Tablets to Flur Tablet vide approval dated 8-11-2008 by Registration Division in name of M/s Nexus Pvt Limited. |
| 577. | 039555 | Nettle Suspension 125mg/5ml<br>Each 5ml contains:<br>Cefaclor…….125mg | 31-08-2005 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for clarification of following from concerned section:<br>The product initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Noor Suspension 500mg to Nettle Suspension 500mg vide approval dated 8-11-2008 by Registration Division in name of M/s Nexus Pvt Limited. |
| 578. | 075973 | Skelebenz 30mg Capsules<br>Each extended release capsules contains:<br>Cyclobenzaprine HCl as extended release pellets equivalent to Cyclobenzaprine HCl….30mg<br>(Manufacturer's Specification)<br>**Source:**<br>M/s RA Chem Pharma Limited, Plot No. A-19/C Road No. 18 , | 31-08-2005 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for issuance of final reminder for submission of differential fee |

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| | | IDA , Nacharam Hyderabad-500 076. A.P. Hyderabad. | | | | |
| 579. | 075975 | Rapitus Syrup<br>Each ml contains:<br>Levodropropizine..6mg<br>(Manufacturer's Specification) | 04-07-2013 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for submission of approval of formulation in reference drug agencies. |
| 580. | 075974 | Skelebenz 15mg Capsule<br>Each extended release capsules contains:<br>Cyclobenzaprine HCl as extended release pellets equivalent to Cyclobenzaprine HCl….30mg<br>(Manufacturer's Specification)<br>**Source:**<br>M/s RA Chem Pharma Limited, Plot No. A-19/C Road No. 18 , IDA , Nacharam Hyderabad-500 076. A.P. Hyderabad. | 04-07-2013 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for issuance of final reminder for submission of differential fee |
| 581. | 039563 | Nitaxim Injection 1gm<br>Each powder vial contains:<br>Cefotaxime (as Sodium)….1gm | 31-08-2005 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for clarification of following:<br>The product initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Noortax Injection to Nitaxim Injection vide approval dated 8-10-2008 by Registration Division in name of M/s Nexus Pvt Limited. |
| 582. | 039562 | Nitaxim Injection 500mg<br>Each powder vial contains:<br>Cefotaxime (as Sodium)……500mg | 04-07-2013 | Dy. No. dated 28-06-2018<br><br>10,000/- | | Deferred for clarification of following from concerned section:<br>The product initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus |

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| | | | | | | Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Noortax Injection to Nitaxim Injection vide approval dated 8-10-2008 by Registration Division in name of M/s Nexus Pvt Limited. |
| 583. | 039633 | Coozip Capsules 20mg<br>Each capsule contains:<br>Omeprazole…..20mg | 24-10-2005 | Dy. No.<br>dated 28-06-2018<br><br>10,000/- | | Deferred for clarification of following from concerned section:<br>The product initially registered in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Shah-OM Capsules to Coozip Capsules vide approval dated 8-10-2008 by Registration Division in name of M/s Nexus Pvt Limited.<br>Submission of differential fee and source of pellets |
| lxvi. | **M/s Noa Hemis Pharmaceuticals, Plot No. 154 Sector 23 Korangi Industrial Area Karachi** | | | | | |
| 584. | 050479 | Isogyl Capsule<br>Each Capsule Contains:<br>Isotretinoin…20mg | 21-08-2008 | Dy.# 22159<br>25-06-2018<br>10,000/- | | Deferred for clarification from firm as the Formulation is not approved in reference agencies |
| 585. | 050492 | Klarida 125mg Suspension<br>Each 5ml Contains:<br>Clarithromycin…125mg | 21-08-2008 | Dy. No.<br>22159 dated<br>25-06-2018<br>10,000/- | | Deferred for confirmation of source of granules from the firm. |
| lxvii. | **M/s. Panacea Pharmaceuticals, Plot # 4, Street # S-6, National Industrial Zone, Rawat, Islamabad.** | | | | | |
| 586. | 050163 | Tasium 50mg Capsule<br>Each capsule contains:<br>Diclofenac Potassium (as Enteric Coated Pellets)…50mg | 23-07-2008 | Dy. No.<br>20627 dated<br>07-06-2018<br><br>10,000/- | | Deferred for the issuance of reminder for rectification of shortcomings by the firm communicated vide letter No. 1-65/2018 (RRR) dated 15-1-2019 |
| 587. | 050162 | Fenum 50mg Capsule<br>Each capsule contains:<br>Diclofenac Sodium (as Enteric Coated Pellets)…50mg | 23-07-2008 | Dy. No.<br>20627 dated<br>07-06-2018<br><br>10,000/- | | -do- |

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| lxviii. | **M/s Paradise Pharma, 23-KM Sheikhupura Road, Lahore** | | | | | |
| 588. | 076913 | Pytacon Oral Suspension<br>Each 5ml Contains:<br>Vitamin B12 (Cyanocobalamin)…35 mcg | 25-06-2013 | Dy. No. 21927 dated 11-06-2018<br><br>10000/- | | Deferred for the GMP status from QA&LT Division. |
| 589. | 076914 | Parasolve Oral Suspension<br>Each 500ml Contains:<br>Sodium Chloride…1.3gm<br>Trisodium Citrate Dihydrate…1.45gm<br>Potassium Chloride…0.75gm<br>Glucose Anhydrous…6.75gm | 25-06-2013 | Dy. No. 21927 dated 11-06-2018<br><br>10000/- | | -do- |
| 590. | 076912 | Parasmith Oral Suspension<br>Each 5ml Contains:<br>Simethicone…25mg<br>Aluminum Hydroxide…215mg<br>Magnesium Hydroxide…80mg | 25-06-2013 | Dy. No. 21927 dated 11-06-2018<br><br>10000/- | | -do- |
| lxix. | **M/s P.D.H. Laboratories (Pvt) Ltd. 9.5-Km, Sheikhupura Road, (Khaki) Lahore** | | | | | |
| 591. | 030609 | Lignocaine 1% Injection Contains:<br>Lignocaine HCl…1% | 30-06-2003 | Dy.# 21117 12-06-2018 10000/- | | Deferred for the confirmation of Ampoule section from the firm. |
| lxx. | **M/s. Qintar Pharmaceuticals, 14-A P.S.I.E, Lahore Road, Sargodha.** | | | | | |
| 592. | 049232 | B-Fit Tablet<br>Each Tablet Contains:<br>Fluoxetine as HCl…20mg | 26-06-2008 | Dy. No. 20292 dated 05-06- 2018 10,000/- | | Deferred for GMP and status of Licence renewal from QA&LT and Licensing Division respectively. |
| 593. | 049231 | Kepinol Forte Tablet<br>Each Tablet Contains:<br>Sulphamethoxazole ……800mg<br>Trimethoprim…160mg | 26-06-2008 | Dy. No. 20292 dated 05-06-2018<br><br>10,000/- | | -do- |
| lxxi. | **M/s. Synchro Pharmaceuticals, 77-Industrial Estate, Kot Lakhpat, Lahore** | | | | | |
| 594. | 076945 | Solanz Capsule 30mg<br>Each capsule contains:<br>Lansoprazole…30mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | | Deferred for approval of source of pellets as the firm has submitted a copy of request for change of their approved i.e. M/s Spansule India to new source i.e. M/s Vision Pharmaceuticals Islamabad. |
| 595. | 076946 | Proset Capsule 0.4mg<br>Each capsule contains:<br>Tamsulosin HCl…0.4mg | 25-06-2013 | Dy. No. 21752 dated 21-06-2018<br><br>10,000/- | | Deferred for approval of source of pellets as the firm has submitted a copy of request for change of their approved i.e. M/s Spansule India to new source i.e. M/s Vision Pharmaceuticals Islamabad. |
| lxxii. | **M/s Searle, F-319, S.I.T.E. Karachi.** | | | | | |
| 596. | 004071 | Tranxene 5mg Capsule Contains:<br>Dipotassium Clorazepate…5mg | 02-07-1978 | Dy. No. 22295 dated 05-06-2018 10000/- | | Deferred for the issuance of final reminder for rectification of shortcomings by the firm. |

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| 597. | 004072 | Tranxene 10mg Capsule<br>Contains:<br>Dipotassium Clorazepate…10mg | 02-07-1978 | Dy. No. 22295 dated 05-06-2018 10000/- | | -do- |
| lxxiii. | **M/s Spencer & Company (Pvt) Ltd. D-105, S.I.T.E., Karachi.** | | | | | |
| 598. | 004184 | Minolad Syrup<br>Each 4ml Contains:<br>Vitamin A…2800IU<br>Vitamin D2…400IU<br>L-Lysine Monohydrochloride …….25mg<br>Iron Choline Citrate …40mg<br>Calcium Glycerophosphate …….20mg<br>Sodium Glycerophosphate…4mg<br>Manganese Sulphate…0.2mg<br>Copper Sulphate…0.2mg<br>Choline Chloride…1mg<br>Methionine…4mg | 18-06-1978 | Dy. No. 20287 dated 05-06-2018 10000/- | | Deferred for the issuance of final reminder for rectification of shortcomings by the firm. |
| lxxiv. | **M/s Standpharm Pakistan, 20-Km, Ferozepur Road, Lahore** | | | | | |
| 599. | 049939 | Deact Injection 1gm<br>Each Vial Contains:<br>Cefoperazone as Sodium…500mg<br>Sulbactum as Sodium…500mg | 17-07-2008<br><br>Change of brand name: 20-11-2009 | Dy. No. 22021 dated 25-06-2018<br><br>10000/- | | Deferred for confirmation of section from licensing division |
| 600. | 049940 | Deact Injection 2gm<br>Each Vial Contains:<br>Cefoperazone as Sodium…1gm<br>Sulbactum as Sodium …1gm | 17-07-2008<br><br>Change of brand name: 20-11-2009 | Dy. No. 22021 dated 25-06-2018<br><br>10000/- | | -do- |
| 601. | 049941 | Buten Tablet 200mg<br>Each sugar coated tablet contains:<br>Sulbutiamine…200mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018 10000/- | | Deferred for clarification from the firm as the Formulation is not approved by RRA |
| 602. | 049957 | Cefidox Tablet 100mg<br>Each film coated tablet contains:<br>Cefpodoxime as Proxetil…100mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br><br>10000/- | | Deferred for confirmation of section from licensing division |
| 603. | 049959 | Tromit Injection 10mg/ml<br>Each 1ml ampoule contains:<br>Ketorolac Tromethamine…10mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br><br>10000/- | | Deferred for clarification from the firm as the Formulation is not approved by RRA |
| 604. | 049960 | Cefidox Dry Powder Suspension<br>Each 5ml contains:<br>Cefpodoxime as Proxetil…40mg | 17-07-2008 | Dy. No. 22021 dated 25-06-2018<br><br>10000/- | | Deferred for confirmation of section from licensing division |

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| 605. | 050266 | Spical Sugar Free Sachet<br>Each sachet contains:<br>Calcium Lactate Gluconate…1000mg<br>Vitamin C…500mg<br>Calcium Carbonate…327mg | 28-7-2008 | Dy. No. 22021 dated 25-06-2018<br><br>10000/- | | Deferred for confirmation of section from licensing division |
| lxxv. | **M/s. Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI Industrial Estate, Rawat, Rawalpindi** | | | | | |
| 606. | 075448 | Sita-Wis 50/500mg Tablet<br>Each film coated tablet contains:<br>Sitagliptin (as Phosphate)…50mg<br>Metformin HCl …500mg | 25-06-2013 | Dy. No. 21892 dated 22-06-2018<br><br>10,000/- | | Defer for the GMP and status of License renewal from QALT & Licensing Division. |
| 607. | 075449 | Sita-Wis 50/1000mg Tablet<br>Each film coated tablet contains:<br>Sitagliptin (as Phosphate)…50mg<br>Metformin HCl …1000mg | 25-06-2013 | Dy. No. 21892 dated 22-06-2018<br><br>10,000/- | | -do- |
| lxxvi. | **M/s Xenon Pharmaceuticals, 9.5-Km, Sheikhupura Road, Lahore.** | | | | | |
| 608. | 022358 | Steron Syrup<br>Each 5ml Contains:<br>Prednisolone…15mg | 11-09-1998<br>Change of formulation dated : 2-7-1999<br>Change of brand name 15-7-1999 | Dy. No. 21879 dated 22-06-2018<br>10000/- | | Defer for clarification from concerned section:<br>Product was initially registered in name of Dawn Laboratories Lahore and Firm didn't provide the evidence of transfer in name of Xenon Pharmaceuticals Lahore |
| 609. | 014727 | Zemvit Tablet<br>Each tablet contains:<br>Vitamin-A…4,000IU<br>Vitamin-D…400IU<br>Vitamin-E…30IU<br>Vitamin-C…100mg<br>Folic Acid…0.8mg<br>Vitamin B-1…1.5mg<br>Vitamin B-2…1.6mg<br>Vitamin B-6…2.5mg<br>Vitamin B-12…4.0mcg<br>Niacinom…18.0mg<br>Calcium Carbonate…600.0mg<br>Ferrous Fumerate…60.0mg<br>Zink Sulphate …25.0mg | 24-11-1993<br><br>Change of brand name dated 8-12-2009 | Dy. No. 21884 dated 22-06-2018<br><br>10000/- | | Defer for clarification from concerned section:<br>Product was initially registered in name of Dawn Laboratories Lahore, Firm didn't provide the evidence of transfer in name of Xenon Pharmaceuticals Lahore |
| **lxxvii.** | **M/s Global Pharmaceuticals, Rawat Islamabad** | | | | | |
| 610. | 049233 | Toxirid 500mg Injection IV<br>Each Vial Contains:<br>Cefoperazone as Sodium…250mg<br>Sulbactam as Sodium…250mg | 26-06-2008 | Dy. No. 22498 dated 28-06-2018<br><br>10000/- | | Defer for clalrifcation regarding approval of formulation in reference agencies. |

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| lxxviii. **M/s Sanofi-Aventis Pakistan, Plot No. 22, Korangi Industrial Area, Karachi.** | | | | | | |
| 611. | 050372 | Amaryl M SR 1mg Tablet<br>Each Bi-Layered Tablet Contains:<br>Glimepiride…1mg<br>Metformin (as HCl)…500mg | 05-08-2008 | Dy. No. 20429 dated 06-06-2018<br><br>10000/- | | Defer for the status of show cause issued by concerned section. |
| 612. | 050373 | Amaryl M SR 2mg Tablet<br>Each Bi-Layered Tablet Contains:<br>Glimepiride…2mg<br>Metformin (as HCl)…500mg | 05-08-2008 | Dy. No. 20430 dated 06-06-2018<br><br>10000/- | | Deferred for the status of show cause issued by concerned section. |
| lxxix. **M/s. Welwrd Pharmaceuticals, Plot No. 3, Block A, Phase I-II, Industrial Estate Hattar-Pakistan** | | | | | | |
| 613. | 049099 | Welcetain Injection<br>Each 2ml Ampoule Contains:<br>Paracetamol…300mg<br>Lidocaine. HCl…20mg | **20-03-2008** | Dy. No. 10390 dated 20-03-2018<br>10000/- | | Deferred for clarification regarding the approval of formulation in reference agencies. |
| lxxx. **M/s Unexolabs, .5-Km, Sheikhupura Road, Lahore.** | | | | | | |
| 614. | 022035 | Dipotil Tablet<br>Each tablet contains:<br>Diphenoxylate HCl…2.5mg<br>Atropine Sulphate…0.025mg | 20-05-1998 | Dy. No. 21605 dated 20-06-2018<br>10000/-<br>10000/-<br>21-1-2019. | 19-5-2023 | Deferred for GMP status from QA&LT Division as the submitted GMP report is of 2016. |
| 615. | 014271 | Methacid Capsule 25mg<br>Each capsule contains:<br>Indomethacin…25mg | 05-08-1993 | Dy. No. 20441 dated 06-06-2018<br>10000/- | 04-08-2023 | -do- |
| 616. | 009910 | Semidine 400mg Tablet<br>Each tablet contains:<br>Cimetidine…400mg | 15-09-1988 | Dy. No. 20441 dated 06-06-2018<br>10000/- | 14-9-2023 | -do- |
| 617. | 009911 | Empicil Capsule 250mg<br>Each capsule contains:<br>Ampicillin as Trihydrate…250mg | 15-09-1988 | Dy. No. 20441 dated 06-06-2018<br><br>10000/- | 14-9-2023 | -do- |

## b. Imported registered drugs from reference countries (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

| Sr. No | Reg. No. | Manufacturer as per registration letter | Brand Name, Composition & Specification | Initial date of Registration | Date of application (R&I) Fee submitted | Renewal validity | Decision |
|---|---|---|---|---|---|---|---|
| **lxxxi. M/s. Medipharm (Pvt) Ltd., 108 Kot Lakhpat Industrial Estate, Lahore** | | | | | | | |
| 618. | 009866 | **Product License Holder:**<br>M/s Bayer Vital GmbH 51368 | Ultravist-300 Solution for Injection or Infusion or Solution for Oral Use 623.4mg Iopromide (corresponding to | 13-06-1988 | Dy. No. 21116 12-6-2018<br><br>20,000/- | | Deferred for submission of following clarifications/ documents :<br>i. The address |

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| | | Leverkusen Germany. **Manufacturer as per CoPP:** Bayer Pharma AG Site 13342 Berlin Germany | 300mg bound iodine) per 1ml solution | | | | of manufacturer as per copy of CoPP dated 27-12-2017 provided by the firm varies from the address as per registration letter, details are as under:**Bulk Manufacturer Packaging & Final Release:**M/s Bayer AG Mullerstrasse 178, 13353 Berlin Germany<br>ii. Original legalized CoPP is required as firm has submitted copy.<br>(Bulk import local repackaging) |
| 619. | 009865 | -do- | Solution for Injection or Infusion or Solution for Oral Use 768.86 mg Iopromide (corresponding to 370 mg bound iodine) per 1ml solution | 13-06-1988 | Dy. No. 21115 dated 12-06-2018<br><br>20,000/- | | -do- |
| lxxxii. **M/s A. Feroz & Co., Medicine Street 1, Marriot Road, Karachi.** | | | | | | | |
| 620. | 014013 | M/s IGS GmbH Postfach 1129, Im Hemmet 1, 79664 Wehr/Baden Germany. | Ethyl Chloride (Anesthetic) Liquid Spray Each Tin of Aerosol Contains: Ethyl Chloride…100ml | 18-07-1993<br><br>Change of manufactur er: 12-7-2008 | Dy. No. 20290 dated 06-06-2018 20000/- | | Defer for issuance of final reminder for rectification of shortcomings communicated vide letter No. 1-65/2018 dated 8-1-2019 |
| lxxxiii. **M/s Martin Dow Pharmaceuticals, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.** | | | | | | | |
| 621. | 021126 | M/s Teijin Limited, 6-7 , Minami – Hemmachi, Japan | Bonalfa Ointment Each gm contains: Tacalcital…2mcg | 01-08-1998 | Dy. No. 22157 dated 25-06-2018<br><br>20000/- | | Defer for clarification of following by the firm:<br>The manufacturing site mentioned in CoPP is M/s Teijin Pharma Limited, Iwakuni Pharmaceutical Factory 2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo, which is different from the site mentioned on the letter. The firm is importing the drug from the aforesaid new site which also evident |

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| | | | | | | | from the invoice submitted by the firm. |

### c. Imported registered drugs from non- reference countries (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

| Sr. No | Reg. No. | Manufacturer as per registration letter | Brand Name, Composition & Specification | Initial date of Registration | Date of application (R&I) Fee submitted | Renewal validity | Decision |
|---|---|---|---|---|---|---|---|
| **lxxxiv. M/s Allied Distributors, 1st Floor 103-K Block-2, P.E.C.H.S. Shahra-e-Qauideen, Karachi.** | | | | | | | |
| 622. | 021190 | | Broadsaf 250mg IM/IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base …….250mg | 15-10-1998 | Dy. No. 22495 dated 28-06-2018 20000/- | | Deferred for issuance of final reminder for rectification of shortcomings coomunicated vide letter No. 1-65/2018 (RRR) dated 1-1-2019. |
| 623. | 021191 | | Broadsaf 500mg IM/IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base …….500mg | 15-10-1998 | Dy. No. 22494 dated 28-06-2018 20000/- | | -do- |
| 624. | 021192 | | Broadsaf 1g IM/IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…1g | 15-10-1998 | Dy. No. 22496 dated 28-06-2018 20000/- | | -do- |
| lxxxv. **M/s. A.J. Mirza Pharma, 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi** | | | | | | | |
| 625. | 047678 | M/s Cipla Limited India | Oxaliplatin for Injection 50mg Each vial contains: Oxaliplatin Ph. Eur…..50mg | 06-08-2008 | Dy. No. 25-06-2018 20,000/- | | Deferred for issuance of final reminder for rectification of shortcomings communicated vide letter No. 1-65/2018 (RRR) dt: 11-1-2019. |
| 626. | 047680 | M/s Cipla Limited India | Oncobine 10mg/ml Injection Each ml contains: Vinorelbine Tartrate USP equivalent to Vinorelbine..10mg | 06-08-2008 | Dy. No. dated 25-06-2018 20,000/- | | -do- |
| 627. | 052260 | M/s Cipla Limited India | Decarb-200 Injection Each vial contains: Dacarbazine USP….200mg | 15-11-2008 | Dy. No. 25-06-2018 20,000/- | | -do- |

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| 628. | 047679 | M/s Cipla Limited India | Oxaliplatin for Injection 100mg Each vial contains: Oxaliplatin Ph. Eur.100mg | 06-08-2008 | Dy. No. dated 25-06-2018<br><br>20,000/- | | -do- |
| 629. | 047681 | M/s Cipla Limited India | Oncobine 50mg/5ml Injection Each ml contains: Vinorelbine Tartrate USP equivalent to Vinorelbine..10mg | 06-08-2008 | Dy. No. dated 25-06-2018<br><br>20,000/- | | -do- |
| lxxxvi. **M/s Ghani Brothers, 2nd floor Karimje Building, Opp. Habib Bank Ltd. North Napier Road, Karachi** | | | | | | | |
| 630. | 072577 | **Manufacturer** M/s Instituto Biologico Contemporaneo S.A (IBC) Chivilcoy-Bogota Benous Aires, Argentina **License Holder:** M/s Laboratorio Dosa S.A. Giradot, Buenos Aries Argentina | Dreico 4mg Injection Each Vial Contains: Zoledronic Acid…4mg | 09-07-2013 | Dy. No. 20955 dated 11-06-2018<br><br>20000/- | | Defer for issuance of final reminder for rectification of shortcomings communicated vide letter No. 1-65/2018 (RRR) dated 11-1-2019. |
| 631. | 072578 | -do- | Solvent for Dreico 4mg Injection | 09-07-2013 | Dy. No. 20955 dated 11-06-2018 20000/- | | -do- |
| 632. | 072570 | **Manufacturer** M/s Laboratorios IMA-S.A.I.C. Palpa Buenos Aries Argentina **License Holder:** M/s Laboratorio Dosa S.A. Giradot, Buenos Aries Argentina | Epirrubicina Dosa 10 Injection Each Vial Contains (Lyophilized): Epirubicin HCl…10mg | 09-07-2013 | Dy. No. 20959 dated 11-06-2018<br><br>20000/- | | -do- |
| 633. | 072571 | -do- | Epirrubicina Dosa 50 Injection Each Vial Contains (Lyophilized): Epirubicin HCl…50mg | 09-07-2013 | Dy. No. 20959 dated 11-06-2018<br><br>20000/- | | -do- |
| 634. | 072572 | -do- | Carboplatino Dosa 150 Injection Each Vial Contains: | 09-07-2013 | Dy. No. 20959 dated 11-06-2018 | | -do- |

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| | | | Carboplatin…150 mg | | 20000/- | | |
| 635. | 072573 | -do- | Nagun 10 Injection Each 5ml Vial contains: Doxorubicin HCl…10mg | 09-07-2013 | Dy. No. 20959 dated 11-06-2018<br><br>20000/- | | -do- |
| 636. | 072574 | -do- | Nagun 50 Injection Each 25ml Vial Contains: Doxorubicin HCl…50mg | 09-07-2013 | Dy. No. 20959 dated 11-06-2018<br><br>20000/- | | -do- |
| 637. | 072575 | -do- | Water for Injection for Epirrubicina 10 Dosa 5ml | 09-07-2013 | Dy. No. 20959 dated 11-06-2018 20000/- | | -do- |
| 638. | 072576 | -do- | Water for Injection for Epirrubicina 50 Dosa 25ml | 09-07-2013 | Dy. No. 20959 dated 11-06-2018<br><br>20000/- | | -do- |
| lxxxvii. **M/s Global Pharmaceuticals, Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad** | | | | | | | |
| 639. | 047665 | | Refron 3MIU Injection Each Vial Contains: Recombinant Human Interferon Alpha 2b…3MIU | 04-08-2008 | Dy. No. 22497 dated 28-06-2018 10000/- | | Referred to Biological Evaluation & Research division for processing at their end |

## d. Locally manufactured registered drugs (Veterinary)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

| Sr. No | Reg. No. | Brand Name, Composition & Specification | Initial date of Registration | Date of application (R&I) Fee submitted | Renewal validity | Decision |
|---|---|---|---|---|---|---|
| lxxxviii. | | **M/s Elko Organization, Plot No. 27 & 28, Sector 12/B, North Karachi, Industrial Area, Karachi.** | | | | |
| 640. | 028600 | LEOX Bolus Each Bolus Contains: Levamisole HCl…1.125gm Oxyclozanide…2.250gm | 02-07-2003 | Dy. No. 20016 dated 04-06-2018 10000/- | | Deferred for submission of evidence of renewal of 2013 by the firm. |
| lxxxix. **M/s. Attabak Pharmaceutical Industries, 5-C I-10/3, Industrial Area, Islamabad** | | | | | | |
| 641. | 075682 | Oxyno Plus Water Soluble Powder Each 1000g Contains: Oxytetracycline HCl…200g Neomycin Sulphate…200g Colistin Sulphate…240MIU | 17-06-2013 | Dy. No. 21328 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 642. | 075683 | E.N.C Man Water Soluble Powder Each 100gm contains: Enrofloxacin HCl…10g Colistin Sulphate…3.5g Amantadine HCl…4g | 17-06-2013 | Dy. No. 21396 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board and status of show cause from concerned section for Amantadine containing formulations. |

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| 643. | 075684 | Enromin Oral Liquid<br>Each 100ml Contains:<br>Enrofloxacin…10gm<br>Colistin Sulphate…3.5g<br>Amantadine HCl…4g | 17-06-2013 | Dy. No. 21410 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board and status of show cause from concerned section for Amantadine containing formulations. |
| 644. | 075685 | Respi Bro Oral Liquid<br>Each ml contains:<br>Doxycycline HCl…200mg<br>Tylosin Tartrate…100mg<br>Colistin Sulphate…500,000IU<br>Bromhexine HCl…5mg | 17-06-2013 | Dy. No. 21409 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 645. | 705686 | Coflox Oral Liquid<br>Each 100ml Contains:<br>Enrofloxacin…10gm<br>Colistin Sulphate…50MIU | 17-06-2013 | Dy. No. 21408 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 646. | 075687 | CRD Kill Injection<br>Each ml contains:<br>Tylosin Tartrate…50mg<br>Colistin Sulphate…10mg<br>Dihydrostreptomycin..100mg | 17-06-2013 | Dy. No. 21417 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 647. | 075688 | Sulpha Super Injection<br>Each ml contains:<br>Sulfadimidine Sodium…33.30% | 17-06-2013 | Dy. No. 21379 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 648. | 075689 | E-Cam Water Soluble Powder<br>Each 100gm contain :<br>Enrofloxacin HCl…10g<br>Colistin Sulphate…4g<br>Amantadine HCl…4.5g | 17-06-2013 | Dy. No. 21392 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board and status of show cause from concerned section for Amantadine containing formulations. |
| 649. | 075690 | Pulmotin Water Soluble Powder<br>Each 1000g Contains:<br>Doxycycline HCl…200g<br>Tylosin Tartrate…100g<br>Colistin Sulphate…480MIU<br>Bromhexine HCl…5g | 17-06-2013 | Dy. No. 21387 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board and Brand name change approval by the firm |
| 650. | 075691 | Col-En 70 Liquid<br>Each 100ml Contains:<br>Enrofloxacin HCl…20g<br>Colistin Sulphate…50MIU | 17-06-2013 | Dy. No. 21406 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 651. | 075692 | Dialysis Water Soluble Powder<br>Each 1000g Contains:<br>Furosemide…20g<br>Calcium Carbonate…40g<br>Sodium Chloride…35g<br>Magnesium Sulphate…35g | 17-06-2013 | Dy. No. 21390 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 652. | 075693 | Coli Liquid<br>Each 100ml Contains:<br>Enrofloxacin…10gm<br>Colistin Sulphate…3g<br>Amantadine HCl…4g | 17-06-2013 | Dy. No. 21412 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board and status of show cause from concerned section for Amantadine containing formulations. |

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| 653. | 075694 | Neomycin 70% Powder<br>Each 100gm contain :<br>Neomycin Sulphate…70g | 17-06-2013 | Dy. No. 21391 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 654. | 075695 | Streptobak Water Soluble Powder<br>Each 1000g Contains:<br>Doxycycline HCl…200g<br>Tylosin Tartrate…100g<br>Dihydrostreptomycin…20g<br>Bromhexine HCl…5g | 17-06-2013<br><br>Change of brand name dated: | Dy. No. 21384 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board and Brand name change approval by the firm |
| 655. | 075696 | Mandox-T Powder<br>Each 1000g Contains:<br>Doxycycline HCl…200g<br>Tylosin Tartrate…100g<br>Amantadine HCl…35g | 17-06-2013 | Dy. No. 21353 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board and status of show cause from concerned section for Amantadine containing formulations. |
| 656. | 075697 | Amantabak 10% Powder<br>Each 1000g Contains:<br>Amantadine HCl…10g | 17-06-2013 | Dy. No. 21382 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 657. | 075698 | Tylobrom-S Powder<br>Each 1000g Contains:<br>Doxycycline HCl…200g<br>Tylosin Tartrate…100g<br>Dihydrostreptomycin…40g<br>Bromhexine HCl…5g | 17-06-2013 | Dy. No. 21381 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 658. | 075699 | Genta-5 Super Injection<br>Each 100ml Contains:<br>Gentamycin Sulphate…5g | 17-06-2013 | Dy. No. 21415 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 659. | 075700 | Genta-10 Super Injection<br>Each 100ml Contains:<br>Gentamycin Sulphate…10g | 17-06-2013 | Dy. No. 21419 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 660. | 075701 | Lincopect Injection<br>Each ml contains:<br>Lincomycin as HCl…50mg<br>Spectinomycin…100mg | 17-06-2013 | Dy. No. 21416 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 661. | 075702 | Cloricox Water Soluble Powder<br>Each gm contains:<br>Sulphachlorpyridazine …33.33%<br>Vitamin K3…3mg | 17-06-2013 | Dy. No. 21388 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 662. | 075703 | Linco Premix 1100 Powder<br>Each 100gm Powder Contains:<br>Lincomycin HCI …. 1100mg | 17-06-2013 | Dy. No. 21389 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 663. | 075704 | Tyco-G Oral Liquid<br>Each 100ml Contains:<br>Doxycycline HCl…20g<br>Tylosin Tartrate…10g<br>Guaifenesin…20g<br>Aminophylline…8g | 17-06-2013 | Dy. No. 21404 dated 14-06-2018<br><br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 664. | 075705 | Brom-Mat Oral Liquid<br>Each ml contains:<br>Bromhexine HCl…50mg | 17-06-2013 | Dy.# 21403 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |

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| 665. | 075706 | Tilmicobak Oral Liquid<br>Each 100ml Contains:<br>Tilmicosin Phosphate…25g | 17-06-2013 | Dy. No. 21411 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 666. | 075707 | Florfenicol Oral Liquid<br>Each ml contains:<br>Florefenicol…250mg | 17-06-2013 | Dy. No. 21405 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 667. | 075708 | Enromat Oral Liquid<br>Each 100ml Contains:<br>Enrofloxacin…10g | 17-06-2013 | Dy. No. 21402 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 668. | 075709 | Gentymat Liquid Injection<br>Each ml contains:<br>Tylosin Tartrate…100mg<br>Gentamicin Sulphate…50mg | 17-06-2013 | Dy. No. 21418 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 669. | 075710 | Meloxi DS Injection<br>Each ml contains:<br>Meloxicam…20mg | 17-06-2013 | Dy. No. 21414 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 670. | 075711 | Lincomat Injection<br>Each ml contains:<br>Lincomycin as HCl…50mg<br>Spectinomycin…100mg | 17-06-2013 | Dy. No. 21413 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 671. | 075712 | Neo-Mix Powder<br>Each 1000g Contains:<br>Oxytetracycline HCl…200gm<br>Neomycin Sulphate…100g<br>Erythromycin Thiocyanate…100g | 17-06-2013 | Dy. No. 21395 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 672. | 075713 | ESP-BAK Powder<br>Each gm contains:<br>Sulphachlorpyridazine…33.33% | 17-06-2013 | Dy. No. 21401 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 673. | 075714 | Clozine-60 Water Soluble Powder<br>Each gm contains:<br>Sulphaclozine Sodium…60% | 17-06-2013 | Dy. No. 21380 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 674. | 075715 | Tylobid Powder<br>Each 1000g Contains:<br>Doxycycline HCl…400g<br>Tylosin Tartrate…200g<br>Bromhexine HCl…10g | 17-06-2013 | Dy. No. 21393 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 675. | 075716 | Eryhtro-25 Powder<br>Each 1000g Contains:<br>Oxytetracycline HCl…100gm<br>Erythromycin Thiocyanate…150gm | 17-06-2013 | Dy. No. 21394 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 676. | 075717 | Oxcinobak Powder<br>Each 1000g Contains:<br>Oxytetracycline HCl…80gm<br>Neomycin Sulphate…70gm | 17-06-2013 | Dy. No. 21397 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 677. | 075718 | TB-Dox Powder<br>Each 1000g Contains:<br>Doxycycline HCl…400g<br>Tylosin Tartrate…200g<br>Bromhexine HCl…10g | 17-06-2013 | Dy. No. 21398 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |

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| 678. | 075719 | Diaprim Powder<br>Each 100gm contain :<br>Sulfadiazine Sodium…40g<br>Trimethoprim…8g | 17-06-2013 | Dy. No. 21399 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 679. | 075720 | Neostrep Powder<br>Each gm contains:<br>Neomycin Sulphate…60mg<br>Oxytetracycline HCl…200g<br>Streptomycin Sulphate…20mg | 17-06-2013 | Dy. No. 21400 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 680. | 075721 | Frusa Min Water Soluble Powder<br>Each 1000g Contains:<br>Furosemide…20g<br>Sodium Chloride…35g<br>Magnesium Sulphate…35g<br>Manganese Sulphate…1g<br>Calcium Carbonate…45g | 17-06-2013 | Dy. No. 21376 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 681. | 075722 | Uritox Powder<br>Each 100gm contain :<br>Methenamine…85g<br>Vitamin B1…700mg<br>Vitamin C…100mg<br>Sorbitol…5g | 17-06-2013 | Dy. No. 21375 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 682. | 075723 | Broncoman Powder<br>Each 1000g Contains:<br>Doxycycline HCl…100g<br>Tylosin Tartrate…50g<br>Amantadine HCl…40g | 17-06-2013 | Dy. No. 21374 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board and status of show cause from concerned section for Amantadine containing formulations. |
| 683. | 075724 | Bella Flush Water Soluble Powder<br>Each 100gm contain :<br>Furosemide…2g<br>Belladona Extract…0.2g | 17-06-2013 | Dy. No. 21373 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 684. | 075725 | Hexamine Water Soluble Powder<br>Each 100gm contain :<br>Methenamine…85mg<br>Vitamin B1…800mg<br>Vitamin…B2…920mg<br>Vitamin…K3…200mg | 17-06-2013 | Dy. No. 21372 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 685. | 075726 | Frusa Super Water Soluble Powder<br>Each 1000g Contains:<br>Furosemide…25g<br>Sodium Chloride…35g<br>Magnesium Sulphate…35g<br>Manganese Sulphate…1g<br>Potassium Chloride…4g<br>Calcium Carbonate…45g | 17-06-2013 | Dy. No. 21386 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |
| 686. | 075727 | Flush-C Powder<br>Each 1000g Contains:<br>Furosemide…20g<br>Magnesium Sulphate…1g<br>Potassium Chloride…4g<br>Calcium Carbonate…45g<br>Vitamin C…5g | 17-06-2013 | Dy. No. 21385 dated 14-06-2018<br>10,000/- | | Deferred for status of decision of Appellate Board. |

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| 687. | 075728 | Levanol Oral Liquid<br>Each Liter Contains:<br>Bithionol Sulfoxide…100gm<br>Levamisole HCl…15gm | 19-06-2013 | Dy. No. 21407 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 688. | 075729 | Samcoc Oral Liquid<br>Each 100ml Contains:<br>Sulfaquinoxaline…20gm<br>Amprolium…30gm | 19-06-2013 | Dy. No. 21377 dated 14-06-2018 10,000/- | | Deferred for status of decision of Appellate Board. |
| 689. | 048214 | Norak-20 Liquid<br>Each 100ml contains:<br>Norfloxacin HCl…..20gm | 19-07-2008 | Dy. No. 21843 dated 22-06-2018 10000/- | | Deferred for status of decision of Appellate Board and status of show cause from concerned section for Amantadine containing formulations. |
| xc. | | **M/s. Delux Chemical Industries, LT, 26 A-1, Landhi Industrial Area, Karachi** | | | | |
| 690. | 029671 | Flum equel 20 Oral Liquid<br>Each 100ml Contains:<br>Flemequine…20gm | 21-07-2003 | Dy. No. 21609 dated 20-06-2018 10,000/- | | Deferred for status of renewal of License and GMP from Licensing & QALT Division. |
| 691. | 029672 | Reomicinia Compound Oral Powder<br>Each 1000g Contains:<br>Tylosin…25gm<br>Colistin…300MIU<br>Furaltadone…75gm | 21-07-2003 | Dy. No. 21609 dated 20-06-2018<br>10,000/- | | -do- |
| 692. | 075611 | Mantobrom Oral Liquid<br>Each 100ml Contains:<br>Bromhexine HCl…2% W/V<br>Menthol…4% | 17-05-2013 | Dy. No. 21609 dated 20-06-2018<br>10,000/- | | -do- |

### e. Pending Cases

Below mentioned products of various firms were submitted in period of January 2018 to May, 2018 which evaluated previously but were incomplete on the part of firm due various shortcoming. After completion of application by the firms the same are placed before Registration Board for consideration. The decision is mentioned in the last column below:

| Sr. No. | Reg. No. | Brand Name, Composition | Initial date of Registration | Date of application (R&I) Fee submitted | Renewal validity | Decision |
|---|---|---|---|---|---|---|
| **i.** | **M/s. Martin Dow Marker Ltd., 7, Jail Road, Quetta ,Pakistan** | | | | | |
| 693. | 075906 | Cosome DA Cough Syrup<br>Each 5ml contains:<br>Acefylline<br>Piperazine….45mg<br>Diphenhydramine Hydrochloride….8mg | 08-05-2013 | Dy. No. 14422 dated 18-04-2018 10000/- | | Deferred for clarification regarding transfer of product from M/s. Merck Pvt. Ltd to M/s Martin Dow Marker Pvt Limited Quetta |
| 694. | 026369 | Omelcid Capsule<br>Each capsule contains:<br>Omeprazole…. 20mg | 12-09-2000<br>Transfer of registration dated **03-03-2008** | Dy. No. 6595 dated 21-02-2018 10000/- | | Deferred for the following:<br>i. clarification regarding transfer of product from M/s. Merck Pvt. Ltd to M/s Martin Dow Marker Pvt Limited Quetta<br>ii. Source fixation approval le |

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| 695. | 010193 | Neurofenac Capsules 50mg<br>Each capsule contains:<br>Diclofenac Sodium USP … 50mg<br><br>Source of pellets:<br>M/s Inventia Healthcare Pvt Limited, Maharashtra State, India. | 05-12-1989<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration dated: 21-3-2018 | Dy. No. 6585 dated 21-02-2018<br><br>10000/- | | Deferred for submission of renewal fee. |
| 696. | 007567 | Refobacin Eye Drops<br><br>Each ml contains:<br>Gentamicin sulfate….5 mg | 15-10-1984<br><br>Transfer of registration dated: 03-03-2008 | Dy. No. 6618 dated 21-02-2018<br><br>10000/- | | Deferred for the following:<br>i. Clarification from the Firm regarding the facility for manufacturing of eye drops.<br>ii. Clarification regarding transfer of product from M/s. Merck Pvt. Ltd to M/s Martin Dow Marker Pvt Limited Quetta.<br>iii. Clarification regarding the production of batch in 2017 |
| 697. | 001492 | Polybion Forte C Tablets<br>Each Film Coated Tablet contains:<br>Vitamin B1 (Thiamine Mononitrate) …..15 mg<br>Vitamin B2 (Riboflavin) ….15 mg<br>Nicotinamide …. 50 mg,<br>Vitamin B6 (Pyridoxine Hydrochloride)… 10 mg<br>Calcium D-Pantothenate……25 mg<br>Vitamin B12 (Cyanocobalamin)..10 mcg<br>Vitamin C (Ascorbic Acid) ……. 300 mg | 15-08-1976<br><br>Transfer of registration dated: 03-03-2008<br><br>Transfer of registration dated: 07-06-2018 | Dy. No. 6605 dated 21-02-2018<br><br>10000/- | | Clarification from the firm regarding the difference in composition of product in Form 5B and registration letter. |
| 698. | 027952 | Mercepam Tablets 1.5 mg<br>Each tablet contains:<br>Bromazepam ……1.5 mg | 14-06-2002<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration dated: 07-06-2018 | Dy. No. 6578 dated 21-02-2018<br><br>10000/- | | Deferred for clarification from Licensing Division. |
| 699. | 000719 | Polybion Strong Tablets<br>Each Film coated Tablet contains:<br>Vitamin B1 (Thiamine Hydrochloride)…..15 mg,<br>Vitamin B2 (Riboflavin)….4 mg<br>Vitamin B6 (Pyridoxine Hydrochloride)…… 10 mg<br>Vitamin B12 | 30-11-1976<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration dated: 07-06-2018 | Dy. No. 6609 dated 21-02-2018<br><br>10000/- | | Deferred for clarification from the firm regarding the difference in composition of product in Form 5B and registration letter. |

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| | | (Cyanocobalamin)…10 mcg<br>Nicotinamide…..50 mg,<br>Calcium D-Pentothenate….6mg | | | | |
| 700. | 033794 | Osteocur-C-Effervescent Granules<br>Each sachet of Effervescent Granules contains:<br>Calcium Lactate Gluconate…….1000 mg,<br>Calcium Carbonate..327mg<br>Ascorbic Acid..... 500 mg | 06-09-2004<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration dated: 07-6-2018 | Dy. No. 6598 dated 21-02-2018<br><br>10000/- | | Deferred for the clarification from the firm regarding the facility for manufacturing of sachets. |
| 701. | 006474 | Sistalgin Injection<br><br>Each 2 ml contains:<br>Pramiverine Hydrochloride….. 2.25 mg | 11-07-1982<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration 07-06-2018 | Dy. No. 6621 dated 21-02-2018<br><br>10000/- | | Deferred for clarification from the firm regarding the approval of formulation in reference agencies. |
| 702. | 032063 | Ibusoft Capsules 200mg<br><br>Each soft gelatin capsule contains:<br>Ibuprofen Micronized Powder…….200 mg | 24-01-2004<br><br>Transfer of registration dated: 03-03-2008 | Dy. No. 6548 dated 21-02-2018<br><br>10000/- | | **Deferred for the clarification regarding the manufacturing facility of soft gelatin capsule from the firm.**<br>Product was initially on toll manufacturing by M/s Catts Karachi, after transfer of registration in 2008 the separate permission for extension in toll is not provided.<br>From the latest batch manufacturing details dated 3-10-2017 provided by the firm indicates that firm is manufacturing the product at its own premises.<br>However the Soft Gelatin Capsule manufacturing facility is not approved by Licensing Division and the product is also not transferred in name of M/s Martin Dow Marker Limited Quetta. |
| 703. | 021394 | Livicod Capsules<br>Each Soft Gelatin capsules contains:<br>Vitamin Rich Cod Oil…275 mg<br>Vitamin A……60,000 I.U.<br>Vitamin D…….6000 I.U.<br>Vitamin E…….3.0mg | 16-05-1998<br><br>Transfer of registration dated: 03-03-2008 | Dy. No. 6561 dated 21-02-2018<br><br>10000/- | | **Deferred for the clarification regarding the manufacturing facility of soft gelatin capsule from the firm.**<br>Soft Gelatin Capsule manufacturing facility is not approved by Licensing Division and |

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| | | | | | | the product is not transferred in name of M/s Martin Dow Marker Limited Quetta. |
| 704. | 010043 | Neurofenac Capsules 25 mg<br><br>Each capsule contains:<br>Diclofenac Sodium ….25 mg | 28-01-1989<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration dated 07-06-2018 | Dy. No. 6588 dated 21-02-2018<br><br>10000/- | | Defer for the clarification regarding justification of using Thiamine, Pyridoxine and Cyanocobalamin in formulation as mentioned in Batch Manufacturing Record. |
| 705. | 032064 | Ibusoft Capsules 400mg<br>Each soft gelatin capsule contains:<br>Ibuprofen... 400 mg | 24-01-2004<br><br>Transfer of registration dated: 03-03-2008 | Dy. No. 6549 dated 21-02-2018<br><br>10000/- | | **Defer for the clarification regarding the manufacturing facility of soft gelatin capsule from the firm.**<br>Product was initially on toll manufacturing by M/s Catts Karachi, after transfer of registration in 2008 the separate permission for extension in toll is not provided.<br>From the latest batch manufacturing details dated 3-10-2017 provided by the firm indicates that firm is manufacturing the product at its own premises.<br>However the Soft Gelatin Capsule manufacturing facility is not approved by Licensing Division and the product is also not transferred in name of M/s Martin Dow Marker Limited Quetta. |
| 706. | 014342 | Neurofenac Capsules 100 mg<br><br>Each capsule contains:<br>Diclofenac Sodium.100 mg | 14-10-1993<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration dated 07-06-2018 | Dy. No. 6587 dated 21-02-2018<br><br>10000/- | | Deferred for the clarification regarding source of pellets from the firm. |
| 707. | 016100 | Laxoberon Tablet<br>Each Tablet Contains:<br>Sodium Picosulfate … 5mg | 21-11-1994<br><br>Transfer of registration dated: 03-03-2008 | Dy. No. 6630 dated 21-02-2018<br><br>10000/- | | Deferred for the clarification regarding transfer of registration in the name of M/s Martin Dow Marker Pvt Limited Quetta from M/s. Merck Pvt. Ltd.from the firm. |
| 708. | 019799 | Laxoberon Liquid<br>Sodium Picosulfate … 5mg | 07-08-1996 | Dy. No. 6629 | | Deferred for the clarification regarding |

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| | | | Transfer of registration dated: 03-03-2008 | dated 21-02-2018<br><br>10000/- | | transfer of registration in the name of M/s Martin Dow Marker Pvt Limited Quetta from M/s. Merck Pvt. Ltd. From the firm. |
| 709. | 024605 | Klaribact Dry Suspension<br><br>Each 5ml Contains:<br>Clarithromycin…..125mg | 21-03-2002<br>Transfer of registration dated: 03-03-2008<br>Transfer of registration dated 21-3-2018 | Dy. No. 6552 dated 21-02-2018<br><br>10000/- | | Defer for the clarification from the firm regarding Source of granules. |
| 710. | 017577 | Azolam Tablet 0.5mg<br><br>Each tablet contains:<br>Alprazolam … 0.5mg | 10-07-1995<br><br>Transfer of registration dated: 03-03-2008<br><br>Transfer of registration 21-3-2018 | Dy. No. 6516 dated 21-02-2018<br><br>10000/- | | Deferred for following:<br>i. Opinion from Legal Affair Division regarding those firms where at the time of registration there is no requirement for approval of Psychotropic section but later on it is mandatory to do so, in the light of decision of Central Licensing Board in its 233rd meeting i.e. as follows:<br>After thorough deliberations and keeping in view the directions of Policy Board, recommendations of DRAP Authority, recommendations of Committee for Allocation of Controlled Substances / Drugs (Inter-Ministerial Committee), views of honorable members, previous decisions of Central Licensing Board on the said issue, and ensuring adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes as highlighted by INCB, the Central Licensing Board decided: -<br>□ To continue the previous policy / decisions of Central Licensing Board of segregated facility for manufacturing of Psychotropic / Narcotic Drugs. |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | □ To process all pending layout plans / applications accordingly in the light of above decision.<br>□ To carryout fresh panel inspections of sections / areas of Psychotropic / Narcotic Drugs considered and deferred in 227th meeting of CLB.<br><br>ii. Clarification from the firm regarding transfer of registration in name of M/s AGP Pvt Limited from the firm. |
| 711. | 017576 | Azolam Tablet 0.25 mg<br><br>Each tablet contains:<br>Alprazolam … 0.25mg | 10-07-1995<br><br>Transfer of registration dated: 03-03-2008<br><br>Transfer of registration dated 21-3-2018 | Dy. No. 6515 dated 21-02-2018<br><br>10000/- | | -do- |
| 712. | 017578 | Azolam Tablet 1mg<br>Each Tablet Contains:<br>Alprazolam … 1mg | 10-07-1995<br><br>Transfer of registration dated: 03-03-2008<br><br>Transfer of registration dated 21-3-2018 | Dy. No. 6517 dated 21-02-2018<br><br>10000/- | | -do- |

## MISCELLENOUS CASES

**i. Renewal application of M/s Marvi Pharmaceuticals Pvt Limited Karachi of Pain Gay Ointment (012777)**

It is submitted that M/s. Marvi Pharmaceuticals had applied for renewal of registration of year 2015 for their following product vide SRO 1005(I)/2017 dated 05th October, 2017. Details pf products are as under:

| Reg. No | Brand Name & Composition | Date of registration as per Form-5B |
|---|---|---|
| 012777 | Pain Gay Ointment<br>Each gm contains:<br>Methyl salicylate ……150mg<br>Menthol….100 | 15-12-1992 |

The Firm was advised to submit the evidence of initial registration letter and post registration variation (if any) for further proceeding the case. In the reply firm submitted only the evidence of renewal of year 2010, however the firm was again requested for submission of initial registration letter. The firm informed that they were granted the registration of Pain Gay Ointment containing Methyl Salicylate 150mg + Menthol 100mg, Registration No. 012777 vide approval letter No. F.3-6/91-Reg-II (M-94) dated 04th August, 1991.Since then they are marketing this product in whole country and export to other countries as well. Furthermore they have also taken Trade Mark Registration of their brand PainGay from the Trade Marks Registry, Government of Pakistan Karachi.

The firm further informed d that due to ill health followed by demise of one of their Director Mr. Nadir Fazwani, several documents were stolen or misplaced/lost which also include registration letters issued to them by Ministry of Health. Due to the reason they fail to apply renewal within due time.

Recently Drug Regulatory Authority of Pakistan's decision /policy vide SRO 1005(I)/2017 dated 5th October, 2017 regarding renewal of registration of products applied after stipulated time. Accordingly we have applied for renewal of Pain Gay Ointment (Reg.No. 012777) along with 3 time applicable fee i.e. Rs.30, 000/- .The firm also stated that that they had already applied for issuance of duplicate registration letter of subject product and applied in concerned section.

It is submitted thataforementioned product is included in the formulary and according to it Pain Gay Ointment was registered in the name of M/s. Marvi Pharmaceuticals Pvt Limited Karachi with the Registration No.012777 and formulation is mentioned as METHYL SALICYCILATE 15gm +MENTHOL 10gm.However initial registration date is not mentioned in the said formulary which is the date as provided by the firm in Form 5B with renewal application.

**Decision: Registration Board deferred the case for the submission of copy of FIR related to documents stolen/misplaced/lost for onward consideration of case.**

**ii. Cases of typographic errors.**

**a. M/s Faas Pharmaceuticals Pvt Limited, F-748L S.I.T.E., Karachi**

Following products of M/s Faas Pharmaceuticals Pvt Limited, F-748L S.I.T.E., Karachi were approved for grant of renewal as indicated below in 286th meeting of Registration Board, however the letter was not issued due to some typographic errors in composition. This correct composition is mentioned below for consideration please.

| Sr. No | Reg. No. | Brand Name, Composition as per minutes of M-286 | Brand name and composition as per Reg. Letter | Initial date of Registration | Renewal validity | Validity |
|---|---|---|---|---|---|---|
| 1. | 073841 | Airy 10mg Tablet<br>Each chewable tablet contains:<br>Montelukast Sodium……10mg | Airy 10mg Tablet<br>Each film coated tablet contains:<br>Montelukast Sodium……10mg | 27-3-2013<br><br>Change of brand name: 09-01-2018 | 26-3-2023 | w.e.f. 27-03-2018 to 26-03-2023. |

| | | | | | | |
|---|---|---|---|---|---|---|
| 2. | 073842 | Des-OD 5mg Tablet<br>Each film coated tablet contains:<br>Desloratadine…5mg | Des-Eze 5mg Tablet<br>Each film coated tablet contains:<br>Desloratadine…5mg | 27-3-2013<br><br>Change of brand name: 09-12-2014 | 26-3-2023 | w.e.f. 27-03-2018 to 26-03-2023. |
| 3. | 073844 | Fasofenac 100mg Tablet<br>Each film coated tablet contains:<br>Moxifloxacin as HCl…….400mg | Fasofenac 100mg Tablet<br>Each film coated Aceclofenac as sodium….100mg | 27-3-2013 | 26-3-2023 | w.e.f. 27-03-2018 to 26-03-2023. |
| 4. | 073845 | Fastcure 150mg Capsule<br>Each film coated tablet contains:<br>Iron Polymaltose Complex eq. to elemental Iron...150mg | Fastcure 150mg Capsule<br>Each capsule contains:<br>Iron Polysaccharide Complex eq. to elemental Iron...150mg | 27-3-2013 | 26-3-2023 | w.e.f. 27-03-2018 to 26-03-2023. |
| 5. | 073846 | Airy Sachet 4mg<br>Each chewable tablet contains:<br>Montelukast as Sodium……5mg | Airy Sachet 4mg<br>Each sachet contains:<br>Montelukast as Sodium……4mg | 27-3-2013<br><br>Change of brand name: 13-02-2018 | 26-3-2023 | w.e.f. 27-03-2018 to 26-03-2023. |

**Decision: Registration Board noted the information.**

**b. M/s. Abbot Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi Karachi.**

| Sr. No. | Reg. No. | Brand Name | Date of Reg. | Decision of the Board | Typographical Error |
|---|---|---|---|---|---|
| 1. | 006709 | Prothiaden Tablet 75mg<br>Each tablet contains:<br>Dosulepin HCl…..75mg | 22-02-1983 | w.e.f. 22-02-2018 till 21-02-2023 | Inadvertently wrong decision has been paste. |
| 2. | 028429 | Ganaton 50mg Tablet<br>Each tablet contains:<br>Itopride HCl….50mg | 07-02-2003 | w.e.f. 07-02-2018 till 06-02-2023 | |

**Decision: Registration Board noted the information.**

**iii. Ossopan 800 Tablet (036422) of M/s AGP Limited Karachi.**

M/s AGP Limited Karachi has applied for renewal of registration for the year 2015 vide SRO 1005 (I)/ 2017 dated 5-10-2017 for the following product.

| Reg. No | Brand Name & Composition | Date of registration |
|---|---|---|
| 036422 | Ossopan 800 Tablet<br>Each tablet contains:<br>Ossein Mineral Complex | 15-01-2005 |

The product was initially registered in name of M/s Elli Lilly Gohar Pvt Limited Karachi. The firm was asked to submit transfer letter in their name, however rather submitting they have informed that product renewal was submitted in 2010, by M/s Elli Lilly Gohar Pvt Limited Karachi. Due to transition phase they miss renewal of 2015. However the transfer of registration in the name of AGP Limited has not been submitted yet.

**Decision: Registration Board decided to confirm tablet manufacturing facility of D-109, SITE, Karachi and also solicit the opinion of Legal Affair Division for the decision related to the following matters encountered by the RRR Section:**

- **i. During the transition phase when the product is in the process of transfer to the new title or new manufacturing site then who will be the responsible for submission of due renewal.**
- **ii. Once the title of firm has been changed by the Licensing Division then what is the status of registered product.**

**iii. Either the M/s. AGP Ltd., Karachi is authorized to submit the renewal while the product is not yet transferred from M/s Elli Lilly Gohar Pvt Limited Karachi to M/s. AGP Ltd., Karachi.**

**iv. M/s Rotex Pharma Pvt Limited Formerly, M/s Rotex Medica Pakistan Pvt Limited Islamabad.**

It is submitted that below mentioned products were referred by Reg-III section for confirmation of renewal. Registration Board considered the applications of renewal of registration of and decision is mentioned in the last column below:

| Sr. No. | Reg. No. | Product Name | Initial date of Registration | Applicatin receiving date | Decision |
|---|---|---|---|---|---|
| 1. | 068596 | Acer Tablet 100mg<br>Each Tablet Contains:-<br>Aceclofenac…100mg | 13-01-2010 | **Due date (12-01-2015)**<br>Fee of Rs.10,000/- deposited on 26-01-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 13-01-2015 to 12-01-2020 |
| 2. | 068606 | Alpha-Plus Tablet 0.5mcg<br>Each Tablet Contains:-<br>Alfacalcidol…0.5mcg | -Do- | **Due date (12-01-2015)**<br>Fee of Rs.10,000/- deposited on 26-01-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 13-01-2015 to 12-01-2020 |
| 3. | 060287 | Galdio 20mg Tablet<br>Each Tablet Contains:-<br>Ebastine…20mg | 18-09-2009 | **Due date (17-09-2014)**<br>Fee of Rs.10,000/- deposited on 30-09-2014. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 18-09-2014 to 17-09-2019 |
| 4. | 056214 | Gastrolux 20mg Capsule<br>Each Capsule Contains:-<br>Esomeprazole (as Magnesium Trihydrate Enteric Coated Pellets)…20mg<br>Source of Pellets: M/s. Smilax Laboratories Ltd., Plot No. 44 CIE Gandhi Nagar, Balanagar, Hyderabad, India | 17-03-2009 | **Due date (16-03-2014)**<br>Fee of Rs.10,000/- deposited on 14-03-2014. As these are imported pellets, so differential fee of Rs.10,000/- deposited by the firm dated 17-10-2018 | w.e.f. 17-03-2014 to 16-03-2019 |
| 5. | 056215 | Gastrolux 40mg Capsule<br>Each Capsule Contains:-<br>Esomeprazole (as Magnesium Trihydrate Enteric Coated Pellets)…40mg<br>M/s. Smilax Laboratories Ltd., Plot No. 44 CIE Gandhi Nagar, Balanagar, Hyderabad, India | -Do- | **Due date (16-03-2014)**<br>Fee of Rs.10,000/- deposited on 14-03-2014. As these are imported pellets, so differential fee of Rs.10,000/- deposited by the firm dated 17-10-2018 | w.e.f. 17-03-2014 to 16-03-2019 |
| 6. | 068603 | Hexalor Tablet 5mg<br>Each Tablet Contains:-<br>Desloratadine…5mg | 13-01-2010 | **Due date (12-01-2015)**<br>Fee of Rs.10,000/- deposited on 26-01-2015. As application received late but within 60 | w.e.f. 13-01-2015 to 12-01-2020 |

| | | | | | |
|---|---|---|---|---|---|
| | | | | days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | |
| 7. | 068599 | Hexalor Tablet 5mg Each Tablet Contains:- Desloratadine…5mg | -Do- | -Do- | w.e.f. 13-01-2015 to 12-01-2020 |
| 8. | 068600 | Isodil Tablet 40mg Each Tablet Contains:- Isosorbide-5Mononitrate…40mg | -Do- | -Do- | w.e.f. 13-01-2015 to 12-01-2020 |
| 9. | 060804 | Kelac 10mg Tablet Each Tablet Contains:- Ketorolac Tromethamine…10mg | 26-09-2009 | **Due date (25-09-2014)** Fee of Rs.10,000/- deposited on 30-09-2014. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 26-09-2014 to 25-09-2019 |
| 10. | 060805 | Kelac 20mg Tablet Each Tablet Contains:- Ketorolac Tromethamine…20mg | -Do- | -Do- | w.e.f. 26-09-2014 to 25-09-2019 |
| 11. | 066519 | Kemex 20mg Tablet Each Tablet Contains:- Piroxicam (as Beta-Cyclodextrin)…20mg | 03-11-2010 | **Due date (02-11-2015)** Fee of Rs.10,000/- deposited on 03-11-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 03-11-2015 to 02-11-2020 |
| 12. | 066395 | Lemoxol DS Tablet Each Tablet Contains:- Artemether…40mg Lumefantrine…240mg | 04-10-2010 | **Due date (03-10-2015)** Fee of Rs.10,000/- deposited on 09-10-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 04-10-2015 to 03-10-2020 |
| 13. | 068604 | Levitra Tablet 250mg Each Tablet Contains:- Levetiracetam…250mg | 13-01-2010 | **Due date (12-01-2015)** Fee of Rs.10,000/- deposited on 26-01-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 13-01-2015 to 12-01-2020 |
| 14. | 068605 | Levitra Tablet 500mg Each Tablet Contains:- Levetiracetam…500mg | -Do- | -Do- | w.e.f. 13-01-2015 to 12-01-2020 |
| 15. | 066520 | Montero 4mg Chewable Tablet Each Chewable Tablet Contains:- Montelukast Sodium eq. to Montelukast…4mg | 03-11-2010 | **Due date (02-11-2015)** Fee of Rs.10,000/- deposited on 03-11-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 03-11-2015 to 02-11-2020 |
| 16. | 068595 | Monoflox Tablet 320mg Each Film Coated Tablet Contains:- Gemifloxacin (as Mesylate)…320mg | 13-01-2010 | **Due date (12-01-2015)** Fee of Rs.10,000/- deposited on 26-01-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 13-01-2015 to 12-01-2020 |

| | | | | | |
|---|---|---|---|---|---|
| 17. | 068609 | Mebetex Tablet 135mg<br>Each Tablet Contains:-<br>Mebeverine Hydrochloride…135mg | -Do- | -Do- | w.e.f. 13-01-2015 to 12-01-2020 |
| 18. | 056213 | Opagis 30mg Capsule<br>Each Capsule Contains:-<br>Lansoprazole (Pellets)…30mg<br>**Source of Pellets: M/s. Smilax Laboratories Ltd., Plot No. 44 CIE Gandhi Nagar, Balanagar, Hyderabad, India** | 17-03-2009 | **Due date (16-03-2014)**<br>Fee of Rs.10,000/- deposited on 14-03-2014. As these are imported pellets, so differential fee of Rs.10,000/- deposited by the firm dated 17-10-2018 | w.e.f. 17-03-2014 to 16-03-2019 |
| 19. | 068601 | Prada Tablet 50mg<br>Each Tablet Contains:-<br>Itopride Hydrochloride…50mg | 13-01-2010 | **Due date (12-01-2015)**<br>Fee of Rs.10,000/- deposited on 26-01-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 13-01-2015 to 12-01-2020 |
| 20. | 066396 | Rotamox 400mg Tablet<br>Each Tablet Contains:-<br>Moxifloxacin (as Hydrochloride)…400mg | 04-10-2010 | **Due date (03-10-2015)**<br>Fee of Rs.10,000/- deposited on 09-10-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 04-10-2015 to 03-10-2020 |
| 21. | 056932 | Timezol 20mg Capsule<br>Each Capsule Contains:-<br>Omeprazole (as Enteric Coated Pellets)…20mg<br>**Source of Pellets: M/s. Smilax Laboratories Ltd., Plot No. 44 CIE Gandhi Nagar, Balanagar, Hyderabad, India** | 29-07-2009 | **Due date (28-07-2014)**<br>Fee of Rs.10,000/- deposited on 17-07-2014. As these are imported pellets, so remaining fee of Rs.10,000/- deposited by firm on dated 17-10-2018 | w.e.f. 29-07-2014 to 28-07-2019 |
| 22. | 056216 | Timezol 40mg Capsule<br>Each Capsule Contains:-<br>Omeprazole (as Enteric Coated Pellets)…40mg<br>**Source of Pellets: M/s. Smilax Laboratories Ltd., Plot No. 44 CIE Gandhi Nagar, Balanagar, Hyderabad, India** | 17-03-2009 | **Due date (16-03-2014)**<br>Fee of Rs.10,000/- deposited on 14-03-2014. As these are imported pellets, so remaining fee of Rs.10,000/- deposited by firm on dated 17-10-2018. | w.e.f. 17-03-2014 to 16-03-2019 |
| 23. | 066516 | Torivas 10mg Tablet<br>Each Tablet Contains:-<br>Atorvastatin (as Calcium Trihydrate)…10mg | 03-11-2010 | **Due date (02-11-2015)**<br>Fee of Rs.10,000/- deposited on 03-11-2015. As application received late but within 60 days after expiry of Reg. So remaining fee of Rs.10,000/- deposited on dated 17-10-2018 | w.e.f. 03-11-2015 to 02-11-2020 |
| 24. | 066517 | Torivas 20mg Tablet<br>Each Tablet Contains:-<br>Atorvastatin (as Calcium Trihydrate)…20mg | -Do- | -Do- | w.e.f. 03-11-2015 to 02-11-2020 |

| | | | | | |
|---|---|---|---|---|---|
| 25. | 066518 | Torivas 40mg Tablet<br>Each Tablet Contains:-<br>Atorvastatin (as Calcium Trihydrate)…40mg | -Do- | -Do- | w.e.f. 03-11-2015 to 02-11-2020 |
| 26. | 069871 | Zepril Capsule 60mg<br>Each Capsule Contains:-<br>Duloxetine as Hydrochloride (Pellets)…60mg<br>Source of Pellets:<br><br>M/s. Alphamed Formulation (Pvt.) Ltd., Survey No. 225, Sampanbole Village Shamirpet Mandal, Ranga Reddu District 500078, A.P. India | 07-04-2011 | **Due date (06-04-2016)**<br>Fee of Rs.10,000/- deposited on 05-04-2016. As these are imported pellets, so remaining fee of Rs.10,000/- deposited by firm on dated 17-10-2018 | w.e.f. 07-04-2016 to 06-04-2021 |

**v. Renewal applications of local manufacturers evaluated as per SOP approved by Registration Board.**

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

| I | II | III | IV | V | VI | VII |
|---|---|---|---|---|---|---|
| **Sr. No.** | **Reg. No.** | **Product Name** | **Initial date of Registration** | **Application receiving date** | **Renewal Validity** | **Decision** |
| **1- M/s. S.J&G Fazul Ellahi (Pvt) Ltd. E/46 S.I.T.E ,Karachi** | | | | | | |
| **1** | 000821-Ex | Glitacin Tablet 250mg<br>Each tablet contains<br>Levofloxacin hemihydrate eq.to,levofloxacin…….250mg | 09-02-2008 | 24-01-2018 | 08-02-2023 | w.e.f. 09-02-2018 to 08-02-2023 with description as per Innovator . |
| **2** | 000820-EX | Glitacin Tablet 500mg<br>Each tablet contains<br>Levofloxacin hemihydrate eq.to,levofloxacin…….500mg | 09-02-2008 | 24-01-2018 | 08-02-2023 | w.e.f. 09-02-2018 to 08-02-2023 with description as per Innovator .. |
| **3** | 000819-EX | Korel Chewable Tablet<br>Each chewable tablet contains<br>Iron III Hydroxide Polymaltose Complex…100mg<br>Folic Acid….0.35mg | 09-02-2008 | 24-01-2018 | 08-02-2023 | w.e.f. 09-02-2018 to 08-02-2023 with description as per Innovator .<br>. |
| **4** | 048441 | Otek tablet 20mg<br>Each tablet contains<br>Piroxicam Beta – Cyclodextrin eq.to Piroxicam…..20mg | 04-02-2008 | 24-01-2018 | 03-02-2023 | w.e.f. 04-02-2018 to 03-02-2023 |
| **5** | 048530 | Ceftizoxime….250mg<br>Grafro Injection 250mg<br>Each vial contains<br>Ceftizoxime sodium eq.to | 08-03-2008 | 24-01-2018 | 07-03-2023 | w.e.f.08-03-2018 to 07-03-2023 |
| **6** | 048531 | Ceftizoxime….500mg<br>Grafro Injection 500mg | 08-03-2008 | 24-01-2018 | 07-03-2023 | w.e.f.08-03-2018 to 07-03-2023 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Each vial contains Ceftizoxime sodium eq.to | | | | |
| **7** | 073809 | Erdozet Capsule: Each capsule contains : Erdosteine…..150mg | 28-02-2013 | 24-01-2018 | 27-02-2023 | w.e.f. 28-02-2018 to 27-02-2023 |
| | 073810 | Erdozet Capsule: Each capsule contains : Erdosteine…..175mg | 28-02-2013 | 24-01-2018 | 27-02-2023 | w.e.f. 28-02-2018 to 27-02-2023 |
| **8** | 030013 | Cefprox Tablet 100mg Each tablet contains Cefpodoxime proxetil eq.to Cefpodoxime ….100mg | 12-03-2003 | 15-02-2018 | 11-03-2023 | w.e.f. 12-03-2018 to 11-03-2023 |
| **9** | 030015 | Cefprox Suspension Each 5ml contains Cefpodoxime proxetil eq.to Cefpodoxime ….40mg | 12-03-2003 | Do | 11-03-2023 | w.e.f. 12-03-2018 to 11-03-2023 |
| **10** | 073850 | Cinoflox Oral Suspension 250mg/5ml Each 5ml contains : Ciprofloxacin HCl eq.to Ciprofloxacin…250mg | 27-03-2013 | Do | 26-03-2023 | w.e.f. 27-03-2018 to 26-03-2023 |
| **11** | 073851 | Cinoflox DS Oral Suspension 250mg/5ml Each 5ml contains : Ciprofloxacin HCl eq.to Ciprofloxacin…250mg | 27-03-2013 | DO | 26-03-2023 | w.e.f. 27-03-2018 to 26-03-2023 |
| **12** | O73852 | Hidrofax Tablet Each film coated tablet contains: Rifaximin…..550mg | 27-03-2013 | Do | 26-03-2023 | w.e.f. 27-03-2018 to 26-03-2023 |
| 2- | **M/s Platinum Pharmaceutical (Pvt)Ltd,A-20 North Western Industrial Zone .Bin Qasim Karachi** | | | | | |
| **15** | 020175 | Protect Tab 80mg Each tablet contains Gliclazide …..80mg | 07-10-1997 change of brand name 25-03-1998 | 20-02-2018 | 24-03-2023 | w.e.f. 25-03-2018 to 24-03-2023 |
| **16** | 075960 | Carbex 100mg/5mlsyrup Each 5ml contains Carbocisteine……100mg | 30-03-2013 change of brand name 05-12-2013 | do | 29-03-2023 | w.e.f. 30-03-2018 to 29-03-2023 |
| **17** | 075961 | Carbex 250mg`/5ml syrup Each 5ml contains Carbocisteine….250mg | 30-03-2013 change of brand name 05-12-2013 | do | 29-03-2023 | w.e.f. 30-03-2018 to 29-03-2023 |
| **18** | 075962 | Carbex 375mg Each capsule contains Carbocisteine….250mg | 30-03-2013 change of brand name 05-12-2013 | do | 29-03-2023 | w.e.f. 30-03-2018 to 29-03-2023 |
| **19** | 075963 | Carbex plus syrup Each 5ml contains Carbocisteine….100mg Promethazine HCL…2.5mg | 30-03-2013 change of brand name 05-12-2013 | do | 29-03-2023 | w.e.f. 30-03-2018 to 29-03-2023 |
| **20** | 020857 | Hi-Salz Toothpaste Contains: Sodium Chloride…..16% Tranexamic Acid….0.05% | 08-01-1998 | 26-12-2017 | 07-01-2023 | w.e.f 08-01-2018 to 07-01-2023 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **21** | 047456 | Easair 6mcg Inhalation Solution<br>Each metered dose contains<br>Formoterol Fumerate Dehydrate…….6mcg | 24-01-2008 | do | 23-01-2023 | w.e.f. 24-01-2018 to 23-01-2023 |
| 3- | **M/s English Pharmaceutical Industries, Link Qatarbund Road,Thokar Niaz Baig ,Multan Road, Lahore** | | | | | |
| **22** | 029014 | Cipronag Tablet 250 mg<br>Each tablet contains :<br>Ciprofloxacin HCl..250mg | 26-12-2002<br>Change of brand name as cipronag 31-03-2003 | 22-12-2017 | 25-12-2022 | w.e.f. 26-12-2017 to 25-12-2022 |
| **23** | 029015 | Cipronag Tablet 500 mg<br>Each tablet contains :<br>Ciprofloxacin HCl..500mg | 26-12-2002<br>Change of brand name as cipronag 31-03-2003 | 22-12-2017 | 25-12-2022 | w.e.f. 26-12-2017 to 25-12-2022 |
| **24** | 074237 | Pantakure 40mg Injection<br>Each vial contains :<br>Pantoprazole Sodium monohydrate eq.to Pantoprazole base…40mg | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **25** | 074238 | Engsol Injection 0.09%w/v<br>Each ampoule contains:<br>Sodium Chloride0…..0.9%<br>(10 ml ampoule) | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **26** | 074239 | Engsol Injection 0.09%w/v<br>Each ampoule contains:<br>Sodium Chloride0…..0.9%<br>(05 ml ampoule) | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **27** | 074240 | Vancotic 1gm Injection<br>Vancomycin HCl eq.to Vancomycin……1gm | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **28** | 074241 | Vancotic 500mg Injection<br>Vancomycin HCl eq.to Vancomycin……500mg | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **29** | 074242 | Enmox 500mg injection<br>Amoxicillin Sodium eq.to.<br>Amoxicillin….500mg | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **30** | 074243 | Amo-Clav1.2gm Injection<br>Amoxicillin Sodium eq.to.<br>Amoxicillin….1000mg<br>Clavulanic Acid….200mg | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **31** | 074244 | Amo-Clav 600mg Injection<br>Amoxicillin Sodium eq.to.<br>Amoxicillin….500mg<br>Clavulanic Acid….100mg | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |

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| **32** | 074245 | Cilliclox 500mg Injection<br>Amoxicillin Sodium eq.to.<br>Amoxicillin….250mg<br>Cloxacillin Sodium eq.to.<br>Cloxacillin….250mg | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| **33** | 074246 | Cilliclox 500mg Injection<br>Amoxicillin Sodium eq.to.<br>Amoxicillin….125mg<br>Cloxacillin Sodium eq.to.<br>Cloxacillin….125mg | 27-12-2012 | do | 26-12-2022 | w.e.f. 27-12-2017 to 26-12-2022 |
| 4- | **M/s Amros Pharmaceutical A-96,S.I.T.E, North Karachi** | | | | | |
| **35** | 020795 | Sulphadimidine Injection<br>Each 100ml contains:<br>Sulphadimidine….33.3g | 20-01-1998<br>Renewal letter till<br>20-01-2013 | 23-01-2018 | 19-01-2023 | w.e.f.20-01-2018 to 19-01-2023 |
| **36** | 020796 | Water for injection<br>Each vial contains:<br>Water for injection …50ml | 20-01-1998<br>Renewal letter till<br>20-01-2013 | 23-01-2018 | 19-01-2023 | w.e.f.20-01-2018 to 19-01-2023 |
| **37** | 020797 | Gentamycin 40mg inj<br>Each ml contains<br>Gentamycin Sulphate eq.to Gentamycin base …..40mg | 20-01-1998<br>Renewal letter till<br>20-01-2013 | 23-01-2018 | 19-01-2023 | w.e.f.20-01-2018 to 19-01-2023 |
| **38** | 020798 | Oxytocin injection<br>Each ml contains:<br>Oxytocin……10 I.U | 20-01-1998<br>Renewal letter till<br>20-01-2013 | 23-01-2018 | 19-01-2023 | w.e.f.20-01-2018 to 19-01-2023 |
| **5-** | **M/s Sami Pharmaceuticals (Pvt) Ltd,F-95 SITE ,Karachi** | | | | | |
| **39** | 036350 | N0voteph Capsules 40mg<br>Each capsule contains:<br>Enteric Coated pellets of Esomeprazole Mg Trihydrate eq.to Esomeprazole (prepared pellets)…… 40mg | 31-12-2004 | 03-12-2014 | 30-12-2019 | w.e.f. 31-12-2014 to 30-12-2019.<br>Letter will be issued after source fixation of pellets. |
| **40** | 045400 | N0voteph Capsules 20mg<br>Each capsule contains:<br>Enteric Coated pellets of Esomeprazole Mg Trihydrate eq.to Esomeprazole …20mg | 14-06-2007 | 13-06-2017 | 13-06-2017 | w.e.f. 14-06-2017 to 13-06-2022<br>Letter will be issued after source fixation of pellets. |
| 6- | **Hamaz Pharmaceutical (Pvt) Ltd,13-Km Boson Road,Multan** | | | | | |
| **41** | 021321 | Mazaclox Drops<br>Each 0.6ml contains:<br>Ampicillin Trihydrate eq. to Ampicillin Base …. 60mg Cloxacillin Sodium eq. to Cloxacillin Base …. 30mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **42** | 021322 | Indocap Capsule<br>Each capsule contains:<br>Indomethacin …. 25mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **43** | 021323 | Skymox Drops 10ml<br>Each 1.25ml contains:<br>Amoxicillin Trihydrate | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |

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| | | eq. to Amoxicillin Base …. 125mg | | | | |
| **44** | 021324 | Skymox Forte Syp<br>Each 5ml contains:<br>Amoxicillin Trihydrate eq. to Amoxicillin Base …. 250mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **45** | 021325 | Tetramaz Cap 250mg<br>Each capsule contains:<br>Oxytetracycline HCI …. 250mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **46** | 021326 | Cedox Cap 100mg<br>Each capsule contains:<br>Doxycycline as Hyclate …. 100mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **47** | 021327 | Erytab Tab 500mg<br>Each tablet contains:<br>Erythromycin Estolate eq. to Erythromycin …. 500mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **48** | 021328 | Estadol Susp<br>Each 5ml contains:<br>Paracetamol …. 120mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **49** | 021329 | Estadol Extra Tab<br>Each tablet contains:<br>Paracetamol …. 500mg<br>Caffeine …. 65mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **50** | 021330 | Cloprel Tab 10mg<br>Each tablet contains:<br>Metoclopramide HCI …. 10mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **51** | 021332 | Phenichlore Susp<br>Each 5ml contains:<br>Chloramphenicol Palmitate as Chloramphenicol base …. 125mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **52** | 021333 | Mazatrim Susp<br>Each 5ml contains:<br>Trimethoprim …. 40mg<br>Sulphamethoxazole **...** 200mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **53** | 021334 | Hamadar Tab<br>Each tablet contains:<br>Sulphadoxine (Sulphanelamide) …. 500mg<br>Pyremethamine …. 25mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **54** | 021335 | Ampimaz Syp<br>Each 5ml contains:<br>Ampicillin Trihydrate eq. to Ampicllin base …. 125mg | 15/05/1998 | 09/05/2018 | 14-05-2023 | w.e.f.15-05-2018 to 14-05-2023 |
| **55** | 048994 | Lavenda Tab 500mg<br>Each tablet contains:<br>Clotrimazole …. 500mg | 21/02/2008 | 17/01/2018 | 20-02-2023 | w.e.f.21-02-2018 to 20-02-2023 |
| **56** | 048995 | Carducin Tab 2mg<br>Each tablet contains:<br>Doxazosin Mesylate …. 2mg | 21/02/2008 | 17/01/2018 | 20-02-2023 | w.e.f.21-02-2018 to 20-02-2023 |

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| **57** | 048920 | Cloprel Drops 20ml<br>Each 5ml contains:<br>Metoclopramide HCI eq. to Meoclopramide …. 5mg | 04/02/2008 | 17/01/2018 | 03-02-2023 | w.e.f.04-02-2018 to 03-02-2023 |
| **58** | 048921 | Cloprel Syrup 50ml<br>Each 5ml contains:<br>Metoclopramide HCI eq. to Meoclopramide …. 5mg | 04/02/2008 | 17/01/2018 | 03-02-2023 | w.e.f.04-02-2018 to 03-02-2023 |
| **59** | 048922 | Estadol Plus Susp 60ml<br>Each 5ml contains:<br>Paracetamol …. 250mg | 04/02/2008 | 17/01/2018 | 03-02-2023 | w.e.f.04-02-2018 to 03-02-2023 |
| **60** | 048923 | Estadol Drops 15ml<br>Each 0.8ml contains:<br>Paracetamol …. 80mg | 04/02/2008 | 17/01/2018 | 03-02-2023 | w.e.f.04-02-2018 to 03-02-2023 |
| **61** | 050225 | Artefrost Tab 140mg<br>Each tablet contains:<br>Artemether …. 20mg<br>Lumefantrine …. 120mg | 24/07/2008 | 02/07/2018 | 23-07-2023 | w.e.f. 24-07-2018 to 23-07-2023 |
| 7- | **M/s. Mass Pharma Pvt. Ltd.,17 Km Ferozepur Road Lahore** | | | | | |
| **62** | 076869 | Amodip-V TABLET 5/80 mg<br>Each tablet contains:<br>Amlodipine (as besylate)..5mg<br>Valsartan…….80mg | 29-05-2013 | 25-05-2018 | 28-05-2023 | w.e.f. 29-05-2018 to 28-05-2023 |
| **63** | 076870 | Amodip-V TABLET 5/160 mg<br>Each tablet contains:<br>Amlodipine (as besylate)..5mg<br>Valsartan…….160mg | 29-05-2013 | 25-05-2018 | 28-05-2023 | w.e.f. 29-05-2018 to 28-05-2023 |
| **64** | 076871 | Amodip-V TABLET 10/160 mg<br>Each tablet contains:<br>Amlodipine (as besylate)..5mg<br>Valsartan…….80mg | 29-05-2013 | 25-05-2018 | 28-05-2023 | w.e.f. 29-05-2018 to 28-05-2023 |
| **65** | 076872 | Vensonor tablet 10mg<br>Each tablet contains :<br>Rosuvastatin(as Calcium)…10mg | 29-05-2013 | 25-05-2018 | 28-05-2023 | w.e.f. 29-05-2018 to 28-05-2023 |
| **66** | 076873 | Vensonor tablet 10mg<br>Each tablet contains :<br>Rosuvastatin(as Calcium)…5mg | 29-05-2013 | 25-05-2018 | 28-05-2023 | w.e.f. 29-05-2018 to 28-05-2023 |
| **67** | 076874 | Defumide Tablets<br>Each tablet contains:<br>Leflunomide…10mg | 29-05-2013 | 25-05-2018 | 28-05-2023 | w.e.f. 29-05-2018 to 28-05-2023 |
| **68** | 076875 | Defumide Tablets<br>Each tablet contains:<br>Leflunomide…20mg | 29-05-2013 | 25-05-2018 | 28-05-2023 | w.e.f. 29-05-2018 to 28-05-2023 |
| **8-** | **M/s Barret Hodgson Pakistan (Private)Ltd,F/423 SITE ,Karachi,** | | | | | |
| **69** | 075856 | Boonest 150mg tablet<br>Each tablet contains:<br>Ibandronate sodium monohydrate eq.to Ibandronic acid…..150mg | 11-04-2013 | Dy.no 2904 22-01-2018 | 10-04-2023 | w.e.f. 11-04-2018 to 10-04-2023 |

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| **70** | 075857 | Inoquin125mg/5ml Dry Suspension<br>Each 5ml contains HCl eq.to Ciprofloxacin……125mg | 11-04-2013 | Dy.no 2904 22-01-2018 | 10-04-2023 | w.e.f. 11-04-2018 to 10-04-2023 |
| **71** | 075858 | Inoquin250mg/5ml Dry Suspension<br>Each 5ml contains HCl eq.to Ciprofloxacin……250mg | 11-04-2013 | Dy.no 2904 22-01-2018 | 10-04-2023 | w.e.f. 11-04-2018 to 10-04-2023 |
| **72** | 075859 | Barilol 2.5mg Tablet<br>Each tablet contains : Bisoprolol fumarate…..2.5mg | 11-04-2013 | Dy.no 2904 22-01-2018 | 10-04-2023 | w.e.f. 11-04-2018 to 10-04-2023 |
| **73** | 075860 | Barilol 5mg Tablet<br>Each tablet contains : Bisoprolol fumarate…..5mg | 11-04-2013 | Dy.no 2904 22-01-2018 | 10-04-2023 | w.e.f. 11-04-2018 to 10-04-2023 |
| **74** | 075861 | Barilol 5mg Tablet<br>Each tablet contains : Bisoprolol fumarate…..5mg | 11-04-2013 | Dy.no 2904 22-01-2018 | 10-04-2023 | w.e.f. 11-04-2018 to 10-04-2023 |
| **75** | 075862 | Barinep Ophthalmic Suspension<br>Each ml contains : Nepafenac ……..1mg | 11-04-2013 | Dy.no 2904 22-01-2018 | 10-04-2023 | w.e.f. 11-04-2018 to 10-04-2023 |
| **9- Nexus Pharma (Pvt) Limited .Plot No.4/19,Sector21, Korangi Industrial Area Karachi** | | | | | | |
| **76** | 075837 | Avogel-C Gel<br>Each gm contains:<br>Metronidazole…….1.0%<br>Chlorhexidine Gluconate…….0.25% | 03-04-2013<br>Change of brand name 07-08-2013 | Dy.no2488 18-01-2018<br>Reply received via dy.no2300 03-07-2018 | 02-04-2023 | w.e.f.03-04-2018 to 02-04-2023 |
| **77** | 075890 | Dentisept Mouthwash<br>Each ml contains :<br>Benzydamine Hydrochloride….0.15%w/v<br>Chlorhexidine Gluconate…….0.2%w/v | 06-05-2013 | Dy.no6085 18-01-2018<br>Reply received via dy.no2346 03-07-2018 | 05-05-2023 | w.e.f.06-05-2018 to 05-05-2023 |
| **78** | O75835 | Dimisinex tablet<br>Each tablet contains:<br>Dihydrartemisinin 40mg<br>Piperaquuinine 320mg | 03-04-2013 | Dy.no.2487 18-01-2018<br>Reply received via dy.no23217 03-07-2018 | 02-04-2023 | w.e.f.03-04-2018 to 02-04-2023 |
| **79** | 075832 | Budex DS Suspension 200mg/5ml<br>Each 5ml contains:<br>Ibuprofen…..200mg | 03-04-2013 | Dy.no.2487 18-01-2018<br>Reply received via dy.no23217 03-07-2018 | 02-04-2023 | w.e.f.03-04-2018 to 02-04-2023 |
| **80** | 075836 | Fosfonex Suspension250mg/5ml<br>Each 5ml contains:<br>Fosfomycin as calcium…250mg | 03-04-2013 | Dy.no.2487 18-01-2018<br>Reply received via dy.no23217 03-07-2018 | 02-04-2023 | w.e.f.03-04-2018 to 02-04-2023 |

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| | **10- Reko Pharmacal(Pvt) Ltd ,13Km Multan Road ,Lahore** | | | | | |
| **81** | 029757 | Ophdic eye Drops<br>Each 5ml contains :<br>Diclofenac Sodium….5.25mg | 19-03-2003 | Dy.no.7703 28-02-2018 Reply received on dy.no.22289 26.06.2018 | 18-03-2023 | w.e.f. 19-03-2018 to 18-03-2023 |
| **82** | 029758 | Tobcin eye drops<br>Each 5ml contains :<br>Tobramycin(as Sulphate)……15mg | 19-03-2003 | Dy.no.7703 28-02-2018 Reply received on dy.no.22289 26.06.2018 | 18-03-2023 | w.e.f. 19-03-2018 to 18-03-2023 |
| **83** | 005640 | Itracon 100mg Capsule<br>Each capsule contains:<br>Itraconazole …….100mg | 25-04-1998 | Dy.no.7703 28-02-2018 Reply received on dy.no.22289 26.06.2018 | 24-04-2023 | w.e.f. 25-04-2018 to 24-04-2023 |
| **84** | 005839 | Rakitac D.S 300mg Tablets:<br>Each tablets contains:<br>Ranitidine (as HCl)…..300mg | 25-04-1998 | Dy.no.7703 28-02-2018 Reply received on dy.no.22289 26.06.2018 | 24-04-2023 | w.e.f. 25-04-2018 to 24-04-2023 |
| **85** | 005840 | Pirox 20mg tablets<br>Each tablet contains:<br>Piroxicam……20mg | 25-04-1998 | Dy.no.7703 28-02-2018 Reply received on dy.no.22289 26.06.2018 | 24-04-2023 | w.e.f. 25-04-2018 to 24-04-2023 |
| | **11- M/s Epla Laboratories(Pvt)Ltd .D-12 Estate SITE,Karachi** | | | | | |
| **86** | 030029 | Eplacin CF tablets<br>Each tablet contains<br>Acetaminophen..325mg<br>Chlorpheniramine Maleate…1mg<br>Dextromethorphan HBr …10mg<br>Pseudoephedrine HCl …36mg | 01-04-2003 | Dy no.5835 16-02-2018 | 31-03-2023 | w.e.f.01-04-2018 to 31-03-2023 |
| **88** | 048565 | Eplalev 500mg tablets<br>Each film coated tablets contains:<br>Levofloxacin (as Hemihydrate)…500mg | 31-03-2008 | Dy.no.1809 Dated 12-01-2018 | 30-03-2023 | w.e.f. 31-03-2018 to 30-03-2023 |
| **89** | 048564 | Eplalev 500mg tablets<br>Each film coated tablets contains:<br>Levofloxacin (as Hemihydrate)…250mg | 31-03-2008 | Dy.no.1812 Dated 12-01-2018 | 30-03-2023 | w.e.f. 31-03-2018 to 30-03-2023 |
| **90** | 048563 | Omxiclav Suspension<br>Each 5ml contains:<br>Amoxicillin (as amoxicillin trihydrate)….125mg<br>Clavulanic Acid(as Potassium salt)…….31.25mg | 31-03-2008 | Dy.no.1814 Dated 12-01-2018 | 30-03-2023 | w.e.f. 31-03-2018 to 30-03-2023 |

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| | **12- M/s Stanely Pharmaceuticals (Pvt) Ltd.,84-B Industrial Estate,Hyatabad ,Peshawar** | | | | | |
| **92** | 029780 | Senam Dry Suspension<br>Each 5ml contains :<br>Cefixime…….100mg | 12-03-2003 | Dy.no.3114<br>23-01-2018 | 11-03-2023 | Deferred for confirmation of section from Licensing Division. |
| **93** | 029781 | Senam DS Dry Suspension<br>Each 5ml contains :<br>Cefixime …….200mg | 12-03-2003 | Dy.no.3114<br>23-01-2018 | 11-03-2023 | Deferred for confirmation of section from Licensing Division. |
| | **13- M/s W.Woodward Pakistan (Pvt) Ltd, F-275,S.I.T.E, Karachi** | | | | | |
| **94** | 048614 | Dermy Cream 2%<br>Each gram contains :<br>Fusidic acid ……20gm | 28-05-2008 | Dy.no 7692<br>28-02-2018 | 27-05-2023 | w.e.f. 28-05-2018 to 27-05-2023 |
| | **14- M/s Tabros Pharma (Pvt)Ltd ,L-20/B Sector 22,F.B, Industrial Area ,Karachi** | | | | | |
| **95** | 030011 | Lexicon 7.5mg tablets<br>Each tablet contains<br>Meloxicam……..7.5mg | 26-03-2003 | Dy.no.1892<br>15-01-2018<br>Reply submitted on<br>Dy.no16559<br>04-05-2018 | 25-03-2023 | w.e.f. 26-03-2018 to 25-03-2023 |
| **96** | 030012 | Lexicon 15mg tablets<br>Each tablet contains<br>Meloxicam……..15mg | 26-03-2003 | Dy.no.1893<br>15-01-2018<br>Reply submitted on<br>Dy.no16559<br>04-05-2018 | 25-03-2023 | w.e.f. 26-03-2018 to 25-03-2023 |
| **97** | 073849 | Metliptin 50/850mg tab<br>Each film coated tablet contains :<br>Vildagliptin…..50mg<br>Metformin HCl……850mg | 27-03-2013 | Dy.no.1894<br>15-01-2018<br>Reply submitted on<br>Dy.no16559<br>04-05-2018 | 26-03-2023 | w.e.f. 27-03-2018 to 26-03-2023 |
| | **15- M/s Fozan Pharmaceuticals Industries (Pvt) Ltd, 36-A Industrial Estate,Hyatabad.Peshawar** | | | | | |
| **98** | 048060 | Ventisol Syrup<br>Ketotifen as Hydrogen Fumarate ….1mg | 15-01-2008 | Dy.no 776<br>05-01-2018 | 14-01-2023 | w.e.f. 15-01-2018 to 14-01-2023 |
| **99** | 048365 | Fozin Syrup<br>Each 5ml contains:<br>Cetrizine 2HCl….5mg | 30-01-2008 | Dy.no 775<br>05-01-2018 | 29-01-2023 | w.e.f. 30-01-2018 to 29-01-2023 |
| **100** | 048061 | Lor Syrup<br>Each 5ml contains:<br>Loratidine USP….5mg | 15-01-2008 | Dy.no 774<br>05-01-2018 | 14-01-2023 | w.e.f. 15-01-2018 to 14-01-2023 |
| | **16- M/s. Usawa Pharmaceuticals, 146-S.I.Z, Risalpur, Nowshera.** | | | | | |
| **101** | 029777 | Farzin Tablet<br>Each tablet contains:-<br>Loratadine … 10mg | 18-03-2003 | Dy.no. 9709<br>15-03-2018<br>Reply submitted on Dy.no. 33036 04-10-2018 | 17-03-2023 | w.e.f.18-03-2018 to 17-03-2023 |
| **102** | 029778 | Loporide Tablet<br>Each tablet contains:-<br>Enalapril Maleate … 10mg | 18-03-2003 | Dy.no. 9709<br>15-03-2018<br>Reply submitted | 17-03-2023 | w.e.f.18-03-2018 to 17-03-2023 |

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| | | | | on Dy.no. 33036 04-10-2018 | | |
| **103** | 029779 | Firax Tablet<br>Each tablet contains:-<br>Cetirizine 2HCl … 10mg | 18-03-2003 | Dy.no. 9709 15-03-2018 Reply submitted on Dy.no. 33036 04-10-2018 | 17-03-2023 | w.e.f.18-03-2018 to 17-03-2023 |
| | **17- M/s. Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi.** | | | | | |
| **104** | 009317 | Betacin Ointment<br>Contains:-<br>Betamethasone Valerate … 0.1% | 16-03-1988 | Dy.no. 4408 06-02-2018 Reply submitted on Dy.no. 29745 05-09-2018 | 15-03-2023 | w.e.f. 16-03-2018 to 15-03-2023 Registration letter was issued on the address of head office concerned section may update their information. |
| | **18- M/s. Treat Pharmaceuticals (Pvt) Ltd., A-37, Small Industrial Estate, Township, Kohat Road, Bannu.** | | | | | |
| **105** | 075540 | Treatagen Injection<br>Each 2ml ampoule contains:-<br>Gentamicin (as Sulphate) … 80mg | 07-01-2013 | Dy.no. 7721 28-02-2018 Reply submitted on Dy.no. 803 16-10-2018 | 06-01-2023 | w.e.f. 07-01-2018 to 06-01-2023 |
| **106** | 075538 | Fev-Treat Injection<br>Each 2ml contains:-<br>Paracetamol … 300mg<br>Lidocaine … 20mg | 07-01-2013 | Dy.no. 7721 28-02-2018 Reply submitted on Dy.no. 803 16-10-2018 | 06-01-2023 | w.e.f. 07-01-2018 to 06-01-2023 |
| | **19- M/s. Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205 Industrial Triangle, Kahuta Road, Islamabad.** | | | | | |
| **107** | 075421 | Tamsol 0.4mg Capsule<br>Each capsule contains:-<br>Extended Release Pellets:-<br>Tamsulosin HCl … 0.4mg | 15-05-2013 | Dy.no. 12424 04-04-2018 Reply submitted on Dy.no. 33166 05-10-2018 | 14-05-2023 | w.e.f. 15-05-2018 to 14-05-2023 |
| | **20- M/s. Pharmatec Pakistan (Pvt) Ltd., D-86/A, S.I.T.E, Karachi.** | | | | | |
| **108** | 004204-EX | Apocam 7.5mg Tablet<br>Each tablet contains:-<br>Meloxicam … 7.5mg | 02-07-2013 | Dy.no.21548 19-06-2018 | 01-07-2023 | w.e.f. 02-07-2018 to 01-07-2023 |
| **109** | 004205-EX | Apocam 15mg Tablet<br>Each tablet contains:-<br>Meloxicam … 15mg | 02-07-2013 | Dy.no.21548 19-06-2018 | 01-07-2023 | w.e.f. 02-07-2018 to 01-07-2023 |
| **110** | 004206-EX | Prepase Tablet<br>Each tablet contains:-<br>Losartan Potassium … 50mg | 02-07-2013 | Dy.no.21548 19-06-2018 | 01-07-2023 | w.e.f. 02-07-2018 to 01-07-2023 |
| **111** | 004207-EX | Prepase-H Tablet<br>Each tablet contains:- | 02-07-2013 | Dy.no.21548 | 01-07-2023 | w.e.f. 02-07-2018 to 01-07-2023 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Losartan Potassium … 50mg<br>Hydrochlorothiazide … 12.5mg | | 19-06-2018 | | |
| **112** | 020341 | Alerid Syrup<br>Each 5ml contains:-<br>Cetirizine Dihydrochloride … 5mg | 31-10-1997<br>Change of brand name dated 18-07-1998 | Dy.no.21548<br>19-06-2018 | 17-07-2023 | w.e.f. 18-07-2018 to 17-07-2023 |
| **113** | 020342 | Alerid Tablet<br>Each tablet contains:-<br>Cetirizine Dihydrochloride … 10mg | 31-10-1997<br>Change of brand name dated 18-07-1998 | Dy.no.21548<br>19-06-2018 | 17-07-2023 | w.e.f. 18-07-2018 to 17-07-2023 |
| | **21- M/s. Getz Pharma Plot No. 30-31, Sector-27, Korangi Industrial Area, Karachi.** | | | | | |
| **114** | 019866 | M-Low 10mg Tablet<br>Each tablet contains:-<br>Amlodipine Besylate … 10mg | 30-06-1997<br>Change of brand name dated 11-02-2009 | Dy.no.43371<br>20-12-2018 | 10-02-2023 | w.e.f. 11-02-2014 to 10-02-2019 |
| **115** | 019865 | M-Low 5mg Tablet<br>Each tablet contains:-<br>Amlodipine Besylate … 5mg | 15-04-1997<br>Change of brand name dated 11-02-2009 | Dy.no.43371<br>20-12-2018 | 10-02-2023 | w.e.f. 11-02-2014 to 10-02-2019 |
| | **22- M/s. Tabros Pharma (Pvt.) Ltd.,Karachi** | | | | | |
| **116** | 021790 | Arix Syrup<br>Each ml contains<br>Cetirizine Dihydrochloride…. 1mg | 20-05-1998 | Dy.no.7522<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **117** | 021791 | Arix Tablets<br>Each tablet contains:<br>Cetrizine Dihydrochloride…10mg | 20-05-1998 | Dy.no.7523<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **118** | 021792 | Motim Tablets<br>Each tablet contains:<br>Domeperidone….10mg | 20-05-1998 | Dy.no.7521<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **119** | 021793 | Motim Suspension<br>Each 1ml contains:<br>Domeperidone….1mg | 20-05-1998 | Dy.no.7511<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **120** | 021798 | Klic Tablet 50mg<br>Each tablet contains:<br>Diclofenac Potassium…..50mg | 20-05-1998<br>Change of brand name dated | Dy.no.7512<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **121** | 021799 | Fusil Cream<br>Contains:<br>Fusidic acid…..2% | 20-05-1998 | Dy.no.7509<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **122** | 021800 | Fusil Ointment<br>Contains:<br>Fusidic acid…..2% | 20-05-1998 | Dy.no.7508<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **123** | 021805 | Ronil Injection 250mg I.V.<br>Each vial dry substance contains:<br>Ceftriaxone USP…250mg<br>(as Ceftriaxone Sodium) | 20-05-1998 | Dy.no.7516<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **124** | 021806 | Ronil Injection 500mg I.V. | 20-05-1998 | Dy.no.7518<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Each vial dry substance contains:<br>Ceftriaxone<br>USP….500mg<br>(as Ceftriaxone Sodium) | | | | |
| **125** | 021807 | Ronil Injection 1g I.V.<br>Each vial dry substance contains:<br>Ceftriaxone<br>USP…..1000mg<br>(as Ceftriaxone Sodium) | 20-05-1998 | Dy.no.7524<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **126** | 021808 | Ronil Injection 250mg I.M.<br>Each vial dry substance contains:<br>Ceftriaxone<br>USP….250mg<br>(as Ceftriaxone Sodium) | 20-05-1998 | Dy.no.7513<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **127** | 021809 | Ronil Injection 500mg I.M.<br>Each vial dry substance contains:<br>Ceftriaxone<br>USP…..500mg<br>(as Ceftriaxone Sodium) | 20-05-1998 | Dy.no.7515<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **128** | 021810 | Ronil Injection 1g I.M.<br>Each vial dry substance contains:<br>Ceftriaxone<br>USP….1000mg<br>(as Ceftriaxone Sodium) | 20-05-1998 | Dy.no.7514<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **129** | 021811 | Zatron Injection 250mg IM/IV<br>Each vial contains:<br>Ceftazidime<br>USP….250mg | 20-05-1998 | Dy.no.7520<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **130** | 021812 | Zatron Injection 500mg IM/IV<br>Each vial contains:<br>Ceftazidime<br>USP….500mg | 20-05-1998 | Dy.no.7519<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **131** | 021813 | Zatron Injection 1gm IM/IV<br>Each vial contains:<br>Ceftazidime<br>USP….1000mg | 20-05-1998 | Dy.no.7517<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| **132** | 021814 | Fenac Tablet<br>Each tablet contains:<br>Diclofenac<br>Sodium….50mg | 20-05-1998 | Dy.no.7510<br>27-02-2018 | 19-05-2023 | w.e.f. 20-05-2018 to 19-05-2023 |
| | **23- M/s. Opal Laboratories Pvt. Ltd.,Karachi** | | | | | |
| **133** | 000841-Ex | Per-Plus Syrup<br>Each 30ml contains:<br>Vitamin B1……25mg<br>Vitamin B2…..10mg<br>Vitamin B6……6mg<br>Vitamin B12……50mcg<br>Calcium Pantothenate…..15mg<br>Inositol …….30mg | 23-02-2008 | Dy.no.4402<br>06-02-2018 | 22-02-2023 | w.e.f. 23-02-2018 to 22-02-2023 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Ascorbic Acid…..450mg<br>Lysine Mono HCl…..200mg<br>Nicotinamide……108mg | | | | |

**v. Correction in Typographical Errors**

Following typographical errors need to be corrected considered in 279th meeting

| Sr. No. | Firm Name | Reg. No. | Brand Name | Date of Reg. | Decision of the Board | Typographical Error |
|---|---|---|---|---|---|---|
| 1. | M/s. Wilshire Laboratories, Lahore | 049007 | Zepose 75mg Tablet<br>Each tablet contains:<br>Irebesartan …. 75mg | 20/08/2008 | w.e.f. 20/08/2018 till 19/08/2023 | Initial Registration date is corrected as 26-02-2008 accordingly validity is corrected as w.e.f 26-02-2018 till 25-02-2023 |
| 2. | M/s. Wilshire Laboratories, Lahore | 049008 | Zepose 150mg Tablet<br>Each tablet contains:<br>Irebesartan …. 150mg | 20/08/2008 | w.e.f. 20/08/2018 till 19/08/2023 | Initial Registration date is corrected as 26-02-2008 accordingly validity is corrected as w.e.f 26-02-2018 till 25-02-2023 |
| 3. | M/s. Wilshire Laboratories, Lahore | 049009 | Zepose 300mg Tablet<br>Each tablet contains:<br>Irebesartan …. 300mg | 20/08/2008 | w.e.f. 20/08/2018 till 19/08/2023 | Initial Registration date is corrected as 26-02-2008 accordingly validity is corrected as w.e.f 26-02-2018 till 25-02-2023 |
| 4. | M/s. Wilshire Laboratories, Lahore | 049976 | Foliant 10mg Tablet<br>Each tablet contains:<br>Naproxyn Sodium …. 250mg | 18/07/2008 | w.e.f. 18/07/2018 till 17/07/2023 | Composition is corrected as Memantine HCl 10mg |
| 5. | M/s. Wilshire Laboratories, Lahore | 052816 | Dmard 2.5mg Tablet<br>Each tablet contains:<br>Methotrexate …. 2.5mg | 18/09/2008 | w.e.f. 18/09/2018 till 17/09/2023 | Initial Registration date is corrected as 18-11-2008 accordingly validity is corrected as w.e.f 18-11-2018 till 17-11-2023 |
| 6. | M/s. Wilshire Laboratories, Lahore | 074294 | Water for Injection<br>Contains:<br>Distilled Water for Injection | 31/01/2013 | w.e.f. 31/01/2018 till 30/01/2023 | Product detail is corrected as Water for Injection |
| 7. | M/s. Wilshire Laboratories, Lahore | 074295 | Lignocaine 1% Injection<br>Contains:<br>Lignocaine HCI …. 10mg | 31/01/2013 | w.e.f. 31/01/2018 till 30/01/2023 | Product detail is corrected as Lignocaine 1% Injection |

**Decision: Registrtaion Board noted the information.**

**vi. Applications Received with Shortcomings**

This section apprised the Board that Directorate of (PE&R) is dealing with number of applications submitted for renewal of drugs which are incomplete or have shortcoming especially with reference to the submitted prescribed renewal fees.

The following applications for renewal of drugs are submitted on Form 5-B after the expiry of validity of the certificate of registration but within **sixty days** after validity of certificate of registration. The applications for renewal are incomplete with reference to renewal application fee or having some other deficiency.

**RULE 27 Drug (Licensing, Registering & Advertising) Rules, 1976 (Duration of certificate of registration).** *A certificate of registration under this chapter, [shall unless earlier suspended or cancelled, be in force for a period of five years from the date of [Registration of the drug] and may thereafter be renewed for period not exceeding five years and a certificate to this effect shall be issued within one month] at a time.*

*Provided that an application for the renewal of registration shall not be entertained unless it has been made within sixty days after the expiry of the registration and when an application has been made aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five yearsand a certificate to this effect shall be issued within one month].*

*Provided further that in case of an imported drug, the renewal may be granted and a renewal certificate shall be issued, if in the opinion of the Registration Board it is necessary to do so in the public interest*

Following cases are placed below for the consideration of Registration Board and the decision is recorded in the last colum below:

**i) With Prescribed Fee**

**a) M/s. Eros Pharma (Pvt) Ltd., 94-95/23, Korangi Industrial Area, Karachi.**

| Sr. No. | Reg. No. | Product Name | Initial date of Registration | Application Receiving date | Decision |
|---|---|---|---|---|---|
| 1. | 067105 | Enac Suspension<br>Each 5ml contains:-<br>Ibuprofen … 100mg<br>Pseudoephedrine HCl … 30mg | 25-11-2010 | **Due date (24-11-2015)**<br>Firm submitted fee of Rs.10,000/-on 30-11-2015.As the renewal application is received late but within 60 days after expiry of Reg.,so fee of Rs.10,000/- submitted by firm on 05-09-2018. | **w.e.f. 25-11-2015 to 24-11-2020** |
| 2. | 011917 | Erocof-A Syrup<br>Each 5ml contains:<br>Ammonium Chloride….100mg<br>Sodium Citrate…..60mg<br>Chlorpheniramine Maleate….2mg<br>Ephedrine HCl….7mg<br>Menthol……1mg | 22-11-1990 | **Due Date (21-11-2015)**<br>Firm submitted fee of Rs.10,000/-on 30-11-2015.As the renewal application is received late but within 60 days after expiry of Reg.,so fee of Rs.10,000/- submitted by firm on 05-09-2018. | **w.e.f. 22-11-2015 to 21-11-2020** |

**b) M/s. Innvotek Pharmaceuticals, Plot No. 35, Industrial Triangle, Kahuta Road, Islamabad.**

| Sr. No. | Reg. No. | Product Name | Initial date of Registration | Application Receiving date |
|---|---|---|---|---|
| 1. | 072851 | Inmox Eye Drops<br>Each ml contains:-<br>Moxifloxacin as HCl … 5mg | 19-08-2011 | **Due date (18-08-2016)**<br>Received within 60 days after expiry of Reg. with fee of Rs.20,000/- deposited on 19-09-2016. |

**Decision: Registration Board acceded to the request of firm and decided to grant the renewal w.e.f. 19-08-2016 to 18-08-2021**

**c) M/s. SPL Pharmaceuticals (Pvt.) Ltd., Peshawar**

| Sr. No. | Reg. No. | Product Name | Initial date of Registration | Application Receiving date |
|---|---|---|---|---|
| 1. | 073351 | Roxim 20mg Capsule<br>Each capsule contains:<br>Piroxicam Beta –cyclodextrin equivalent to Piroxicam…..20mg | 07-09-2012 | **Due date (06-09-2017)**<br>Received within 60 days after expiry of Reg. with fee of Rs.20,000/- deposited on 03-10-2017. |
| 2. | 073352 | Polyfol 100mg Capsule<br>Each capsule contains:<br>Iron Polymaltose Complex equivalent to Elemental Iron…..100mg<br>Folic Acid…..550mcg | 07-09-2012 | **Due date (06-09-2017)**<br>Received within 60 days after expiry of Reg. with fee of Rs.20,000/- deposited on 03-10-2017. |
| 3. | 073353 | Q-Flox 250mg Tablet<br>Each tablet contains:<br>Ciprofloxacin (as HCl)……250mg | 07-09-2012 | **Due date (06-09-2017)**<br>Received within 60 days after expiry of Reg. with fee of Rs.20,000/- deposited on 03-10-2017. |
| 4. | 073354 | Voflox 250mg Tablet<br>Each tablet contains:<br>Levofloxacin Hemihydrate Equivalent to Levofloxacin….250mg | 07-09-2012 | **Due date (06-09-2017)**<br>Received within 60 days after expiry of Reg. with fee of Rs.20,000/- deposited on 03-10-2017. |

**Decision:** **Registration Board considered the above products and decision is mentioned in the last column, however the letter will be issued after the settlement of cases of management in the court as per information of Licensing Division.**

**vii. Cases For Imported Pellets**

**a) M/s. Hoover Pharmaceuticals (Pvt.) Ltd., Lahore**

| Sr. No | Reg. No | Products/Name | Initial Date of Registration | Application receiving date and fee submitted date and due date |
|---|---|---|---|---|
| **1** | 065932 | Gatolin Capsule 20mg<br>Each capsule contains:<br>Omeprazole (Pellets)….20mg | 06-10-2010 | Due Date (05-10-2015) Fee of Rs. 10,000/- deposited on 29-09-2015. As these are imported Pellets from **M/s.Similax Laboratories Ltd. Rajbhavan Road Somajiguda Hyderabad India** So remaining Fee of Rs. 10,000/- deposited on 17-10-2018. |

**Decision:** **Registration Board acceded to the request of firm and decided to grant the renewal w.e.f. 06-10-2015 to 05-10-2020.**

**b) M/s. Getz Pharma (Pvt.) Ltd., Karachi**

| Sr. No | Reg. No | Products/Name | Initial Date of Registration | Application receiving date and fee submitted date and due date |
|---|---|---|---|---|
| **1** | 019364 | Risek 20mg Capsule<br>Each capsule contains:<br>Omeprazole….20.00mg | 25-06-1996 | Due Date (24-06-2016) Fee of Rs. 20,000/- deposited on 13-04-2016. As these are imported Pellets from M/s. Shouguang Fukang Pharmaceutical, Co. Ltd. North-East of Dongwaihuan Road Dongcheng Industrial Area, Shougang City Shangdong Province China. |

**Decision:** **Registration Board acceded to the request of firm and decided to grant the renewal w.e.f. 25-6-2016 to 24-6-2021.**

**viii. Cases For Differential Fee**

**M/s. Galaxy Pharma (Private) Limited, Karachi**

| Sr. No | Reg. No | Products/Name | Initial Date of Registration | Application receiving date and fee submitted date and due date | Decision |
|---|---|---|---|---|---|
| **1** | 059079 | Utrogestan Vaginal 200mg Soft Capsule<br>Each capsule contains:<br>Micronized Progesterone……200mg<br><br>Manufacturer abroad M/s Besins Healthcare, Brussels Belgium | 16-10-2009 | Due Date (15-10-2014) Fee of Rs. 20,000/-on 22-10-2014 ,remaining fee of Rs 20,000 was paid on 04-12-2017 | w.e.f. 16-10-2014 to 15-10-2019 |
| | 062214 | Utrogestan Vaginal 100mg Soft Capsule<br>Each capsule contains:<br>Micronized Progesterone……100mg<br><br>Manufacturer abroad M/s Besins Healthcare, Brussels Belgium | 27-4-2010 | Due date (23-4-2015) Fee of Rs. 20,000/-on 27-4-2010 ,remaining fee of Rs 20,000 was paid on 04-12-2017 | w.e.f. 27-4-2015 to 26-4-2020 |

**Decision: Registration Board acceded to the request of the firm and decided in last column mentioned above.**

**ix. Cases of Bulk Import and Local Repacking**

It is submitted that previously case has been placed in 284th meeting of Registration Board, and inadvertently certain information has been missed in the previous agenda. Case has again placed with the complete detail of post registration variation for the consideration of Board. Accordingly due date and validity of renewal will be changed.

**a) M/s. Sanofi Aventis, Karachi.**

| Sr. No. | Reg. No. | Product Name | Initial date of Registration | Application Receiving date | Decision |
|---|---|---|---|---|---|
| 1. | 019564 | Tritace 2.5mg Tablets<br>Each tablet contains:<br>Ramipril…..2.5mg | 08-07-1997<br>Change of company name from M/s. Hoechst Marion Roussel to M/s. Aventis Pharma (Pakistan) Limited, Karachi Dated<br>**24-01-2002**<br>Change of registration from import in finished form to bulk import and local repacking dated<br>**11-02-2005**<br>Change of manufacturing site abroad from Germany to Aventis S.p.A, scopptio (A.Q) Italy<br>**02-06-2005**<br>Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated<br>**28-07-2006** | **Due date (27-07-2016)**<br>Fee of Rs.10, 000/- deposited on 09-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi-aventis S.p.A. Italy**So remaining Fee of Rs.10, 000/- deposited on 25-06-2018. | **w.e.f 28-7-2016 to 27-7-2021** |

| | | | | | |
|---|---|---|---|---|---|
| | | | Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy<br>Dated<br>**20-01-2007** | | |
| 2. | 019565 | Tritace 5mg Tablets<br>Each tablet contains:<br>Ramipril…..5mg | -do- | **Due date (27-07-2016)**<br>Fee of Rs.10, 000/- deposited on 09-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi-aventis S.p.A. Italy**So remaining Fee of Rs.10, 000/- deposited on 25-06-2018. | **w.e.f 28-7-2016 to 27-7-2021** |
| 3. | 045390 | Tritace 10 mg Tablets<br>Each tablet contains:<br>Ramipril…..10mg | 13-06-2007 | Due date (12-06-2017)<br>Fee of Rs.10,000/- deposited on 17-06-2016. As it is bulk import and locally repacked product from **M/s. Sanofi-aventis S.p.A. Italy**.So remaining Fee of Rs.10,000/- deposited on 25-06-2018. | **w.e.f 13-6-2017 to 12-6-2022** |
| 4. | 019567 | Amaryl 1 mg tablets<br>Each tablets contains<br>Glimepride…..1mg | **08-07-1997**<br>Change of source from M/s. Hoechst Marion Roussel Germany to M/s. Hoechst Marion Roussel Italy for bulk import and local repacking<br>Dated<br>**22-12-1997**<br>Change of company name from M/s. Hoechst Marion Roussel to M/s. Aventis Pharma (Pakistan) Limited, Karachi<br>Dated<br>**24-01-2002**<br>Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated<br>**28-07-2006**<br>Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy<br>Dated **20-01-2007** | Due date (27-07-2016)<br>Fee of Rs.10,000/- deposited on 04-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi-aventis S.p.A. Italy**.. So remaining Fee of Rs.10,000/- deposited on 25-06-2018. | **w.e.f 28-7-2016 to 27-7-2021** |

| | | | | | |
|---|---|---|---|---|---|
| 5. | 019568 | Amaryl 2 mg tablets<br>Each tablets contains<br>Glimepride…..2mg | -do- | Due date (27-07-2016)<br>Fee of Rs.10, 000/- deposited on 02-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi-aventis S.p.A. Italy**. So remaining Fee of Rs.10, 000/- deposited on 25-06-2018. | **w.e.f 28-7-2016 to 27-7-2021** |
| 6. | 021094 | Amaryl 3 mg tablets<br>Each tablets contains<br>Glimepride…..3mg | 22-05-1998<br>Change of company name from M/s. Hoechst Marion Roussel (Pakistan),Karachi to M/s. Aventis Pharma (Pakistan) Ltd., Karachi<br>Dated<br>24-01-2002<br>Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated<br>**28-07-2006**<br>Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy<br>Dated **20-01-2007** | Due date (27-07-2016)<br>Fee of Rs.10, 000/- deposited on 04-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi-aventis S.p.A. Italy**. So remaining Fee of Rs.10, 000/- deposited on 25-06-2018. | **w.e.f 28-7-2016 to 27-7-2021** |
| 7. | 021095 | Amaryl 4 mg tablets<br>Each tablets contains<br>Glimepride…..4mg | 22-05-1998<br>Change of company name from M/s. Hoechst Marion Roussel (Pakistan),Karachi to M/s. Aventis Pharma (Pakistan) Ltd., Karachi<br>Dated<br>24-01-2002<br>Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated<br>**28-07-2006**<br>Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy<br>Dated **20-01-2007** | Due date (27-07-2016)<br>Fee of Rs.10, 000/- deposited on 04-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi-aventis S.p.A. Italy**. So remaining Fee of Rs.10, 000/- deposited on 25-06-2018. | **w.e.f 28-7-2016 to 27-7-2021** |

**Decision: Registration Board deferred the above for clarification regarding the status of bulk import from the firm.**

## Item No. III Division of Biological Evaluation & Research

| Sr. No. | Details of application | No. of Cases |
|---|---|---|
| A | Imported Human Biologicals from Reference Countries/ WHO PQ | 1 |
| B | Imported Human Biologicals from non- Reference Countries | 3 |
| C | Imported Veterinary Biologicals from Reference Countries | 4 |
| D | Imported Veterinary Biologicals from Non-Reference Countries | 2 |
| E | Miscellaneous/ Deferred cases | 25 |
| F | Additional Agenda | 13 |
| **Total** | | **48** |

| Sr. No. | Assistant Director | Designated No. | No. of Cases |
|---|---|---|---|
| 1. | Mr. M. Sarfraz Nawaz | AD-II | 19 |
| 2. | Mr. M. ZubairMasood | AD-III | 29 |

## A: Imported Human-Biological from Reference Countries.

| | | |
|---|---|---|
| **1.** | Name and address of Importer | M/s Hakimsons (Impex) (Private) Ltd., Hakimsons Building, 19 West Wharf Road, Karachi |
| | Detail of DSL | Copy of DSL No. 0481 valid till 15-09-2019 |
| | Name and address of Manufacturer | Product License Holder & Manufacturer:<br>M/s CSL Behring GmbH Emil-von-Behring-Strabe 76 35041 Marburg Germany |
| | Brand Name +Dosage Form + Strength | Beriate® 250<br>Powder and solvent for solution for injection or infusion |
| | Diary No. Date of R& I & fee | Dy. No. 33702/2018(R&I) Date: 11-10-2018.<br>Rs. 100,000/- dated 09-10-2018 |
| | Composition | The package contains:<br>1 vacuum vial with 90-134mg of dried substance containing a human plasma fraction enriched in blood coagulation factor VIII and having a factor VIII activity (F VIII:C) of 250 I.U., total protein: 0.5-2.5mg |
| | Pharmacological Group | Blood Factor VIII |
| | Type of Form | Form-5F |
| | Finished Product Specification | Ph. Eur. Spec's |
| | Shelf Life | 36Months at 2-8$^0$C |
| | Document Details | Valid legalized CoPP No. BaCR40 |
| | Pack size & Demanded Price | Pack with 250IU contain:<br>1 vial with powder<br>1 vial with 2.5ml water for injection<br>1filter transfer device 20/20<br>1 disposable 5ml syringe<br>1 venipuncture set<br>2 alcohol swabs<br>1 non-sterile plaster.<br><br>1's=RS. 12930 |
| | International Availability | Germany |
| | Products already registered in Pakistan | ANTI HEMOPHILIC FACTOR VIII (HUMAN) by M/S Opulent International, Karachi |
| | Remarks of the evaluator | |
| **Decision:** | **Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of Germany (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.** | |

## B: Imported Human Biologicals from Non-Reference Countries.

| | | |
|---|---|---|
| **1.** | Name of Importer | M/s CCL Pharmaceuticals (Pvt.) Ltd. 65 Industrial Estates, KotLakhpat, Lahore, Pakistan. |
| | DSL Detail | DLS No. 0011000 0002336 valid upto 06-10-2020 |
| | Name of Manufacturer | M/s AryoGen Pharmed., address No: 140, corner of Tajbakhsh street, 24$^{th}$ Km Tehran- Karaj Makhsous road, Alborz, Iran |
| | Brand Name +Dosage Form + Strength | AryoTrust(Trastuzumab) 150mg<br>White to pale yellow powder for concentrate for solution for IV infusion |
| | Composition | Each vial contains:<br>Trastuzumab…….150mg |
| | Finished product specifications | As per Innovator |
| | Pharmacological Group | Monoclonal antibody |
| | Shelf life | 2 years at 2-8$^0$C |
| | International availability | Iran |
| | Products already registered in Pakistan | HERTRAZ$^{TM}$ 150 by M/s AGP Limited<br>Karachi |
| | Type of Form | Form 5-A, |

| | | |
|---|---|---|
| | Dy No & Date of application,<br>Fee submitted | Dy. No. 34035(R&I) Date: 15-10-2018<br>Rs. 50,000/- Date: 15-10-2018 |
| | Demanded Price / Pack size | As per brand leader<br>1's vial |
| | General documentation | CoPP, Certificate No. 665/37430<br>Dated 21/07/2018 |
| | Remarks of Evaluator | |
| **2.** | **Name of Importer** | M/s CCL Pharmaceuticals (Pvt.) Ltd.<br>65 Industrial Estate, KotLakhpat, Lahore, Pakistan. |
| | Name of Manufacturer | M/s AryoGen Pharmed., address No: 140, corner of Tajbakhsh street, 24th Km Tehran- Karaj Makhsous road, Alborz, Iran |
| | Brand Name +Dosage Form + Strength | AryoTrust(Trastuzumab) 440mg<br>White to pale yellow powder and solvent for concentrate for solution for IV infusion |
| | Composition | Each vial contains:<br>Trastuzumab…….440mg<br>+<br>Bacteriostatic water for injection….20ml |
| | Finished product specifications | As per Innovator |
| | Pharmacological Group | Monoclonal antibody |
| | Shelf life | 2 years at 2-8$^0$C |
| | International availability | Iran |
| | Products already registered in Pakistan | HERTRAZTM 440<br>Trastuzumab for injection (r-DNA origin) 440mg/vial<br>(Multiple use vial) Combo pack by M/s AGP Limited<br>Karachi |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form 5-A,<br>Dy. No. 34034(R&I) Date: 15-10-2018<br>Rs. 50,000/- Date: 15-10-2018 |
| | Demanded Price / Pack size | As per brand leader<br>(1'sPowder vial + 1's 20ml BWFI vial) Combo pack |
| | General documentation | CoPP, Certificate No. 665/37442<br>Dated 21/07/2018 |
| | Remarks of Evaluator | |

The firm has submitted the bio-similarity data as per following detail:

| **WHO Biosimilarity guidelines** | **Data Submitted by the firm** |
|---|---|
| **Quality Comparison**<br>Physicochemical characterization | Comparative Structure elucidation<br>i. Molecular Size<br>ii. Peptide mapping for primary structure<br>iii. Glycan profile by HPLC<br>iv. Amino acid sequence<br>v. Anti- proliferation Assay (Potency) of AryoTrust and Herceptin.<br>vi. Charge variant by IEx-HPLC Method.<br>vii. Concentration by UV/Vis spectrophotometry.<br>viii. Purity by SDS-PAGE. |
| Biological Activity | Biological activity by parallel line assay |
| Immunochemical properties | i. Complement-Dependent Cytotoxicity (CDC) Assays (Biological Activity) of Herceptin® and AryoTrust drug Product.<br>ii. Antibody-Dependent Cell Cytotoxicity (ADCC) Assay (Biological Activity) of AryoTrust and Herceptin® Drug Product.<br>iii. Binding assay of AryoTrust drug product to the C1q complex using ELISA method.<br>iv. Binding assay of AryoTrust and Herceptin® drug product to the HER-2 using |

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| | v. ELISA method Stud.<br>vi. Affinity Assay of AryoTrust and Herceptin® to Fcγ. |
| Impurities | i. Determination of Host cell DNA by Real time PCR<br>ii. Determination of Host cell protein by ELISA method<br>iii. Determination of aggregated form by SE HPLC |
| Stability Studies | |
| **Non-clinical Studies**<br>In-vivo Studies | In-vitro studies<br>i. Primary Pharmacodynamics<br>ii. Relative potency incomparison to Herceptin® reference standard was assessed; as a result, BT-474 cell line was chosen to provide optimum HER2 receptor expression.<br>In-vivo studies<br>If the quality biosimilar comparability exercise and the nonclinical in vitro studies are considered satisfactory and no issues are identified which would block direct entrance into humans, an in vivo animal study may not be considered necessary (Guidelines on evaluation of monoclonal antibodies as similar biotherapeutic products (SBPs EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION Geneva, 17 to 21 October 2016) |
| **Clinical Studies** | A Phase III, randomized, two-armed, patient-outcome assessor-data analyzer blinded, parallel activecontrolled, non-inferiority clinical trial study of AryoTrust (AryoGentrastuzumab) efficacy and safety in Human Epidermal Growth Factor Receptor 2–Positive breast cancer in comparison to Herceptin® (Genentech/Roche) control (n=108, 54 pt. in each group). |

**Decision: Keeping in view the biosimilarity data and valid legalized CoPPs provided by the firm indicating the products are available in country of origin; Registration Board approved the products subject to compliance of current Import policy for finished drugs.**

| **3.** | **Name of Importer** | M/s Sindh Medical Store,<br>Sector 13B/B-10, Block 6, PECHS, Karachi |
|---|---|---|
| | DSL details | DSL No. DHSKDK(Drug)/247 dated 07-02-2019 valid till 01-07-2020 |
| | Name of Manufacturer | M/s Serum Institute of India Pvt. Ltd.,<br>212/2, Hadapsar, Pune 411028 Maharashtra State, India. |
| | Brand Name +Dosage Form + Strength | Rabishield-100 (Injectable, Solution for Injection)<br>Rabies Human Monoclonal Antibody (rDNA) 100IU/2.5mL |
| | Composition | Each ml contains:<br>Rabies Human Monoclonal Antibody……..40IU |
| | Finished product specifications | Innovator Specs |
| | Pharmacological Group | Rabies Immunoglobulin |
| | Shelf life | 36 months ($2^0$C-$8^0$C) |
| | International Availability of this product | Uzbekistan, Tajikistan |
| | Similar Product already registered in Pakistan | Not Registered. |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A<br>Dy. No. 31433(R&I) dated 18-09-2018<br>Rs. 50000/-<br>18-09-2018 |
| | Demanded Price/ Pack size | 1's Vial (2.5mL)/ Price not provided. |
| | General documentation | Valid legalized CoPP No. COPP/CERT/PD/70919/2018/11/23240/ 120168 dated 10-04-2018 valid till 09-11-2018. |
| | Remarks of Evaluator | • The submitted CoPP was valid at the time of submission till 09-11-2018 and is expired now. The firm has submitted copy of valid CoPP and submitted that they will submit legalized updated document within two weeks.<br>• The firm has submitted WHO position paper April, 2018 which states that: *"A single monoclonal antibody (mAb) product against rabies, which was licensed in India in 2017, has been demonstrated to be safe and effective in clinical trials. This mAb neutralizes a broad panel of globally prevalent RABV isolates. The comparative advantages of mAb products include large-* |

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| | | *scale production with standardized quality, greater effectiveness than RIG, elimination of the use of animals in the production process, and reduction in the risk of adverse events."*<br>• WHO in its technical report series 1012 stated that:<br>*"RIGs are in short supply throughout the world. New technology may lead to use of mAbs in Post Exposure Prophylaxis. WHO has recommended use of mAb "cocktails" containing at least two antibodies against RABV, as alternatives for RIGs in PEP. Several human mAbs have been tested against rabies. The first (a single mAb) was recently licensed by the Serum Institute of India. Studies so far show the equivalence of its performance to human RIG. The availability of this mAb could fill critical public health gaps. As it is made by recombinant technology, it will be less prone to problems such as availability, safety and purity. It should be recommended for use in public health programmes, depending on the epidemiological and geographical setting, with monitoring of its safety and efficacy (clinical outcomes) during post-marketing use."*<br>• Real time stability data provided is of 18 months for commercial batches while 36 months data is provided for experimental batches.<br>• Rabies immunoglobulin is required in category III contact with suspected rabid animal.<br>• In three reference countries i.e., France, USA, and UK only human blood derived RIG is available. The said formulation is not marketed in reference regulatory authorities (Dog bite Rabies is a third world disease, most of the Reference countries are either dog bite rabies free or immunize the susceptible animal population for rabies control).<br>• Rabies is a fatal disease, in severe bite cases (Type III) RIG has to be given immediately and equine RIG is in short supply throughout the world and NIH Islamabad is also not producing eRIG. Hence mbRIG is a national need. |
| | **Decision: Registration Board deliberated that as product is not approved by any reference regulatory authorities, thus the Board deferred the case for seeking expert opinion regarding the need of Rabies Human Monoclonal Antibody and evaluation of safety and efficacy data submitted by the firm by following experts:**<br>**1. Brig. Ijaz Ghani, Head of Virology, AFIP.**<br>**2. Dr. Naseem Salahuddin, Indus Hospital Karachi.**<br>**3. Brig. Gohar Zaman, Head of Microbiology, AFIP.** | |

## C: Imported Veterinary Biologicals from reference countries.

| | | |
|---|---|---|
| 1. | **Name of Importer** | M/s Vety Care (Pvt.) Ltd.<br>Plot No. 77, Street No.6, I-10/3 Islamabad. |
| | DSL details | DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018.<br>Copy of Renewal receipt dated 26-12-2018 |
| | Name of Manufacturer | M/s Intervet International B.V.<br>Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands. |
| | Brand Name +Dosage Form + Strength | Nobivac Tricat Trio<br>Lyophilisate and solvent for suspension for injection |
| | Composition | <u>After Freeze-drying</u><br>Each dose contains:<br>Live FCV strain F9……at least 4.6 $\log_{10}$ PFU<br>Live FVR strain G2620A……at least 5.2 $\log_{10}$ PFU<br>Live FPLV strain MW-1……at least 4.3 $\log_{10}$ $TCID_{50}$<br><u>Nobivac Solvent:</u><br>Each ml contains:<br>Disodium phosphate dihydrate.....0.31mg<br>Potassium dihydrogen Phosphate ….0.21mg<br>Water for injections to 999.16 mg |
| | Finished product specifications | Innovator Specs |
| | Pharmacological Group | Veterinary Vaccine |
| | Shelf life | 33 months (2-8$^0$C) |
| | International availability | Not Provided. |
| | Products already registered in Pakistan | Not Available as per record. |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A<br>Dy. No. 11336(R&I) Dated 28-03-2018<br>Rs. 100000/-<br>28-03-2018 |
| | Demanded Price / Pack size | 1's Vial Powder<br>1's Vial Solvent |
| | General documentation | Valid legalized CoPP No. 249028 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands. |
| | Remarks of Evaluator | • The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration.<br>• Real time stability data provided is of 0,9,15,21,27,36 months instead of appropriate time intervals and **only titer and residual moisture** is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies:<br>Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate. |

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

**a. Approval status of above product registration by reference regulatory authorities.**

**b. Complete stability data indicating all the parameters tested in COA.**

| | | |
|---|---|---|
| 2. | Name of Importer | M/s Vety Care (Pvt.) Ltd.<br>Plot No. 77, Street No.6, I-10/3 Islamabad. |
| | DSL details | DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018.<br>Copy of Renewal receipt dated 26-12-2018 |
| | Name of Manufacturer | M/s Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands |
| | Brand Name +Dosage Form + Strength | Innovax ND-IBD |
| | Composition | Each dose(ml) contains:<br>Live Herpesvirus of turkey strain HPV 360*….at least $10^{3.3}$PFU**<br>* HPV 360 is a HVT-based recombinant encoding the NDV F protein and the IBDV VP2 protein.<br>**Plaque Forming Units |
| | Finished product specifications | Innovator Specs |
| | Pharmacological Group | Veterinary Vaccine |
| | Shelf life | 36 months<br>(Liquid Nitrogen) |
| | International availability | Not Provided. |
| | Products already registered in Pakistan | Not Available as per record. |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A<br>Dy. No. 11337(R&I) Dated 28-03-2018<br>Rs. 100000/-<br>28-03-2018 |
| | Demanded Price / Pack size | 1's Vial (2000 doses) |
| | General documentation | Valid legalized CoPP No. 249030 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands. |
| | Remarks of evaluator | • The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration.<br>• Real time stability data provided is of 0, 6, 12, 18, 24, 30, 36, 39 months instead of appropriate time intervals and only **titer** is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies:<br>Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate. |
| **Decision:** | **Registration Board deferred the case for submission of following by the firm:**<br>**a. Approval status of above product registration by reference regulatory authorities.**<br>**b. Complete stability data indicating all the parameters tested in COA.** | |
| 3. | Name of Importer | M/s Vety Care (Pvt.) Ltd.<br>Plot No. 77, Street No.6, I-10/3 Islamabad. |
| | DSL details | DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018.<br>Copy of Renewal receipt dated 26-12-2018 |
| | Name of Manufacturer | M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands |

| | | |
|---|---|---|
| | Brand Name+ Strength | Nobilis MS Live |
| | Composition | Before Freeze-drying<br>Each dose(ml) contains:<br>Live attenuated *Mycoplasma synoviae strain* MS1……0.67ml<br>After Freeze-drying<br>Each dose contains:<br>Live attenuated *Mycoplasma synoviae strain* MS1….≥$10^{6.5}$ CFU* and ≤$10^{8.0}$ CFU<br>*Colony Forming Units |
| | Finished product specifications | Innovator Specs |
| | Pharmacological Group | Veterinary Vaccine |
| | Shelf life | 24 months<br>($2^0$C-$8^0$C) |
| | International availability | Not Provided. |
| | Products already registered in Pakistan | Not Available as per record. |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A<br>Dy. No. 7302(R&I) Dated 26-02-2018<br>Rs. 100000/-<br>26-02-2018 |
| | Demanded Price / Pack size | 1's Vial (1000 doses) |
| | General documentation | Valid legalized CoPP No. 245782 dated 09-08-2016 issued by Ministry of Economic Affairs, The Netherlands. |
| | Remarks of Evaluator | • The firm then submitted another CoPP vide no. 249031 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands indicating that the product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration.<br>• Real time stability data provided is of 0, 6,9, 12,15, 21,24, 27 months instead of appropriate time intervals and **only titer and residual humidity** are tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies:<br>Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate. |
| **Decision:** | **Registration Board deferred the case for submission of following by the firm:**<br>**a. Approval status of above product registration by reference regulatory authorities.**<br>**b. Complete stability data indicating all the parameters tested in COA.** | |
| 4. | Name of Importer | M/s Vety Care (Pvt.) Ltd.<br>Plot No. 77, Street No.6, I-10/3 Islamabad. |
| | DSL details | DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018.<br>Copy of Renewal receipt dated 26-12-2018 |
| | Name of Manufacturer | M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands |
| | Brand Name +Dosage Form + Strength | Nobilis IB Primo QX<br>Lyophilisate for suspension for spray |
| | Composition | Each dose of reconstituted vaccine contains:<br>Live attenuated avian infectious bronchitis virus, strain D388…$10^{4.0}$-$10^{5.5}$ $EID_{50}$*<br>*50% egg infective dose |

| | | |
|---|---|---|
| | Finished product specifications | Innovator Specs |
| | Pharmacological Group | Veterinary Vaccine |
| | Shelf life | 15 months<br>($2^0$C-$8^0$C) |
| | International availability | Not Provided. |
| | Products already registered in Pakistan | Not Available as per record. |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A<br>Dy. No. 5721(R&I) Dated 16-02-2018<br>Rs. 100000/-<br>16-02-2018 |
| | Demanded Price / Pack size | 10Cupsx 10000 doses |
| | General documentation | Valid legalized CoPP No. 01/17/113770 dated 13-10-2017 issued by EMA indicating product availability in exporting region. |
| | Remarks of Evaluator | • Real time stability data provided is of 0, 6, 11, 18 months instead of appropriate time intervals and only **titer and residual humidity** are tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies:<br>Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate. |
| **Decision: Registration Board deferred the case for submission of complete stability data indicating all the parameters tested in COA.** | | |
| **5.** | **Name and address of Importer** | M/s Mustafa Brothers P-186-D, People Colony No. 1, Faisalabad |
| | **DSL Details** | License No. CEO (H) 272/-FTC/DL valid upto 12-02-2019 |
| | Name and address of Manufacturer | M/s CZ Veterinaria, S.A. La Relva s/n- Torneiros 36410 Porrino (Spain) |
| | Brand Name +Dosage Form + Composition | **RB-51 CZV**<br>**Powder and solvent for suspension for injection**<br><br>Each dose contains:<br>*B. abortus*, strain RB51 (rough phase) … 10-34x$10^9$cfu<br>phosphate saline buffer |
| | Diary No. Date of R& I & fee | 12948/2017(R&I) dated 22-08-2017.<br>Rs. 200,000/- dated 22-08-2017. |
| | Pharmacological Group | Bacterial vaccine for cattle |
| | Type of Form | Form 5-A |
| | Finished Product Specification | Innovator's specification |
| | Shelf Life | 1 Year for vaccine & 1 year for solvent (2-$8^0$C) |
| | Document Details | Valid Legalized FSC dated 17-03-2017<br><br>GMP online verification dated 07-02-2019<br>Certificate number NCF-1/18-GAL<br>http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do<br>inspection end date 2018-02-21 |
| | Pack size & Demanded Price | 10x5 Doses of RB-51 CZV vaccine & 10x10ml Solvent<br>Decontrolled |

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| | International Availability | Spain |
| | Products already registered in Pakistan | BovishotBrucel Vaccine By M/S Tarobina Corporation, Lahore |
| | Remarks of evaluator | Provided GMP is expire firm provided the link of official website of EUDRA from where the latest GMP status of the firm was verified.<br>Certificate number NCF-1/18-GAL<br>http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do<br>inspection end date 2018-02-21.<br>Accessed on dated 07-02-2019 |
| **Decision: Keeping in view the valid GMP available on official website and valid legalized FSC; Registration Board approved the product subject to compliance of current Import Policy for Finished Drugs.** | | |

**D. Imported Veterinary Biologicals from Non-Reference countries.**

| | | |
|---|---|---|
| **1.** | **Name of Importer** | M/s Vet Line International,<br>55/S, 1st Floor Main Shadman Market, Lahore. |
| | DSL details | No. 60-A/DGBT/11/2015 dated 12-02-2015 valid till 11-02-2019 |
| | Name of Manufacturer | **Product License Holder:**<br>M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd.,<br>1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arched'Oe 2,37390, Notre Dame D' Oe, France.<br>**Contract Manufacturer:**<br>M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary. |
| | Brand Name +Dosage Form + Strength | Sterile Diluent of Avipox Vaccine |
| | Composition | Each vial of 10ml contains:<br>Glycerol…….1.5ml<br>Water, highly purified……..ad10ml |
| | Finished product specifications | As per Innovator. |
| | Pharmacological Group | Diluent for veterinary vaccine |
| | Shelf life | 60 months<br>($2^0$C-$8^0$C) |
| | International availability | Egypt, Bangladesh |
| | Products already registered in Pakistan | Sterile Diluent to be used with already registered vaccine AviPox (Reg. No. 085010) |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A<br>Dy. No.033700(R&I) dated 11-10-2018<br>Rs. 100000/-<br>11-10-2018 |
| | Demanded Price / Pack size | 20 Vials x 10ml |
| | General documentation | i. Valid Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary.<br>ii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 for Avipox Vaccine issued by Directorate of Veterinary Medicinal Products, Hungary.<br>iii. Valid Legalized FSC No. 02.2/3917-2/2018 dated 13-07-2018 issued by Directorate of Veterinary Medicinal Products, Hungary. |
| | Remarks of Evaluator | In real time stability studies, tests are performed at the end of shelf life i.e. **60 months only** instead of regular intervals. |
| **Decision: Registration Board deferred the case for submission of clarification regarding not importing diluent in combo pack by the firm.** | | |

**Case No. IV: Miscellaneous/ Deferred Cases**

**1. Registration of veterinary vaccines from one importer to another importer applied by M/s Hipra Pakistan Limited, Lahore**

M/s Hipra Pakistan Limited, Lahore applied for the registration of already approved veterinary vaccines in their name from M/s Marush Private Limited, Lahore as per following details:

| Reg. No. | Brand Name & composition as per CoPP | Brand Name & composition as per Initial Reg. letter | Initial Registration Date | Date of Last Renewal Submission |
|---|---|---|---|---|
| 081814 | EVALON<br>Suspension and solvent for oral spray<br>Each dose (0.007ml) of undiluted vaccine contains:<br>Eimeriaacervulina, strain 003.. 332-450 sporulated oocytes<br>Eimeria maxima, strain 013 196-265 sporulated oocytes<br>Eimerianecatrix, strain 033, 340-460 sporulated oocytes<br>Eimeriabrunetti, strain 034, 213-288 sporulated oocytes<br>Eimeriatenella, strain 004, 276-374 sporulated oocytes<br><br>Composition of the Solvent<br>-Brilliant blue (E 133)<br>-Red AC (E129)<br>-Vanillin<br>-Montanide IMS<br>One vial (suspension) + 1 vial (solvent) | EVALON<br>Oral solution<br><br>Each dose contains:<br>Eimeriaacervulina, strain 003.. 332-450 sporulated oocytes<br>Eimeria maxima, strain 013……. 196-265 sporulated oocytes<br>Eimerianecatrix, strain 033….340-460 sporulated oocytes<br>Eimeriabrunetti, strain 034… .213-288 sporulated oocytes<br>Eimeriatenella, strain 004…….276-374 sporulated oocytes | 03-11-2016 | 02-11-2021 |

The firm has submitted the following documents:

1. Application on Form-5A
2. Fee Challan of Rs. 100000/- for each product.
3. Copy of Initial registration letter and last renewal submission.
4. Termination letter in name of M/s Marush Private Limited, Lahore.
5. Sole Agency Letter in name of M/s Hipra Pakistan Limited, Lahore.

**Decision of 286th meeting of RB:**

"Registration Board deferred the case for submission of valid legalized CoPP by the firm"
Now the firm has submitted the valid legalized CoPP issue by EMA (No. of Certificate 02/16/99203 dated 01-06-2016).

**Decision:** **Keeping in view valid legalized CoPP and approval of EMA (Reference Regulatory Authority); Registration Board cancelled the registration of above product from the name of M/s Marush Private Limited, Lahore and granted the registration in name of M/s Hipra Pakistan Limited, Lahore subject to compliance of current Import policy for finished drugs and storage facility verification of M/s Hipra Pakistan Limited, Lahore.**

## 2. Imported Human Biologicals from non-reference countries.

| | |
|---|---|
| **Name and address of Importer** | **M/s 3A Diagnostics**<br>12-F-1, MehmoodChowk, Main Johar Town, Lahore |
| Details of DSL | Copy of DSL No. 25-A/AiT/11/2014 Valid upto 11-08-2018 |
| Name and address of Manufacturer | M/s Ningbo Rongan Biological pharmaceutical Co., Ltd.<br>No.21, ChuangyeAveneu, Free Trade West Zone, Ningbo, P.R.C. |
| Brand Name +Dosage Form + Strength | **Olvaxtar-RAB** |
| Diary No. Date of R& I & fee | 14665/2018(R&I) dated 18-04-2018.<br>PKR. 100,030/- dated 16-04-2018. |
| Composition | Each dose contains:<br>Rabies Virus Antigen..... .....≥2.5IU |
| Pharmacological Group | Rabies Vaccine |
| Type of Form | Form 5-A |
| Finished Product Specification | The firm has demanded BP specs |
| Shelf Life | 36 Months 2-8$^0$C |
| Document Details | 1. Valid Legalized CoPP issued by the Market Supervision and Administration of Ningbo on 19-09-2017.<br>2. Legalized invalid GMP Certificate issued byChina Food and Drug Administration No.CN20130188 dated 18-07-2013. Expired o 18-07-2018.<br>3. Original Marketing Authorization dated 03-05-2017.<br>4. Legalized Free Sale Certificate issued by Market Supervision and Administration of Ningbo on 03-05-2017. |
| Pack size & Demanded Price | 1's vial<br>1's x 5 vials<br>/950 PKR per vial |
| International Availability | China |
| Products already registered in Pakistan | Verorab of M/s Sanofi-Aventis, Pakistan |
| Remarks of the evaluator | 1. CoPP and free sale are issued by Market Supervision and Administration of Ningbo for which the firm has submitted clarification that the Market Supervision and Administration of Ningbo is the Municipal FDA works under Chinese FDA. CFDA will not directly certify CoPP, and the certificate will be issued by municipal FDA of each city. The market supervision and administration of Ningbo is Incharge of the certifying of CoPP in Ningbo, Zhejiang province China. |
| **Decision of 284th meeting of RB:**<br>Registration Board deferred the product for clarification by the firm on CoPP and free sale are issued by Market Supervision and Administration of Ningbo instead of state FDA. | |

Now the firm has submitted following reply:

We, Ningbo Rongan Bio-pharmaceutical Co., Ltd hereby declare that The Market Supervision and Administration of Ningbo is established as the municipal government department mainly responsible for industry and commerce administration and food and drug administration, hanging the board and playing the roles of Ningbo Administration for Industry and Commerce, Ningbo Food and Drug Administration and Office of Food Safety Commission of Ningbo and related official document is attached below.

Official Paper of Ningbo Municipal People's Government Office

**Ningbo Municipal People's Government Office**

Notices on Issuing the Regulations for Main Duties, Internal Bodies and Staffing of Market Supervision and Administration of Ningbo

Notices on Issuing the Regulations for main duties, Internal Bodies and Staffing of Market Supervision and Administration of Ningbo was reviewed by Committee for establishing

Municipal Government Organization, and already approved by municipal government and allowed for issuing now. Dated 06th May 2014

According to Implementation Opinions of the Ningbo Municipal People's Government on Reforming and Improving the Food and Drug Supervision System in Ningbo ((2014)No.1 Issued by Ningbo Government), establish The Market Supervision and Administration of Ningbo. It's the municipal government department mainly responsible for industry and commerce administration and food and drug administration, hanging the board and playing the roles of Ningbo Administration for Industry and Commerce, Ningbo Food Drug Administration and Office of Food Safety Commission of Ningbo.

**1.** Duty Adjustment

(1) Included duties

1. Integrate the duties of previous municipal Administration for Industry and Commerce and municipal Food Drug Administration, incorporate them into municipal Market Supervision and Administration.

2. Incorporate the duties of municipal office of Food Safety Commission in municipal Market Supervision and Administration, including comprehensive coordination of food safety, organizing to investigate serious incidents of food safety, examination and inspection of food safety.

3. Incorporate the duties of municipal Bureau of Quality and Technical Supervision in municipal Market Supervision, including food drug safety supervision in manufacturing process, administrative licensing and onsite inspection as well as compulsory test for cosmetics manufacturing.

**2.** Main duties

(1) Carry out laws, regulations, provisions and policies in industry & commerce administration and food and drug administration; draft relevant local rules and regulations.

(2) Responsible for the registration of market entities such as various enterprises, cooperatives, units and individuals engaged in business activities, and resident representative offices of foreign (regional) enterprises, and administrative licensing for food, drug, medical equipment, health care food, cosmetics, etc.

**Decision:** **Keeping in view the shortage of Rabies vaccine in Pakistan and valid legalized CoPP indicating product availability in country of origin; Registration Board approved the above product subject to compliance of current Import policy for finished drugs. Registration Board advised DBER to send an email to China FDA regarding verification of authorization of Market Supervision and Administration of Ningbo for issuance of CoPPs. The same will be verified during inspection of manufacturer abroad. Registration Board has authorized its Chairman for issuance of registration letter after said confirmation.**

## 3. Product applied by M/s Immunonet Pharma (Pvt.) Ltd Lahore deferred in 286th meeting of Registration Board.

Following human Biological applied by M/s Immunonet Pharma (Pvt.) Ltd Lahore deferred in 285th meeting of Registration Board as per following details:

| | |
|---|---|
| Name of Importer | M/s Immunonet Pharma (Pvt.) Ltd.,<br>12-F-1, Mahmood Chowk, Johar Town, Lahore, Pakistan |
| DSL details | License No: 05-352-0066-034495D valid upto 05-July-2020 |
| Name of Manufacturer | M/s Xi'an Huitian Blood Products Co., Ltd<br>Add: No.2369 the 2ndBaiiu Road, Modern Textile industrial Park, China |
| Brand Name +Dosage Form + Strength | Human Immunoglobulin (pH4) for Intravenous Injection |

| | |
|---|---|
| Composition | Each mL contains:<br>Human immunoglobulin-G (active ingredient) ….50mg<br>Maltose (Stabilizer) ……..….90-110mg |
| Finished product specifications | B.P Specs |
| Pharmacological Group | Plasma derivative product |
| Shelf life | 36 months at 2-8$^0$C |
| Approval status in Reference countries | Flebogamma DIF 50 mg/ml solution for infusion |
| International availability | China |
| Products already registered in Pakistan | Human Immunoglobulin (PH4) For Intravenous Injection. of M/s 3a Diagnostics, Lahore |
| Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form 5-A,<br>Dy. No. 14466(R&I) Date: 18-04-2018<br>Rs. 100,000/- Date: 12-04-2018 |
| Demanded Price / Pack size | Rs. 38000Pkr. / 50ml vial |
| General documentation | Valid legalized GMP Certificate No. CN20160017 valid until 22/02/2021<br>Valid legalized FSC Certificate No. 2017-S001 Issuing date 05-07-2017 valid for two years. |
| Remarks of Evaluator | Accelerated Stability data of applied product is not submitted by the firm. Firm submitted a document in which they highlighted the Heat stability test which shows that "No gelation at 57$^0$C for 4 hours. |
| **Decision of 285th meeting of Registration Board:**<br>*"Registration Board deferred the case for submission of data of accelerated stability studies for three (03) batches"*<br>Now the firm has submitted the accelerated stability data.<br><br>**Decision of 286th meeting of RB:**<br>*"Registration Board deferred the application and advised DBER to summarize the data in next board meeting."* | |

Under the heading of stability data following test performed by the firm:

**Parameters:**

i. Physical appearance
ii. P$^H$
iii. IgG content
iv. Purity
v. IgG components
vi. Diphtheria antibody titer
vii. Anti-HBs
viii. ACA (%) Anti-complement activity
ix. PKA (pre-kallikrein activator)
x. Sterility

**Decision: Keeping in view valid legalized GMP and FSC indicating product availability in country of origin; Registration Board approved the above product subject to compliance of current Import policy for finished drugs.**

## 4. Imported Veterinary Biologicals from non-reference countries.

| | |
|---|---|
| **Name of Importer** | M/s Hivet Animal Health Business, Lahore |
| DSL details | License to sell drug as Distributor renewed upto: 09-02-2019 |
| Name of Manufacturer | M/s Beijing sinder-vet technology co., ltd. Address: No. 118, shunyu road, Beijing Tianzhu airport economic development zone, shunyi district Beijing |
| Brand Name +Dosage Form + Strength | SINVAC ND+H9<br>Emulsion |
| Composition | Each dose contains:<br>Newcastle disease antigen inactivated (La Sota strain) (before inactivated virus content $\geq 10^{8.0}EID_{50}$/0.1ml)<br>Avian influenza antigen inactivated (H9 subtype, SS strain) (before inactivated virus content $\geq 10^{7.4}EID_{50}$/0.2ml) |
| Finished product specifications | As per innovator specification. |
| Pharmacological Group | Poultry vaccine |
| Shelf life | 18 months at 2-8$^0$C |
| International availability | China |
| Products already registered in Pakistan | ME FLUVAC H9+ND of M/s Bromed animal health, Lahore |
| Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form 5-A,<br>Dy. No. 21702(R&I) Date: 21-06-2018<br>Rs. 100,000/- Date: 21-06-2018 |
| Demanded Price / Pack size | Decontrolled/ 500ml/Bottle |
| General documentation | Valid legalized GMP valid 04/01/2016-3/1/2021<br>Original Valid legalized FSC dated 12-09-2018 |
| **Remarks of Evaluator** | Firm submit accelerated Stability data of applied product at room temperature for 2 days and for 6 months at 10$^0$C. |

**Decision of 286th meeting of RB:**

"Registration Board deferred the application for clarification on submission of 2 days accelerated stability studies"

Firm requested for exemption of accelerated stability data as per decision of 286th meeting of Registration Board.

**Remarks of evaluator:**

Registration Board in its 286th meeting adopted the European framework for stability testing of vaccines for veterinary use developed in the light of European Pharmacopoeia 9.5 (General Monograph (0062) and European Directive 2001/82/EC (II-Title) for all veterinary vaccines which states that the stability should be evaluated under the recommended storage conditions. As the storage conditions of vaccines is 2-8$^0$C (unless otherwise stated), the European Pharmacopoeia requires to perform the stability studies only at 2-8$^0$C. Moreover, the European Directive 2001/82/EC (II-Title) does not require performing accelerated stability studies for vaccines.

**Decision:** **Registration Board exempted the accelerated stability studies of above product as per European Guidelines on Stability Studies of Veterinary vaccines adopted in 286th meeting of Registration Board for all veterinary vaccines and approved the product subject to compliance of current Import policy for finished drugs keeping in view the valid legalized GMP and FSC indicating product availability in country of origin.**

**5. Request for issuance of registration letter on new company name/title.**

Following products of M/s. Merck, specialties (private) limited Karachi have been approved in 240th meeting of Registration Board. Registration letters were not issued due to change in importer name which is now approved in 279th meeting of Registration Board from M/s Merck Specialties (Private) Limited to M/s Martin Dow Marker Specialties (Private) Limited.
Now firm requested to issue the registration letter with new approved importer name. The details of approved products are as under:

| Sr. # | Importer/ Manufacturer | Brand Name & Composition | Decision of RB |
|---|---|---|---|
| 1. | M/s Martin Dow Marker Specialties (Private) Limited. Karachi<br><br>M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. FrazioneZona Industriale), Italy. | Gonal-***f*** Pen 300 IU (22 ug)/0.5ml<br>Solution for Injection in a pre-filled pen<br>Each 0.5ml contains: -<br>One cartridge delivers 300IU Follitropin Alpha, equivalent to 22 Micrograms.<br>(Gonadotropins) | **M-240**<br>Approved |
| 2. | | Gonal-***f*** Pen 450 IU (33 ug)/0.75ml<br>Solution for Injection in a pre-filled pen<br>Each 0.75ml contains: -<br>One cartridge delivers 450IU Follitropin Alpha, equivalent to 33 Micrograms.<br>(Gonadotropins). | |
| 3. | | Gonal-***f*** Pen 900 IU (66 ug)/1.5ml<br>Solution for Injection in a pre-filled pen<br>Each 1.5ml contains: -<br>One cartridge delivers 900IU Follitropin Alpha, equivalent to 66 Micrograms.<br>(Gonadotropins) | |
| 4. | | Ovidrel 250ug/0.5ml<br>Solution for Injection Pre-filled Syringe<br>Each pre-filled syringe contains; -<br>Choriogonadotropin alpha……250ug<br>(Gonadotropins) | |

**Decision of 279th meeting of RB regarding change in importer name:**

Registration Board approved the change in name of importer of Gonal-F 75IU Injection (Reg. No. 028418) & Erbitux 5mg/ml Injection (Reg. No. 052292) from M/s Merck Specialities (Private) Limited to M/s Martin Dow Marker Specialities (Private) Limited.

The firm has submitted following documents:

a. Application with Fee Challans of Rs. 100,000/- for each product.
b. Copy of Drug Sale License with new name valid till 27th Nov. 2019.
c. Copy of Approval of new name by SECP / registrar of firm.
d. NOC with new name of importer by Manufacturer instead of Sole Agency agreement.
e. Undertaking by the firm that no case is pending at any forum / court of law regarding previous name.
f. Undertaking that the provided information/ documents are true/ correct.

**Decision: Registration Board approved the change in name of importer of Gonal-f 300IU, Gonal-f 450IU, Gonal-f 900IU and Ovidrel 250µg/0.5ml from M/s Merck Specialities (Private) Limited to M/s Martin Dow Marker Specialities (Private) Limited.**

**6. Inclusion of Japanese Pharmacopoeia specification of Jilifen 300ug injection.**

M/s AA Pharma, Karachi applied for the inclusion of Japanese pharmacopoeia specifications in registration letters of following products;

| Reg. No. | Name of Manufacturer | Name & Composition of the Product | Date of initial Registration | Date of transfer of Registration | Date of Submission of renewal |
|---|---|---|---|---|---|
| 045618 | M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., Hangzhou, China | Jilifen 300ug/1.2ml Injection<br>Each 1.2mL contains:<br>RHG-CSF…300ug. | 16-04-2007 | 08-06-2011 | 14thJan, 2012<br>&<br>08-06-2016 |

The firm has submitted following documents;

i. Fee of Rs. 5000/-.
ii. Copy of initial Registration letter
iii. Copy of transfer of Registration
iv. Original Renewal applications.
v. Undertaking from Principal.
vi. Official Monograph of Japanese Pharmacopeia.

**Decision: Registration Board acceded to the request of the firm for inclusion of Japanese Pharmacopoeia Specifications in registration letter of Jilifen 300µg/1.2ml Injection (Reg. No. 045618).**

**7. Imported veterinary Biologicals approved in 286th meeting of Registration Board**

M/s. Hipra Pakistan (Private) Limited, Lahore request for registration of following registered imported veterinary drugs from the name of previous importer M/s. Marush (Pvt) Limited, K-123, Model Town, Lahore to their name were approved in 286th meeting of Registration Board. The details are submitted as under:-

| Sr. No. | Registration letter processed with Brand Name & composition | Approved Brand Name & composition |
|---|---|---|
| 1. | **HIPRAVIAR-B1/H120**<br>Freeze-dried tablet and solvent for suspension<br>Composition per dose (0.03ml)<br>Live Newcastle disease virus attenuated B1 strain…….$10^{6.5} – 10^{7.8}$ $EID_{50}$<br>Live Infectious Bronchitis virus, attenuated H120 strain…….$10^3 – 10^5$ $DIE_{50}$<br>*50% infective dose in chicken embryo<br>**Solvent for suspension**<br>Disodium phosphate dodecahydrate …..0.087mg<br>Potassium dihydrogen phosphate....00006mg<br>Sodium chloride……..0.24mg<br>Potassium chloride…….0.006mg<br>Patent blue (E-131)…..……0.003mg<br>Water for injection……..……0.03ml q.s.ad. | **HIPRAVIAR-B1/H120**<br>Freeze-dried tablet and solvent for suspension<br><br>Composition per dose (0.03ml)<br>Live Newcastle disease virus attenuated B1 strain<br>….$10^{6.5} – 10^{7.8}$ $EID_{50}$<br>Live Infectious Bronchitis virus, attenuated H120 strain<br>..$10^3 – 10^5$ $DIE_{50}$<br>*50% infective dose in chicken embryo |
| 2. | **HIPRABOVIS-4**<br>Lyophilisate and solvent for Injectable suspension<br><br>Composition per dose (3ml):<br>**Composition of Liquid fraction:**<br>Inactivated Infectious Bovine Rinotracheitis Virus, strain LA……..…ELISA≥50<br>Inactivated Parainfluenza-3 virus, strain SF4…….……IHA≥1/16<br>Inactivated Bovine Viral Diarrhoea Virus, strain NADL……ELISA≥50 | **HIPRABOVIS-4**<br>Lyophilisate and solvent for Injectable suspension<br><br>Composition per dose (3ml):<br>Inactivated Infectious Bovine Rinotracheitis Virus, strain LA……ELISA≥50<br>Inactivated Parainfluenza-3 virus, strain SF4…….IHA≥1/16<br>Inactivated Bovine Viral Diarrhoea Virus, strain NADL……ELISA≥50<br>Live Bovine Respiratory Syncytial Virus, strain Lym-56……..≥$10^4$TCID |

| | | |
|---|---|---|
| | **Composition of freeze-dried fraction:**<br>Live Bovine Respiratory Syncytial Virus, strain Lym-56……...≥$10^4$TCID<br>*ELISA: Antibody titre determined by ELISA in vaccinated rabbits.<br>**IHA: Antibody titre determined by hemagglutination inhibition in vaccinated rabbits.<br>***$CCID_{50}$: Cellular culture infective dose 50% | *ELISA: Antibody titre determined by ELISA in vaccinated rabbits.<br>**IHA: Antibody titre determined by hemagglutination inhibition in vaccinated rabbits.<br>***$CCID_{50}$: Cellular culture infective dose 50% |

[

Registration letter are prepared as per composition in CoPP and Form-5A (detailed of solvent incorporated from form-5A).

**Decision: Registration Board acknowledged the above information.**

**8. Imported Human biological applied by M/s Novo Nordisk Pharma (Private) Limited, Karachi approved in 253rd meeting of Registration Board.**

Following product of M/s Novo Nordisk Pharma (Private) Limited, Karachi was approved in 253rd meeting of Registration Board as per following details:

| Name of manufacturer | Brand Name & composition | Document Details | Decision of RB in 253rd meeting |
|---|---|---|---|
| M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark | RyzodegPenfill 100 unit ml Sol for Inj<br>05 Cartridge<br>Penfill contains 600 Units nmol of (420 Degludec+ 180 Aspart Insulin) | Valid legalized CoPP No. 02/15/89704 dated 15-07-2015 issued by EMA. | *Approved*. |

The price of aforementioned product has been fixed vide SRO 1608 (I)/2018 dated 31-12-2018 as per following details:

| Sr. No. | Brand Name & Composition | Pack Size | Approved M.R.P |
|---|---|---|---|
| 1. | RyzodegPenfill 100 Unit MI Sol For Inj<br>05 Cartridge Penfill Contains:<br>600 Units NMOL OF (420 Degludec + 180 Aspart Insulin) | 5x3ml | Rs. 11,392 (originator Brand) |

In this context it is submitted that the firm has submitted two CoPPs of above products one is issued by EMAwhile the other one is issued by Danish Health and Medicines Authority. The composition mentioned in the minutes of 253rd meeting is different from both CoPPs. The composition mentioned in minutes, CoPP issued by EMA and CoPP issued by Danish Authority is tabulated as under:

| Brand Name & Composition mention in minutes | Brand Name & Composition mentioned in EMA CoPP | Brand Name & Composition mentioned in Danish CoPP |
|---|---|---|
| Ryzodeg Penfill 100 unit ml Sol for Inj<br>05 Cartridge<br>Penfill contains 600 Units nmol of (420 Degludec+ 180 AspartInsulin) | Ryzodeg<br>Solution for injection<br>Each ml solution contains:<br>Insulin degludec/ Insulin Aspart in the ratio of 70/30…100 units (equivalent to 2.56 mg insulin degludec and 1.05 mg insulin aspart) | Ryzodeg 100IU/ml, 3ml Penfill<br>Composition of insulin degludec/ insulin aspart 100U/ml<br>Insulin degludec….420nmol<br>Inslinaspart……180nmol |

Moreover, the price is also fixed with composition mentioned in minutes indicating that 05 Cartridge penfill contains 600 units nmol of (420 Degludec + 180 Aspart Insulin) which is different from both CoPPs. The compositions in EMA and Danish CoPPs are similar but in

different units. The composition mentioned on Form-5A submitted with initial application is as per EMA CoPP.

**Decision: Keeping in view the position explained above and valid legalized CoPP issued by EMA (Reference Regulatory Authority); Registration Board approved the product as per following details.**

| Name of Manufacturer | Brand Name & Composition | Pack Size |
|---|---|---|
| **M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark** | **Ryzodeg<br>Solution for Injection<br>Each ml solution contains:<br>Insulin degludec/ Insulin Aspart in the ratio of 70/30…100 units (equivalent to 2.56 mg insulin degludec and 1.05 mg insulin aspart)** | **5's x 3ml** |

**9. Imported Human biological applied by M/s Novo Nordisk Pharma (Private) Limited, Karachi approved in 262nd meeting of Registration Board.**

Following product of M/s Novo Nordisk Pharma (Private) Limited, Karachi was approved in 262nd meeting of Registration Board as per following details:

| Name of Manufacturer | Brand Name & Composition | Document Details/ Pack Size | Decision of RB in 262nd meeting |
|---|---|---|---|
| Novo Nordisk A/S<br>Novo Alle DK-2880<br>Bagsvaerd<br>Denmark | Xultophy<br>One prefilled pen contains:<br>Insulin degludec….. 300Units<br>Liraglutide…….. 10.8mg<br>Shelf life: 2years | Copy of Legalized CoPP No. 06/16/98682 Dated 18-05-2016<br>3x 3ml<br>5x 3ml | Keeping in view the EMA approval, Registration Board approved the product as per Import Policy for Finished Drugs and as per valid legalized CoPP. |

The price of aforementioned product has been fixed vide SRO 1608 (I)/2018 dated 31-12-2018 as per following details:

| Brand Name & Composition | Pack Size | Approved M.R.P |
|---|---|---|
| Xultophy<br>One prefilled pen contains:<br>Insulin degludec……300 units<br>Liraglutide…….10.8mg | 3ml x 1's<br>3ml x 3's<br>3ml x 5's | Rs. 7090<br>Rs. 20,419<br>Rs. 34,032<br>(originator Brand) |

Now the firm has submitted an application for the correction in pack size as mentioned in initially submitted Form-5A. The firm submitted that the above product was approved by the honorable Registration Board in its 262nd meeting as 3ml x 5's and 3ml x 3s and due to mistake 1' pack was missing. They have submitted updated Form-5A along with this application for the correction of 3ml x 1's in the initial application. The firm has submitted the following documents:

a. Revised Form-5A
b. Fee Challan of Rs. 5000/-
c. Copy of above mentioned CoPP

In this context, it is submitted that initially the firm has submitted pack sizes of **3ml x 5's** and **3ml x 3's** which were accordingly approved by Registration Board in its 262nd meeting. The Federal Government vide SRO 1608(I)/2018 dated 31-12-2018 notified the price of **3ml x 1's** pack in along with already approved pack sizes. Now, the firm have requested for the inclusion of 1's pack in the initial application as at the time of initial submission they could not mention the details of 1's pack of Xultophy in Form-5A. The firm further requested to consider their case as an inclusion in the initial application not as an additional pack and to correct the pack sizes as mentioned in 262nd meeting and include 3ml x 1's pack in minutes.

**Decision: Registration Board acceded to the request of the firm and approved the pack size of 1's x 3ml of Xultophy in addition to already approved pack sizes of 3's x 3ml and 5's x 3ml as approved in 262nd meeting of Registration Board.**

## 10. Imported Human biological applied by M/s RG Pharmaceutica (Pvt.) Ltd., Karachi deferred in 285th meeting of Registration Board.

Following product of M/s RG Pharmaceutica (Pvt.) Ltd., Karachi was deferred in 285th meeting of Registration Board as per following details:

| | |
|---|---|
| Name and address of Importer | M/s RG Pharmaceuticals Pvt. Ltd.,<br>Progressive Square No. 703, Block-6 PECHS, Shahra e Faisal, Karachi |
| Detail of DSL | DSL No. 0277 dated 27-01-2017 valid till 17-01-2019 |
| Name and address of Manufacturer | M/s Laboratorio Farmaceutico S.I.T.<br>Via Cavour 70 27035 Mede (PV), Italy |
| Brand Name +Dosage Form + Strength | Buccalin<br>Film-coated tablet |
| Diary No. Date of R& I & fee | Dy. No. 9184 (R&I) dated 19-07-2017 Rs. 100000/- dated 19-07-2017 |
| Composition | Each film coated tablet contains:<br>*Streptococcus pneumoniae* (Inactivated)…….1000 million cells<br>*Streptococcus agalactiae* (Inactivated)…….1000 million cells<br>*Staphylococcus aureus* (Inactivated)…….1000 million cells<br>*Haemophilusinfluenzae* (Inactivated)…….1500 million cells |
| Pharmacological Group | Human Vaccine |
| Type of Form | Form-5A |
| Finished Product Specification | Innovator's Specs |
| Shelf Life | 60 months (<25$^0$C) |
| Document Details | Valid Legalized CoPP No. 10514434 dated 14-12-2017 issued by Federal Office for Safety in Health Care Austria indicating availability of product in exporting country. |
| Pack size & Demanded Price | 1's Blister (7 Film-coated Tablets)/ Rs. 1000/- |
| International Availability | Australia, New Zealand, Switzerland etc. |
| Products already registered in Pakistan | Innovator Brand |

**Decision of RB in 285th meeting:**

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

a. *Submission of valid legalized GMP certificate of M/s Laboratorio Farmaceutico S.I.T.Via Cavour 70 27035 Mede (PV), Italy*
b. *Clarification is required regarding batches used for stability studies either pilot or commercial.*

Now the firm has submitted the following:

a. Valid legalized GMP certificate No. IT/85-3/H/2017 dated 15-05-2017 M/s Laboratorio Farmaceutico S.I.T.Via Cavour 70 27035 Mede (PV), Italy valid till 24-06-2019.
b. Stability study data as per following details:

**Stability Storage Condition:**

Real Time: 25$^0$C±2$^0$C; 60%±5%
Accelerated: 40$^0$C±2$^0$C; 75%±5%

**Time Period:**

Real time: 60 months
Accelerated: 06 months

**Frequency:**

Real Time: 0,3,6,9,12,18,24,36,48,60
Accelerated: 0,3,6

**Batch No.:**

Real Time: 2076A, 2148A, 2075A
Accelerated: 7496B, 7497A, 7498A

**Manufacturing Date:**

Real Time: 02/2012, 03/2012, 02/2012
Accelerated: 09/2017, 09/2017, 09/2017

**Decision:** **Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of Austria (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**

**11. Application for Change of Address of M/s Roche Pakistan Limited, Karachi for already registered products;**

M/s Roche Pakistan Limited, Karachi has applied for change in address of their head office for already registered following human biologicals as per following details:

| Sr. No. | Reg. No. | Product Name | Date of Initial Registration | Previous Address of Importer | New Address of Importer |
|---|---|---|---|---|---|
| 1. | 083134 | Actemra 80mg | 28-04-2017 | 37-C, Block 6, P.E.C.H.S., Karachi | 1st Floor, 37-B, Block 6 PECHS, Karachi |
| 2. | 083135 | Actemra 200mg | 28-04-2017 | | |
| 3. | 083136 | Actemra 400mg | 28-04-2017 | | |
| 4. | 090643 | Actemra 162mg/0.9ml | 29-06-2018 | | |
| 5. | 087084 | Gazyva | 20-12-2017 | | |
| 6. | 088527 | Herceptin | 16-03-2018 | | |
| 7. | 087085 | Kadcyla 100mg | 22-12-2017 | | |
| 8. | 087086 | Kadcyla 160mg | 22-12-2017 | | |
| 9. | 094764 | Mabthera Solution for subcutaneous Injection 1400mg | 29-01-2019 | | |
| 10. | 094763 | Ocrevus Injection 300mg/10ml | 23-01-2019 | | |
| 11. | 087083 | Perjeta | 20-12-2017 | | |
| 12. | 090644 | Tecentriq 1200mg/ml | 12-07-2018 | | |

The firm has submitted following documents;

i. Fee of Rs. 5000/- for each product.
ii. Copy of registration letter of above-mentioned products.
iii. Valid DSL for new address.

In this context, it is submitted that the firm has applied for new address as **"1st Floor, 37-B, Block 6 PECHS, Karachi"**while in the address mentioned on new Drug sale license is "**1st 37-B, Block 6 PECHS, Karachi**" and word "Floor" is missing. Moreover, the address of godowns where the above products will be stored as per new DSL are as under:

"1. R-PI, Plot No. 116, Sector 15, K.I.A, Karachi.
2. R-PI, Plot No. 56, Sector 15, K.I.A, Karachi."

**Decision:** **Keeping in view the valid Drug Sale License, Registration Board approved the change in address of importer of above products from M/s Roche Pakistan Limited, 37-C, Block 6, P.E.C.H.S., Karachi to M/s Roche Pakistan Limited, 1st Floor, 37-B, Block 6 PECHS, Karachi subject to storage facility verification of new godowns situated at R-PI, Plot No. 116, Sector 15, K.I.A, Karachi and R-PI, Plot No. 56, Sector 15, K.I.A, Karachi.**

**Item No. IV Division of Quality Assurance & Laboratory Testing**

| Sr.#. | Subject | Status |
|---|---|---|
| 01 | Manufacture & sale of substandard Vorenac 50 Tablets, Batch No.AVT-01 Manufactured by M/s Mission Pharmaceuticals, Karachi. | Personal Hearing |
| 02 | Manufacture & sale of substandard Zentro 40mg Tablets Batch No. 18008 Manufactured by M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi. | Personal Hearing |
| 03 | Case referred by PQCB Lahore regarding Substandard Alenstran 10 mg Tablet Batch No. F-T-940 Manufactured by M/s Farmaceutics International Karachi**.** | Personal Hearing |
| 04 | Case referred by PQCB Punjab regarding Substandard Meronide Tablet 400mg Manufactured by M/s Irza Pharma (Pvt) Ltd Sheikhupura Road, Lahore. | Personal Hearing |
| 05 | Case referred by PQCB Punjab regarding Substandard Losara-P 50mg Tablets Batch No. 9E-100 Manufactured by M/s Aneeb Pharmaceuticals, Lahore. | Personal Hearing |
| 06 | Request to Transfer "Not to Dispose Of" Stock from Pharmacy National Institute of Child Health (NICH), Karachi. | |
| 07 | Case referred by PQCB Punjab regarding Substandard Levaox Liquid Manufactured by M/s Intervac (Pvt) Ltd 18KM Lahore Sheikhupura Road, Sheikhupura. | |

**Case No.01**: **Manufacture & Sale of Substandard Vorenac 50 Tablets, Batch No. AVT-01 by M/s Mission Pharmaceuticals, Karachi.**

The FID-VI, DRAP Karachi visited the premises of M/s Mission Pharmaceuticals (Pvt.) Ltd., A-94, SITE Super Highway, Karachi, on 24-09-2018 to check the GMP compliance level of the firm and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3:

| | |
|---|---|
| Name: | Vorenac 50 Tablets. |
| Composition: | Each tablet contains 50mg Diclofenac Sodium. |
| Registration No: | 080324 |
| Batch No: | AVT-01 |
| Manufacturing Date: | Jan-2018 |
| Expiry Date: | Jan-2020 |
| Manufactured By: | M/s Mission Pharmaceuticals (Pvt.) Ltd., A.94, SITE Super Highway, Karachi, |

The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-130-133/2018-FID-VI (K) dated 25-09-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

The Federal Government Analyst, CDL, Karachi declared the sample as of **Sub-standard** quality **on the basis of dissolution** vide test/analysis report **No.KQ.649/2018** dated 05th October, 2018 which is violation of Section 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under.

The area FID-VI, Karachi vide letter No.ARS-130-133/2018-FID-VI (K) dated 10th October, 2018 has asked the firm M/s Mission Pharmaceuticals (Pvt.) Ltd., A.94, SITE Super Highway, Karachi to explain their position in the matter of manufacturing and selling of substandard drug with direction to recall the above said batch from the market.

M/s Mission Pharmaceuticals (Pvt.) Ltd., A.94, SITE Super Highway, Karachi submitted their reply vide letter No: MIS/QA/016-18 dated 16th October, 2018 wherein it is stated that they have checked their portion and retained sample of the subject cited drug and found a few tablets out of specifications. However rests of the parameters were very much aligned. They also recalled the remaining marketed portion of the said drug and the portion in hand is quarantined. They added that further investigations are possible underway to find out the root cause of the problem. All the investigation and subsequent CAPA in this connection would also be shared.

In pursuance of Section 19 (7) of the Drugs Act, 1976 The FID-VI, DRAP, Karachi submitted the complete case for placement in the upcoming meeting of Registration Board and provided the names of responsible which are as under:

| S.No. | Name | Designation | CNIC |
|---|---|---|---|
| 1 | Salman Sheikh | Production Manager | 42201-4158738-7 |
| 2 | Ahamd Hanif | Q.C. Manager | 42201-5736676-6 |

The Division of Drug Licensing, DRAP Islamabad was requested to verify the names provided by the FID-VI, Karachi and they provided the following names being responsible persons and technical persons.

| | |
|---|---|
| M/s Mission Pharmaceuticals (Pvt.) Ltd., Karachi | Muhammad Aleem Mirza (Managing Director) M/s Mission Pharmaceuticals (Pvt.) Ltd., Karachi |
| Salman Shaikh (Production Incharge) M/s Mission Pharmaceuticals (Pvt.) Ltd., Karachi | Ahmad Hanif (Q.C Manager) M/s Mission Pharmaceuticals (Pvt.) Ltd., Karachi |

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-82/2018-(QC) dated 16-01-2019. The show cause notice was served to the firm and accused persons but the firm did not submit their reply in response to show cause notice.

**Proceeding and Decision of the 288th Meeting of Registration Board.**

Mr. Salman Shaikh (42201-4158783-7) Production Incharge of M/s Mission Pharmaceuticals (Pvt.) Ltd., Karachi appeared on behalf M/s Mission Pharmaceuticals (Pvt.) Ltd., Karachi to plead instant case of Substandard Vorenac 50 Tablets, Batch No. AVT-01, Reg.No.080324 before the Board in its 288th meeting on 15th February, 2019.

Representatives of the firm informed that they have checked their portion and retained sample of the subject cited drug and found a few tablets out of specifications. He also submitted that they have also recalled the remaining marketed portion of the said drug and the portion in hand is quarantined. He further added that investigations are underway to find out the root cause of the problem. All the investigation and subsequent CAPA in this connection would also be shared.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided as under:

- **The firm will perform root cause analysis (RCA) & corrective and preventive action (CAPA) and inform the QA&LT Division.**
- **Data will be evaluated & if required physical verification will be conducted by the panel approved by the Director QA&LT, DRAP, Islamabad and will be submitted for consideration of Registration Board.**
- **Meanwhile the product Registration will remain suspended for a period of six (06) months or till decision of Registration Board whichever is later.**

**Case No.02**: **Manufacture & Sale of Substandard Zentro 40mg Tablets Batch No.18008 Manufactured by M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi.**

The FID-VI, DRAP Karachi visited the premises of M/s Khan Medicos, Shop No.16, Block No. 11-A, Karimabad market ST-2, FB Area, Karachi on 11-04-18 and taken following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/ analysis on prescribed Form-3:

| | |
|---|---|
| Name: | Zentro 40mg Tablet. |
| Composition: | Each Tablet contains 40mg Pantoprazole. |
| Registration No: | 035547 |
| Batch No: | 18008 |
| Manufacturing Date: | 07-17 |
| Expiry Date: | 06-20 |
| Manufactured By: | M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi. |

The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-25-26/2018-FID-VI (K) dated 11-04-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

The FID-VI, DRAP, Karachi has also forwarded one sealed portion of sample as Board's Portion vide letter No. ARS-25-26/2018-FID-VI (K) dated 13-04-2018 as required under Section 19(3)(ii) of the Drugs Act, 1976.

The Federal Government Analyst, CDL, Karachi declared the sample as of **Sub-standard** quality **on the basis of dissolution** vide test/analysis **report No.KQ.SC.249/2018** dated 06th June, 2018 which is violation of Section 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under.

The area FID-VI, Karachi vide letter No.ARS-25-26/2018-FID-VI (K) dated 13-06-2018 & 28-06-2018 has asked the M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi to explain their position in the matter of manufacturing and selling of substandard drug with direction to recall the above said batch from the market.

M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi submitted their reply vide letter No.GMRA/221/090718 dated 10th July, 2018 wherein as per contents of their reply they are not satisfied with the results of test report of CDL, Karachi but has not challenged it properly rather submitted to close the case.

The FID-VI, Karachi submitted that the samples of all available generic Pantoprazole capsules/tablets were taken for test & analysis on the complaints of several healthcare professionals regarding the efficacy of almost all generics amid the shortage of market brand. The CDL in-vitro test also confirmed the same. Therefore it is recommended that thorough investigations may be carried out encompassing manufacturers of brand leaders and generics also re-sampling of all available generics Pantoprazole throughout the country may be carried out for further investigations. It is further recommended provided the names of responsible which are as under:

| S.No. | Name | Designation | CNIC |
|---|---|---|---|
| 1 | Shaikh Mohiuddin Chawla | Managing Director and Warrantor | (42201-2175782-3) |
| 2 | Muhammad Ishaq | Production Incharge | (42101-1581154-7) |
| 3 | Imtiaz Ahmad | Quality Control Incharge | (42401-4079608-7) |
| 4 | SM Chawla | Warrantor | |

The Division of Drug Licensing, DRAP Islamabad was requested to verify the names provided by the FID-VI, Karachi and provided the following names being responsible persons and technical persons.

| | |
|---|---|
| M/s Bosch Pharma (Pvt.) Ltd,<br>221, Sector 23, Korangi Industrial Area, Karachi | Shaikh Mohiuddin Chawla, **(Director)**<br>M/s Bosch Pharma (Pvt.) Ltd,<br>221, Sector 23, Korangi Industrial Area, Karachi |
| Mr. Ahmad Nasib, **(Director)**<br>M/s Bosch Pharma (Pvt.) Ltd,<br>221, Sector 23, Korangi Industrial Area, Karachi | Mr. Farhan Chawala **(Director)**<br>M/s Bosch Pharma (Pvt.) Ltd,<br>221, Sector 23, Korangi Industrial Area, Karachi |
| Mr. Zakarya Nasib, **(Director)**<br>M/s Bosch Pharma (Pvt.) Ltd,<br>221, Sector 23, Korangi Industrial Area, Karachi | Muhammad Ishaq, (**Production Incharge)**<br>M/s Bosch Pharma (Pvt.) Ltd,<br>221, Sector 23, Korangi Industrial Area, Karachi |
| Imtiaz Ahmad, (**Quality Control Incharge)**<br>M/s Bosch Pharma (Pvt.) Ltd,<br>221, Sector 23, Korangi Industrial Area, Karachi | |

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-47/2018-(QC) dated 16-01-2019. The show cause notice was served to the firm and accused persons but the firm did not submit their reply in response to show cause notice.

**Proceeding and Decision of the 288th Meeting of Registration Board.**

Mr. Navaid Ahmad Akhtar , Group Manager Regulatory affairs (42201-3315232-1) & Dr. Syed Saad Hussain, Manager Pharmacovigilance (42201-8305042-1) of M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi appeared on behalf of M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi to plead instant case of Substandard Zentro 40mg Tablets, Batch No. 18008, Reg.No.035547 before the Board in its 288th meeting on 15th February, 2019.

Representatives of the firm submitted that they are not satisfied with the results of the CDL, test report as the protocols were not followed properly. Only stage one of the dissolution was performed while stage II & III were not performed. Also speed of 75 RPM was applied instead of 100 RPM.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided as under:

> **"*The QA&LT Division Shall direct the area FID to take samples as per prescribed procedure from portion of Zentro 40mg Tablets, Batch No. 18008 retained by its manufacturer (10 packs as per claim of the firm) i.e. M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi for the purpose of test and analysis from CDL, Karachi and submit report for consideration of Registration Board immediately without waiting for the minutes of the meeting. The sample should be divided into three (03) equal portions as prescribed under the law"***

**Case No. 03: Case Referred By PQCB Lahore Regarding Substandard Alenstran 10mg Tablet Batch No. F-T-940 Manufactured By M/S Farmaceutics International, Karachi.**

The Secretary, PQCB, Punjab vide letter no. PQCB/R 151-04/2016 dated 31-7-2018, which are about order of PQCB for Tehsil Darya Khan District Bhakkar stating the proceeding and decision of PQCB regarding Sub-standard Alenstran 10 mg tablet batch no. f-T-940 manufactured by M/s Farmaceutics International, F1-A3, S.I.T.E Karachi, in its 190th meeting held on 31-7-2018.

That case states that Provincial Inspector of Drugs, Tehsil Darya Khan District Bakkhar reported that:

i. He, on 23-12-2015, inspected the business premises of M/s Yousaf Medical Store AddaKohawarKalan District Bakkar and took samples of two different types of drugs on Form 4 for the purpose of test and analysis.

ii. One out of the two drug samples after test/ analysis was declared as sub-standard by Government Analyst Drug Testing Laboratory Faisalabad as detailed below:

| **Name of drug** | **Batch no** | **Name of manufacturer** | **DTL report TRA no. and date** | **DTL test report results** |
|---|---|---|---|---|
| Tablet Alenstran 10 mg | f-T-940 | M/s Farmaceutics International F1-A3, S.I.T.E, Karachi | TRA no. 4222/DTL Dated: 15-4-2016 | **Analysis with specifications:**<br>**Manufacturer's specifications**<br>**Description:**<br>Oblonged, biconvex film coated tablets, having line of bisection at one side, contained in plastic blister of 10 tablets, packed in unit carton. The blister contains 8 tablets instead of 10 tablets moreover do not bear batch no. of the product on blister.<br>**Assay: (**Cetirizine)<br>Percentage: 96.50%<br>Limit: 90-110%<br>**Disintegration:** Not More Than 30 minutes. |

| | | | | |
|---|---|---|---|---|
| | | | | **Determined:** comply with the specifications**.** **Result:** the Sample is sub-standard/ misbranded on the basis of tests performed. |

That M/s Farmaceutics International, Karachi challenged the DTL report. But the request was not processed as the sample got expired at that time.
That the case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its 175th meeting held on 29-11-2017 and 176th meeting held on 15-12-2017. The board decided to Conduct Product Inspection by the said panel as under:
Prof. Dr. Mehmood Ahmad (Member PQCB) convener
Mr. Munawar Hayat (Chief Drugs Controller, Punjab (member PQCB) member

The conclusion is as under:
*"The product tablet Alenstran 10 mg, B. no. f-T-940 was declared sub-standard/ misbranded on physical grounds "blister contains 8 tablets of 10 tablets and batch number not mentioned on blister". As per DTL test report assay was 96.5%. The firm is directed, before starting actual blistering procedure, took specimen samples of blisters and make a part of batch manufacturing record to verify batch number, manufacturing and expiry date. The firm is advised to improve quality control checks on the packaging of tablets (sorting) of blisters before packaging."*

The case was again considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act, 1976 in its 190th meeting held on 31-7-2018. Chief Drugs Controller Punjab (member of inspection panel) presented the above-mentioned product specific inspection report and apprised the board regarding major short comings observed during inspection which includes " In-House specifications/ methods of test/ analysis of drugs were not validated, Daily calibration of the instruments such as UV Spectrophotometer, weighing balance and glassware was not being performed, non-availability of the instruments i.e FTIR and TOC and incorrect schedule for ongoing stability studies etc. The report was reviewed critically and the board expressed serious concerns over these short comings/ nonconformities which were critical in nature. The board agreed with the recommendations/ advice tendered by the inspection panel to the firm.

*The board after due deliberation on various aspects of the case and detailed scrutiny of the inspection report and keeping in view the gravity of nonconformities, unanimously decided to refer the Product Specific Inspection (PSI) report to the Central Licensing Board (CLB) DRAP Islamabad through Chief Executive Officer DRAP for information and necessary action as required under law.*

**Proceeding and Decision of the 286th Meeting of Registration Board.**

*The case was presented before the Registration Board in its 286th meeting on 16th November, 2018 and the Board after perusing the record/ document of the instant case deliberated the matter in depth and decided as under:*

*"to issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore for manufacturing and selling of substandard Alenstran 10mg tablets, Batch No. f-T-940, manufactured by M/s Farmaceutics International F1-A3, S.I.T.E, Karachi."*
Show cause notice was served to the firm as per decision of the Registration Board vide file No.03-86/2018-QC (286-RB) on 16th January 2019.

In response to the Show cause notice, the firm submitted their reply vide their letter No. Nil dated 22nd January, 2019 which is reproduced as under:
*"The said report is not yet shared with us, neither from CLB nor from the author.*
*Panel has never inspected the facility and we are worried, whether it is mistakenly quoted or otherwise as modus operandi.*

*There is absolutely no issue on quality of product and test report of Govt. Analyst on which SCN builds itself confirm compliance of drug with all quality parameter. There is absolutely no safety, efficacy or quality issue with the product.*
*It is therefore requested to read our earlier letter since, it is time barred case, (DTL report issued on dated 15-04-16) after nine month delay drug inspector send us report on 19-01-17). It is sincerely hoped that rule of law will be respected in its spirit. We will thankful of protecting interest of justice."*

**Proceeding and Decision of the 288th Meeting of Registration Board.**
Mr. Jameel Hussain Querishi, Advocate High Court (38403-21018809-1) of M/s Farmaceutics International F1-A3, S.I.T.E, Karachi appeared on behalf of M/s Farmaceutics International, F1-A3, S.I.T.E Karachi to plead instant case of substandard Alenstran 10 mg Tablets, Batch No. F-T-**940** before the Board in its 288th meeting on 15th February, 2019.
Representatives of the firm submitted that Panel has never inspected their facility.

The Board after hearing the accused deliberated the matter in depth in the light of available record & decided as under:

- **Inspection report shall be obtained from provincial Quality Control Board (PQCB), Lahore for product specific inspection of M/s Farmaceutics International, F1-A3, S.I.T.E Karachi and the matter will be placed before the Registration Board or the Central Licensing Board as the case may be.**
- **The area Federal Inspector of Drugs shall take the samples of the said product for test analysis from Central Drug Laboratory, Karachi and submit the report to QA&LT, DRAP, Islamabad.**

**Case No. 04: Case referred by PQCB Lahore regarding substandard Meronide Tablet 400mg manufactured by M/s Irza Pharma (Pvt) Ltd Sheikhupura Road, Lahore.**

Abid Saeed Baig, Secretary Provincial Quality Control Board, Punjab has forwarded the cases which are about orders of PQCB for Districts Narowal, Sargodha, and Faisalabad, dated 28-4-2018 stating the proceedings and decision of PQCB regarding sub-standard Meronide tablet 400mg manufactured by M/s Irza Pharma (pvt) ltd, 10.2 km Sheikhupura Road, Lahore , in its 185th meeting held on 28-4-2018.

Case no.1 state the brief of the case as under;
Inspector of Drugs, Tehsil & district Narowal reported that:

i. He, on 13-04-2016, inspected the premises of MSD, EDO (H) Narowal situated at old DHQ Hospital Narowal and took the sample of below mentioned drug on form-4 which after test/ analysis was declared substandard by Government Analyst Drug Testing Laboratory, Faisalabad as detailed below:

| Name of Drug | Batch No. | Name of Manufacturer | DTL Report TRA No &Date | DTL Report Result |
|---|---|---|---|---|
| Tablet Meronide 400 mg | 6A13 | M/s Irza Pharma ltd,, 10.2 km Sheikhupra road Lahore. | TRA no. 4545/DTL Dated: 22-04-2016 | Substandard on the basis of Friability test |

ii. The Storekeeper of MSD, EDO (H) Narowal situated at old DHQ hospital Narowal provided invoice/warranty nos. 5165, 5164, 5163, 5162, 5160, 5159, 5158, 5157, 5156 dated 8-4-2016 issued by M/s Irza Pharma, Lahore as a proof of their purchase.

iii. A copy of test report of the drug sam0ple was sent to M/s Irza Pharma, Lahore and they were asked to explain their position and to provide requisite information in this regard but they failed to do so.

Case no.2 state the brief of the case as under;

Inspector of Drugs, tehsil & district Sargodha reported that:

i. His predecessor, on 12-04-2016, inspected the premises of Main Medicine Store, DHQ Teaching Hospital, Sargodha and took the twenty four samples of below mentioned drugs on form-4 for test/ analysis.

ii. One out of twenty four samples after test/ analysis was declared substandard by Government Analyst Drug Testing laboratory Faisalabad as detailed below:

| Name of Drug | Batch No. | Name of Manufacturer | DTL Report TRA No & Date | DTL Report Result |
|---|---|---|---|---|
| Tablet Meronide 400 mg | 6A10 | M/s Irza Pharma Ltd,, 10.2 km Sheikhupra Road Lahore. | TRA no. 5014/DTL Dated: 30-04-2016 | Substandard on the basis of friability test |

iii. He, on 20-7-2017, also seized the stock of subject substandard drug on form 5.

iv. The Storekeeper of Main Medicine Store, DHQ teaching hospital Sargodha provided invoice/warranty nos. 4755, dated 16-03-2016 issued by M/s Irza pharma, Lahore as a proof of their purchase.

v. Warrantor portion and a copy of test report of the drug sample was sent to M/s Irza pharma, Lahore and they were asked to explain their position and to provide requisite information in this regard.

Case no. 3 states the brief of the case as under;

Inspector of Drugs, Tehsil Samundri, District Faisalabad, reported that:

i. His predecessor, on 28-03-2016, inspected the business premises of THQ Hospital Tehsil Samundri district Faisalabad and took samples of one type of drug on form 4 for the purpose of test and analysis.

ii. The sample after test/ analysis was declared substandard by Government Analyst drug Testing Laboratory Faisalabad as detailed below:

| Name of Drug | Batch No. | Name of Manufacturer | DTL Report TRA No & Date | DTL Report Result |
|---|---|---|---|---|
| Tablet Meronide 400 mg | 6B4 | M/s Irza Pharma Ltd,, 10.2 km Sheikhupra road Lahore. | TRA no. 4578/DTL Dated: 23-04-2016 | Substandard on the basis of friability test |

iii. Stock Keeper THQ Hospital Tehsil Samundri district Faisalabad provided invoice/warranty nos. 4596, dated 11-3-2016 issued by M/s Irza Pharma, Lahore as a proof of their purchase.

iv. A copy of test report & warrantor portion was sent to M/s Irza Pharma ltd Sheikhupra road, Lahore and they were asked to explain their position but they failed to do so.

Case no.4 state the brief of the case as under;

Inspector of Drugs, DHQ Teaching Hospital, Sargodha reported that:

i. His predecessor, on 20-05-2016, inspected the Main Medicine Store, DHQ Teaching hospital Sargodha and took the samples of one drug on form-4 for test/ analysis.

ii. The sample after test/ analysis was declared substandard by Government Analyst drug testing laboratory Faisalabad as detailed below:

| Name of Drug | Batch No. | Name of Manufacturer | DTL Report TRA No & Date | DTL Report Result |
|---|---|---|---|---|
| Tablet meronide 400 mg | 6A9 | M/s Irzapharma Ltd,, 10.2c km sheikhupra road Lahore. | TRA no. 6846/DTL Dated: 09-06-2016 | Substandard on the basis of friability test |

iii. He, on 20-7-2017, also seized the stock of subject substandard drug on form 5.

iv. The Storekeeper, Main Medicine Store, DHQ Teaching Hospital Sargodha provided invoice/warranty nos. 4755 dated 16-3-2016 issued by M/s Irza Pharma, Lahore as a proof of their purchase.

v. Warrantor portion and copy of test report was sent to M/s Irza Pharma, Lahore and they were asked to explain their position and to provide requisite information in this regard but they failed to do so.

Case no. 5 states the brief of the case as under;

Inspector of Drugs, Layyalpur Town, district Faisalabad reported that:

v. He, on 29-03-2016, inspected the Main Medicine Store office of Executive District Officer (Health) Faisalabad and took thirty samples of drugs on Form-4 for test/ analysis.

vi. One out of these sample after test/ analysis was declared substandard by Government Analyst drug Testing Laboratory Faisalabad as detailed below:

| Name of Drug | Batch No. | Name of Manufacturer | DTL Report TRA No & Date | DTL Report Result |
|---|---|---|---|---|
| Tablet Meronide 400 mg | 6B4 | M/s IrzaPharma ltd,, 10.2 km Sheikhupra road Lahore. | TRA no. 4427/DTL Dated: 20-04-2016 | Substandard on the basis of friability test |

vii. Incharge of Main Medicine Office of Chief Executive Officer (Health) Faisalabad provided invoice/warranty nos. 4583, 4584, 4589, 4590 and 4591 dated 11-3-2016 issued by M/s IrzaPharma, Lahore as a proof of their purchase.

viii. A copy of test report & warrantor portion was sent to M/s Irza Pharma ltd Sheikhupura road, Lahore and they were asked to explain their position and to provide requisite information in this regard.

Case no. 6 states the brief of the case as under;

Inspector of Drugs, tehsil Bhalwal district Sargodha reported that:

i. Drug inspector, on 02-04-2016, inspected the premises of Medicine Store T.H.Q hospital Bhalwal district Sargodha and took samples of three different types of drugs on form-4 for test/ analysis.

ii. One out of these sample after test/ analysis was declared substandard by Government Analyst Drug Testing Laboratory Faisalabad as detailed below:

| Name of Drug | Batch No. | Name of Manufacturer | DTL Report TRA No & Date | DTL Report Result |
|---|---|---|---|---|
| Tablet Meronide 400 mg | 6A9 | M/s IrzaPharma Ltd,, 10.2 km Sheikhupra road Lahore. | TRA no. 4246/DTL Dated: 16-04-2016 | Substandard on the basis of friability test |

iii. Medical Superintendent of T.H.Q hospital, Bhalwal provided invoice/warranty nos. 4735 dated 16-3-2016 issued by M/s Irza Pharma, Lahore as a proof of their purchase.

iv. Warrantor portion was sent to the M/s irza Pharma, Lahore. A copy of test report was sent to M/s Irza Pharma was directions to explain their position and provide requisite information in this regard.

Case no. 7 states the brief of the case as under;

Inspector of Drugs, Lyallpur town, district Faisalabad reported that:

i. He, on 28-4-2016, inspected the main medicine store office of Executive District Officer (Health), Faisalabad and took samples of four types of drugs on form-4 for test/ analysis.

ii. Two out of four samples after test/ analysis was declared substandard by Government Analyst Drug Testing Laboratory Faisalabad as detailed below:

| Name of Drug | Batch No. | Name of Manufacturer | DTL Report TRA No & Date | DTL Report Result |
|---|---|---|---|---|
| Tablet Meronide 400 mg | 5L3 | M/s IrzaPharma ltd,, 10.2c km sheikhupra road Lahore. | TRA no. 5417/DTL Dated: 10-05-2016 | Substandard on the basis of friability test |
| Tablet Meronide 400 mg | 6B5 | M/s IrzaPharma ltd,, 10.2c km Sheikhupra road Lahore. | TRA no. 5418/DTL Dated: 10-05-2016 | Substandard on the basis of friability test. |

iii. Incharge main medicine store provided invoice/warranty nos. 5410 dated 23-4-2016 issued by M/s Irza pharma, Lahore as a proof of their purchase.

iv. Incharge main medicine store provided invoice/warranty nos. 5411 dated 23-4-2016 issued by M/s Irza Pharma, Lahore as a proof of their purchase.

v. A copy of test report and warrantor portion was sent to M/s Irza Pharma with directions to explain their position and provide requisite information in this regard.

All the Drug Inspectors as mentioned above requested for grant for prosecution against the firm and accused persons who have contravened the provisions of sections 23/27 of the Drugs Act, 1976/ DRAP Act 2012 and rules framed there under.

The said cases were presented before PQCB Lahore in its 177th meeting held on 30-12-2017. The board decided to conduct PSI of M/s Irza Pharma Lahore.

The conclusion of PSI is as under:

"*The firm is manufacturing uncoated tablet Meronide without research and development. Whereas the leading brands of this product are available in film coating form in market. The firm has shifted the uncoated formulation into film coating in May 2016 without any permission/ intimation to DRAP. On evaluation of bmr it was observed that following changes in the master formula was made by adding sugar in two batches and without adding sugar in four batches. The result of friability result varying by adding binder and non-addition of binder. Average weight of tablet shows that amount of excepients added in 400 mg tablet is slow. In this regard firm is violating many conditions of schedule B-II of the Drugs Act 1976. So. The firm is directed to redesign and reevaluate its formulation and perform stability study of following products under intimation and approval of DRAP.*

*Tablet Meronide 400mg* *R.no 025636*

*Tablet meronide200mg* *R. N 025635"*

The PSI report was presented before PQCB in its 185th meeting held on 28-4-2018. The board unanimously decided to grant permission for prosecution against the following accused persons in the drug court.

i. M/s Irza Pharma ltd, 10.2 km Sheikhpura road, Lahore through its chief executive Muhammad Imran Jawa.

ii. Muhammad Imran Jawa Chief Executive

iii. Abid Ali Jawa Warrantor

iv. IftikharMasud Plant Manager

| | | |
|---|---|---|
| v. | Savaira Sultan | Director |
| vi. | Azamali | production Incharge |
| iv. | AsimMehmood | Quality Control Incharge |

Of M/s Irza pharma Lahore for the offences of

i. Manufacturing for sale/ stocking for sale/ sale of substandard drug.
ii. Issuance of its false warranty.

*The Board further decided to recommend Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of the registration of the subject drug product i.e Meronide tablet.*

**Decision of 284th meeting of Registration Board**

The board decided to issue the show cause notice and personal hearing to firm responsible persons as provided by PQCB lahore for manufacturing and selling of different batches of substandard i.e meronide tablets.

The show cause notice was served to the firm on 23rd October, 2018.

**Proceeding and Decision of the 286th Meeting of Registration Board.**

Mr. Muhammad Imran Jawa (Managing Director) and Azam Ali (production Manager) of M/s Irza Pharma ltd, 10.2 km Sheikhupra road Lahore appeared on behalf of M/s Irza Pharma, Lahore plead instant case of Substandard drug Meronide 400 mg Tablet, Batch No. 6A13, 6A10, 6B4, 6A9, 5L3 and 6B5 before the Board in its 286th meeting on 16th November, 2018.The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided as under:

1. ***Show cause notice should be served to the firm for violation of the condition of the registration as the firm was having registration of the uncoated tablets. Why they shifted for manufacturing of coated tablets without prior approval from Registration Board, DRAP, Islamabad.***
2. ***They should submit product development data for change in the coating of the tablets.***
3. ***The registration of the said product shall remain suspended till the verification of data following panel:***
    a. ***Director DTL, Lahore.***
    b. ***Area FID, DRAP, Lahore.***

Show cause notice was served to the firm as per decision of the Registration Board vide file No.03-86/2018-QC (286-RB) on 16th January 2019.

In response to the show cause notice, the firm submitted their reply vide reference No. IP/04/2019 dated 25-01-2019 and is reproduced as under:

*"Both Meronide 200mg tablets and Meronide 400mg tablets were registered in 12-05-2000 with the DRAP having registration # 025635 and 025636 respectively.*

*There was nothing mentioned FILM COATED etc in the drug registration letter.*

*The honorable PQCB board suggested at the time of hearing to apply for Film-coat to the DRAP Islamabad for both products to avoid discrepancy (Friability). Therefore we applied on 25-10-18. Reg. #IP/05/2018 to DRAP. Then received the letter "Correction in formulation/specification with film coat permission"*

*As M/s Irza Pharma is serving the nation since 1971 and has the recognition among the people of our beloved country as manufacturing unit of quality products.*

*The minor deviation in the formulation of the Meronide tablets (Both 400mg & 200mg) as mentioned in the letter received from your good office. In this regard it is humbly stated that the possibilities of deviation might be there due to environmental circumstances (Machine operator/Equipment being used/analyst etcetcand the formulator/production manager may take the onset decision (which must be documented) to verify their particular problems like capping, lamination, desired hardness, chipping etc.*

*The pharmaceutical products are based upon by quality of design. This has firm relationship between the product and the patient. If product is chemically fine having no risk of any potential hazard the post formulation variation has no value to object. Si it's not fall in violation as mentioned. Although we have the R&D section and w make Pre-Requisite prior to formulate any product. (as desired by the DRAP) and then we started film coating.*
*The said product had been tested/analysed by almost four major DTL's of Punjab like;*

- *DTL Lahore*
- *DTL Multan*
- *DTL Bahawalpur*
- *DTL Rawalpindi*

*These are the state of art and reliable DTLs but only Fiasalabad DTL failed our product on the basis of Friability which has no impact upon the health nor health injurious.*
*We have supplied millions of Meronide tablets all over the country but none of the DTL (with a few exceptions) questioned upon the quality (potency/strength. All parameters were in compliance.*
*Anyhow we M/s Irza Pharma provides the dossier of product development data of both products for your kind perusal and technical evaluation.*
*Therefore it is prayed to your honor to please have a sympathetic consideration and wave off the case in the best interest of the patients due to our cost effective quality medicine. We assure your good office that we shall not leave any stone unturned for the compliance of GMP.*
*We do hope for justice and sympathetic consideration to resume the registration of both products in the best interest of the nation.*
*We M/s Irza Pharma requested your good office if the supported documents does not in compliance with the demanded information then please rehear in person before honorable board to fulfill the dispensation of the justices equality. We shall very oblige for this favour."*

**Proceeding and Decision of 288th Meeting of Registration Board.**

Mr. Iftekhar Masood, Plant Manager (35201-3876518-9) & Mr. Azam Ali, Production Incharge (31104-9772326-3) of M/s Irza Pharma (Pvt.) ltd Sheikhupura Road, Lahore appeared on behalf of M/s Irza Pharma (Pvt.) ltd Sheikhupura Road, Lahore to plead instant case of substandard Meronide tablet 400mg with different Batch numbers before the Board in its 288th meeting on 15th February, 2019.
Representatives of the firm submitted that they have provided the product development data as per decision of the 286th meeting of the Registration Board. He further added that we were not manufacturing coated tablets without prior permission from DRAP, Islamabad.

The Board after hearing the accused deliberated the matter in depth in the light of available record & decided as under:

- **The Board decided to direct the panel constituted in 286th meeting of Registration Board to conduct the product specific inspection and also verify the product development data provided by the firm and submit report for consideration of the Board. The report of the said panel may be submitted for consideration of this Board.**
- **The Area Federal Inspector of Drugs shall take the samples of the said product for test analysis from Central Drug Laboratory, Karachi and submit the report to QA&LT, DRAP, Islamabad.**

**Case No. 05: Case referred by PQCB Lahore regarding substandard Losara-P 50mg Tablets Batch No. 9E-100 manufactured by M/s Aneeb Pharmaceuticals, Lahore.**

The Secretary, PQCB, Punjab vide letter no. PQCB R-521-09/2009 dated 31-7-2018, which are about order of PQCB for Tehsil Rahim Yar Khan stating the proceeding and decision of PQCB regarding Sub-standard Losara-P tablets batch no. 9E-100 manufactured by M/s Aneeb Pharmaceuticals, Lahore, in its 190th meeting held on 31-7-2018.

That case states that Provincial Inspector of Drugs, Tehsil Rahim Yar khan reported that:

i. He took the drugs sample tablet Losara-P 50mg batch no. 9E-100 for the purpose of test/ analysis from the premises of medicine store Sheikh Zaid Medical College Rahim Yar Khan.

ii. The drug sample was declared as sub-standard by Government Analyst Drug Testing Laboratory Lahore as detailed below:

| Name of drug | Batch no | Name of manufacturer | DTL report TRA no. and date | DTL test report results |
|---|---|---|---|---|
| Tablet Losara-P 50mg | No. 9E-100 | M/s Aneeb Pharmaceutical, Lahore | TRA no. 7925/DTL Dated: 02-09-2009 | **Analysis with specifications:** **Manufacturer's specifications** **Description:** Pink color round coated tablets. Having rough outer surface with white patches and have granular appearance packed in blister. A part of some tablets remained stick with aluminum foil on pressing out tablet from blister **Assay:** (Losartan Potassium) Percentage: 97.4% **Result:** the sample is sub-standard on the basis of tests performed. |

**PREVIOUS PROCEEDINGS AND DECISION BY THE BOARD**:

The case was considered in 60th meeting of PQCB dated: 30-1-2010. The board decided to issue warning to the firm with direction to replace the entire substandard stock with fresh stock and the destruction of substandard stock according to contractual obligations. The board further decided to constitute a committee comprising of the followings for inspection of the firm to ascertain GMP compliance and submit the report.

- Professor Dr. Naveed Iqbal Ansari (Member PQCB).
- Professor Dr. MahboobRabbani (Member PQCB).
- Muazzam Ali khan (Chief Drugs Inspector).

That the case was again considered by the Provincial Quality Control Board in its 161st meeting held on 15-4-17. The board reconstituted the inspection committee comprising of Chief Drug Controller, Punjab to conduct Specific Inspection along with drug inspectors industries and submit report to PQCB. The conclusion is as under:

- *The panel is of opinion that batch size 9E100 was 2000000 tablets while capacity of film coating pan was less than batch size (200000/ pan & two pans were available) so coating was performed in different portions. Coating was also not uniform that lead to physical deformity.*
- *The firm is directed to produce batch size of each product according to capacity of production equipment.*

The case was again considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act, 1976 in its 190th meeting held on 31-7-2018. Secretary PQCB informed the board the subject case had already been disposed of with warning to the firm however report of the inspection committee was awaited. Chief Drugs Controller Punjab (the inspection committee) presented the above- mentioned inspection report and apprised the board that coating of tablets

was being performed in multiple cycles due to limited capacity of the coating pans. Resultantly the coating was not uniform. This nonconformity was the possible reason for physical deformity in tablets as reported by the Government Analyst vide above- mentioned test/ analysis. The board agreed with the recommendations/ advice tendered by the inspection panel to the firm to overcome this nonconformity.

*The board after due diligence and deliberation on various aspects of the case and detailed scrutiny of the inspection report unanimously decided to forward the Product Specific Inspection (PSI) report to the Central Licensing Board (CLB) DRAP Islamabad through Chief Executive Officer DRAP for information and necessary action as required under law.*

*Proceeding and Decision of the 286th Meeting of Registration Board.*

**The case was presented before the Registration Board in its 286th meeting on 16th November, 2018 and the Board after perusing the record/ document of the instant case deliberated the matter in depth and decided as under:**

*"to issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore for manufacturing and selling of substandard Losara-P 50mg tablets, Batch No. 9E-100, Manufactured by M/s Aneeb Pharmaceutical, Lahore."*

Show cause notice was served to the firm as per decision of the Registration Board vide file No.03-86/2018-QC (286-RB) on 16th January 2019 but the firm didn't submit their reply till to date.

**Proceeding and Decision of the 288th Meeting of Registration Board.**

Mr. Atif Sharif, Managing Director (35201-3876518-9) of M/s Aneeb Pharmaceuticals, Lahore, appeared on behalf of M/s Aneeb Pharmaceuticals, Lahore to plead instant case of substandard Losara-P 50 mg Tablets, Batch No. 9E-100 before the Board in its 288th meeting on 15th February, 2019.

Representatives of the firm submitted that 40 samples of the said drug were tested out of which 35 have been declared as of standard quality while only five products have been declared as of substandard quality. He further claimed that in the five substandard cases warning was issued by the PQCB in two cases whereas prosecution was granted in three cases. Subsequently, he was acquitted by the courts in the three cases. He further added that the main reason of sticking of some parts of tablets to the aluminum file was due to non compliance to written storage instructions on the label.

The Board after hearing the accused deliberated the matter in depth in the light of available record & decided as under:

- **The firm should conduct accelerated & real time stability studies in the container closure system to confirm that product meets the specifications during the allocated shelf life. The data should be submitted to DRAP, Islamabad for evaluation with packaging validation of the product in question.**
- **The Area Federal Inspector of Drugs shall take the samples of the said product for test analysis from Central Drug Laboratory, Karachi and submit the report to QA&LT, DRAP, Islamabad.**

**Case No. 06: Request to transfer "Not to Dispose Of" stock from Pharmacy National Institute of Child Health (NICH).**

The Federal Inspector of Drugs, DRAP Karachi (FID-V) has referred letter No. ADMN/2018/4183/NICH dated 21st December 2018 received from the Director, National Institute of Child Health (NICH) for shifting of stock of following medicine, that were ordered not to dispose of under section 18(1) of the Drugs Act, 1976 on form-I, due to space constraints at the premises of NICH pharmacy.

| Name of Drug | B. No. | Quantity | Manufacturer | Orders made by | Dated | Reasons | Extension vide DRAP and dated |
|---|---|---|---|---|---|---|---|
| 1. Syp. Zancpal | D288 | 60mlx31000 | Zanctok, Hyderabad | FID-V (K) | 26-7-18 | Substandard | F. 13-49/2018 QC dated 29-8-18 |
| 2. Syp. Zancpal | D281 | 60mlx22000 | Zanctok, Hyderabad | Addl. Director (K) | -do- | Substandard | Nil |
| 3. Inj. Elitopine. | 157 | 2mlx31x25 | Elite, Lahore | -do- | 07-3-18 | Substandard | Nil |
| 4. Inj. Ceuticsaxime | F-SI-369 | | Farmaceutics Karachi | -do- | -do- | Substandard & Adulterated | Nil |
| 5. Water for Inj. | F-1-412 | 5mlx21734 | Farmaceutics Karachi | -do- | -do- | | Nil |
| 6. Inj. Lignocain | 405 | 10mlx50 Box | Elite, Lahore | -do- | 05-3-18 | Substandard & Adulterated | Nil |

The FID-V, DRAP, Karachi informed that there is extension of period of orders not to dispose of for drugs mentioned at serial from 3 to 6 above not received as yet despite of letters.

The FID-V, DRAP, Karachi further added that keeping in view of the difficulties of said institute and space problems, it is proposed that the said stock may be shifted to another premises under safe custody preferably at the premises of relevant manufacturers. It is therefore requested that:

*i. Grant of necessary pending extension of said orders from CLB.*

*ii. Necessary permission of shifting stocks ordered not to dispose of from NICH to another safe custody.*

*iii. Necessary permission for release of drug namely Elitopine Injection Batch No.157 as appellate lab declared as standard quality vide its report No. 013-M/2018 dated 18th July, 2018.*

It is submitted that the product at serial No.1 was declared as of standard quality by the Central Drug Laboratory, Karachi.

It is further submitted that products at serial No. 3 & 6 have been declared by the Appellate laboratory, NIH, Islamabad as of standard quality vide their test report 013-M/2018 dated 18th July, 2018 & 011-M/2018 dated 21st May, 2018 respectively.

**Proceeding and Decision of 288th Meeting of Registration Board.**
**The Board after thorough deliberations directed as follows:**

- **Advised area FID to seize products at S.No.02, 04 and 05.**
- **Directed that the investigation shall be completed for all the drugs from S.No.01 to 06 and complete case shall be submitted to the Board for final decision.**
- **Products at S.No.01, 03 and 06 shall remain not to dispose of till decision of the case as requested by the FID.**

**Case No.07: Case referred by PQCB Punjab regarding sub-standard Levaox Liquid manufactured by M/S Intervac (Pvt) Ltd 18KM Lahore Sheikhupura Road, Sheikhupura.**

The Secretary, PQCB, Punjab vide letter no. PQCB/R 202-209/2017 dated 05-11-2018 requested for cancellation of registration of LEVAOX Liquid for Veterinary 1 liter manufactured by M/s Intervac (Pvt.) Ltd., 18km Lahore Sheikhupura road, Sheikhupura.

**Brief Facts of the Case:**

Provincial Inspector of Drugs Aroop Town, Gujranwala reported that:

i. He, on 16-06-2017, inspected the medicine Store of Director Livestock Division, Aroop Town, Gujranwala and took samples of 11 types of drugs on Form-4 for the purpose of test and analysis.

ii. Eight out of these drugs samples after test/analysis, were declared substandard by Government Analyst Drug Testing Laboratory, Faisalabad as detailed below:

| Name of the Drug | Batch No. | Name of Manufacturer | DTL Report TRA No. & Date | DTL Report results |
|---|---|---|---|---|
| Levaox Liquid 1 Liter | LX-276 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10857/DTL Dated: 18-07-2017 | **Analysis with specifications:** Manufacturer's specification **Description:** **Stated:** Light yellow colored liquid. **Determined:** Mustard colored liquid. **(Does not comply with specifications)** **Label claim:** Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm **Identification:** Levamisol and Oxyclozanide identified. **Assay:** Per 100ml of liquid: **Levamisole HCl:** Stated: 1.50gm Determined: 1.5165gm Percentage: 101.1% Limit: 90-110% **Oxyclozanide:** Stated: 3.0gm Determined: 3.024gm Percentage: 100.8% Limit: 90-110% **Result:** The sample is **substandard** as defined in drugs Act, 1976. |
| Levaox Liquid 1 Liter | LX-277 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10858/DTL Dated: 18-07-2017 | **Analysis with specifications:** Manufacturer's specification **Description:** **Stated:** Light yellow colored liquid. **Determined:** Mustard colored liquid. **(Does not comply with specifications)** **Label claim:** Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm **Identification:** Levamisol and Oxyclozanide identified. **Assay:** Per 100ml of liquid: **Levamisole HCl:** Stated: 1.50gm Determined: 1.638gm Percentage: 109.2% Limit: 90-110% **Oxyclozanide:** |

| | | | | |
|---|---|---|---|---|
| | | | | Stated: 3.0gm<br>Determined: 3.069gm<br>Percentage: 102.3%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** as defined in drugs Act, 1976. |
| Levaox Liquid 1 Liter | LX-278 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10859/DTL Dated: 18-07-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>**Stated:** Light yellow colored liquid.<br>**Determined:** Mustard colored liquid.<br>**(Does not comply with specifications)**<br>**Label claim:**<br>Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm<br>**Identification:** Levamisol and Oxyclozanide identified.<br>**Assay:** Per 100ml of liquid:<br>**Levamisole HCl:**<br>Stated: 1.50gm<br>Determined: 1.55gm<br>Percentage: 103.7%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm<br>Determined: 2.868gm<br>Percentage: 95.6%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** as defined in drugs Act, 1976. |
| Levaox Liquid 1 Liter | LX-279 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10860/DTL Dated: 18-07-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>**Stated:** Light yellow colored liquid.<br>**Determined:** Mustard colored liquid.<br>**(Does not comply with specifications)**<br>**Label claim:**<br>Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm<br>**Identification:** Levamisol and Oxyclozanide identified.<br>**Assay:** Per 100ml of liquid:<br>**Levamisole HCl:**<br>Stated: 1.50gm<br>Determined: 1.4715gm<br>Percentage: 98.1%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm<br>Determined: 2.712gm<br>Percentage: 90.4%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** as defined in drugs Act, 1976. |
| Levaox Liquid 1 Liter | LX-280 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10861/DTL Dated: 18-07-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>**Stated:** Light yellow colored liquid.<br>**Determined:** Mustard colored liquid.<br>**(Does not comply with specifications)** |

| | | | | |
|---|---|---|---|---|
| | | | | **Label claim:**<br>Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm<br>**Identification:** Levamisol and Oxyclozanide identified.<br>**Assay:** Per 100ml of liquid:<br>**Levamisole HCl:**<br>Stated: 1.50gm<br>Determined: 1.461gm<br>Percentage: 97.4%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm<br>Determined: 2.73gm<br>Percentage: 91.0%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** as defined in drugs Act, 1976. |
| Levaox Liquid 1 Liter | LX-281 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10862/DTL Dated: 18-07-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:** Mustard colored liquid having putrid smell contained in plastic bottle.<br>**Stated:** Light yellow colored liquid.<br>**Determined:** Mustard colored liquid.<br>**(Does not comply with specifications)**<br>**Label claim:**<br>Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm<br>**Identification:** Levamisol and Oxyclozanide identified.<br>**Assay:** Per 100ml of liquid:<br>**Levamisole HCl:**<br>Stated: 1.50gm<br>Determined: 1.473gm<br>Percentage: 98.2%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm<br>Determined: 2.784gm<br>Percentage: 92.8%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** as defined in drugs Act, 1976. |
| Levaox Liquid 1 Liter | LX-282 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10863/DTL Dated: 18-07-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:** Mustard colored liquid having putrid smell contained in plastic bottle.<br>**Stated:** Light yellow colored liquid.<br>**Determined:** Mustard colored liquid.<br>**(Does not comply with specifications)**<br>**Label claim:**<br>Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm<br>**Identification:** Levamisol and Oxyclozanide identified.<br>**Assay:** Per 100ml of liquid:<br>**Levamisole HCl:**<br>Stated: 1.50gm<br>Determined: 1.5105gm<br>Percentage: 100.7% |

| | | | | |
|---|---|---|---|---|
| | | | | Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm<br>Determined: 2.991gm<br>Percentage: 99.7%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** as defined in drugs Act, 1976. |
| Levaox Liquid 1 Liter | LX-283 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | TRA No. 10864/DTL Dated: 18-07-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:** Mustard colored almost odorless liquid contained in plastic bottle.<br>**Stated:** Light yellow colored liquid.<br>**Determined:** Mustard colored liquid.<br>**(Does not comply with specifications)**<br>**Label claim:**<br>Each 100ml contains: Levamisol HCl B.P 1.50gm, Oxyclozanide B.P Vet 3.00gm<br>**Identification:** Levamisol and Oxyclozanide identified.<br>**Assay:** Per 100ml of liquid:<br>**Levamisole HCl:**<br>Stated: 1.50gm<br>Determined: 1.5045gm<br>Percentage: 100.3%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm<br>Determined: 2.94gm<br>Percentage: 98.0%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** as defined in drugs Act, 1976. |

iii. Store keeper of Medicine store of Director Livestock Division, Aroop Town Gujranwala provided invoice/warranty No. 7420 dated 03-06-2017 of M/s Intervac Pvt Ltd Head office 113/3, Allama Iqbal Road, Ghari Shahu Lahore as a proof of its purchase.

iv. Warrantor portion of the drug sample and copies of the test reports of Drug sample were sent to Invertac Pvt Ltd., with direction to explain their position and provide requisite information in this regard. In response they requested for retest/analysis from appellate laboratory, NIH, Islamabad.

v. Persuant to their request, the drug samples were sent to NIH, Islamabad from where the drug samples have been declared substandard as detaile below:

| Name of the Drug | Batch No. | Name of Manufacturer | NIH report No. & Date | NIH Report results |
|---|---|---|---|---|
| Levaox Liquid for Veterinary 1 Liter | LX-276 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0305-P/2017 dated 07-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:**<br>Stated: 1.50gm/100ml<br>Determined: 1.523gm/100ml<br>Percentage: 101.52% |

| | | | | |
|---|---|---|---|---|
| | | | | Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 3.20gm/100ml<br>Percentage: 106.91%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |
| Levaox Liquid for Veterinary 1 Liter | LX-277 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0304-P/2017 dated 07-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:**<br>Stated: 1.50gm/100ml<br>Determined: 1.544gm/100ml<br>Percentage: 102.94%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 3.10gm/100ml<br>Percentage: 103.46%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |
| Levaox Liquid for Veterinary 1 Liter | LX-278 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0307-P/2017 dated 07-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:**<br>Stated: 1.50gm/100ml<br>Determined: 1.49gm/100ml<br>Percentage: 99.35%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 2.78gm/100ml<br>Percentage: 92.77%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |
| Levaox Liquid for Veterinary 1 Liter | LX-279 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0306-P/2017 dated 07-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:** |

| | | | | |
|---|---|---|---|---|
| | | | | Stated: 1.50gm/100ml<br>Determined: 1.48gm/100ml<br>Percentage: 98.69%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 3.11gm/100ml<br>Percentage: 103.77%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |
| Levaox Liquid for Veterinary 1 Liter | LX-280 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0303-P/2017 dated 19-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:**<br>Stated: 1.50gm/100ml<br>Determined: 1.527gm/100ml<br>Percentage: 101.86%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 3.20gm/100ml<br>Percentage: 106.97%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |
| Levaox Liquid for Veterinary 1 Liter | LX-281 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0302-P/2017 dated 19-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:**<br>Stated: 1.50gm/100ml<br>Determined: 1.536gm/100ml<br>Percentage: 102.44%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 3.06gm/100ml<br>Percentage: 102.32%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |
| Levaox Liquid for Veterinary 1 Liter | LX-282 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0301-P/2017 dated 19-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid** |

| | | | | |
|---|---|---|---|---|
| | | | | **is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:**<br>Stated: 1.50gm/100ml<br>Determined: 1.505gm/100ml<br>Percentage: 100.34%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 3.139gm/100ml<br>Percentage: 104.65%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |
| Levaox Liquid for Veterinary 1 Liter | LX-283 | M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura | Test Report No. 0300-P/2017 dated 19-12-2017 | **Analysis with specifications:**<br>Manufacturer's specification<br>**Description:**<br>Mustard colored suspension contained in labeled plastic bottle.<br>**(Does not comply with manufacturer's specifications which states that Levaox liquid is light yellow in color)**<br>**Assay:**<br>**Levamisole HCl:**<br>Stated: 1.50gm/100ml<br>Determined: 1.533gm/100ml<br>Percentage: 102.2%<br>Limit: 90-110%<br>**Oxyclozanide:**<br>Stated: 3.0gm/100ml<br>Determined: 3.076gm/100ml<br>Percentage: 102.55%<br>Limit: 90-110%<br>**Result:** The sample is **substandard** on the basis of tests performed. |

vi. Copies of NIH test report were sent to M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura with direction to explain their position and provide requisite information in this regard but they failed to do so.

vii. In this way the above mentioned accused persons have contravened the provision of section 23/27 of the Drugs Act, 1976 and Rules framed their under by the way of:

**Manufacturing for sale/sale of substandard drugs and issuance of its false warranty**

Show cause/personal hearing notice(s) issued to accused person(s)/petitioners

**PREVIOUS PROCEEDINGS BY THE BOARD:**

**188TH MEETING HELD ON 28-06-2018:**

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its 188th meeting held on 28-06-2018. Secretary PQCB appraised the Board that all the accused persons were absent although letter of personal hearing were sent to them through courier service. The Board after discussion decided to pend the case due to non appearance of accused persons in best interest of justice. The Board further decided to provide another but final opportunity of personal hearing to the accused persons. Personal hearing notice(s) issued to accused person(s).

**CURRENT PROCEEDING & DECISION BY THE BOARD:**

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its 189th meeting held on 12-07-2018. Secretary DQCB Gujranwala Miss Sonia Irshad and Drug inspector Saleh Muhammad both were present along with original case record.

Secretary PQCB apprised the Board that show cause/personal hearing notice(s) was issued to the accused persons through courier service. Counsel for the firm Mr. Talha Ahmad Khan Advocate submitted that the sample was declared substandard by DTL Bahawalpur and NIH, Islamabad merely on the basis of color. The drug complies chemical assay as well as all other tests performed by both laboratories. He added that the CEO of the firm is in Peshawar and unable to appear before the Board due to short notice. He requested to adjourn the case for the next date of hearing.

The Board after detailed scrutiny of the case record, Report of DTL, Bahawalpur, report of NIH, Islamabad and statement of the council of the firm observed that the same problem was observed in all the batches of the product. In order to dig out the root cause of defect in production of the said product there is dire need of product specific inspection. Therefore, the Board decided to constitute a committee comprising of the following to conduct Product Specific Inspection (PSI) of M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura and submit report within fortnight for consideration by the Board.

| | |
|---|---|
| 1 | **Prof. Dr. Mahmood Ahmad,** Member PQCB |
| 2 | **Mr. Muhammad Munawar Hayat**<br>Chief Drugs Controller, Punjab/Member |
| 3 | **Area Drug Inspector Industries** |

***Inspection report of M/s Intervac pharmaceuticals***

***Date of inspection****: 19-09-18*

*Note: The production department was closed at the time of inspection due to maintenance of its doors and will remain closed till 27-09-2018. This was informed by manufacturer to DRAP.*

***Premises:***

*The unit was established in 2005, total area is 59895 sq. ft. Production area and quality control for products in question is on ground floor.*

*The product range includes Oral liquid Hormones, antibiotic powder, Dry powder bolus, oral liquids.*

*Total Number of registered products is 125.*

***Staff****.*

| *Designation* | *Current* | *Previous* |
|---|---|---|
| *Chief Executive Officer* | *Ishfaq Ahmad* | *Ishfaq Ahmad* |
| *Director* | *Hafiz Tanveer* | *Hafiz Tanveer* |
| *Production manager* | *Muhammad Qasim Aziz* | *Muhammad Qasim Aziz* |
| *QC Manager* | *Manzoor Hussain* | *Manzoor Hussain* |
| *Warrantor* | *Ishfaq Ahmad* | *Manzoor Hussain & M Qasim Aziz* |
| *QA Manger* | *Vivian Joy* | *Vivian Joy* |

***Products*** *(List provided)*

***Background information:***

*Total 22 batches of Levaox Liquid 1 Litre were supplied to the Director Livestock Division Gujranwala; 8 batches (LX-276, LX-277, LX-278, LX-279, LX-280, LX-281, LX-282, LX-283) were declared substandard on the basis of Physical parameter i.e. change in color from light yellow to Mustard. Batch Size is 2000L (2000 bottles).*

***Observations:***

*1. DTL Lahore declared 8 batches substandard and two with putrid smell, however assay was within limits. On appeal for retest, NIH, declared the same result except any "Putrid Smell" remarks.*

*2. The preparation of Levaox Liquid IL (Oxyclozanide BP Vet + Levamisole HCL BP) is non-pharmacopeial and no information regarding its brand leader could be retrieved.*

*3. On the inspection of Sample retain room of the manufacturer; it was observed that the batch manufactured in OS/2017 was contained in clear plastic bottle; however, the batch manufactured in*

*04/2017 was contained in opaque plastic bottle. Similarly, the container for government supply resembled Mineral water bottle, but off-white gallon shaped container was used for commercial market.*
*4. Only one bottle was retained as retention sample. Also, the oldest batch that could be retrieved from sample retention area was batch No.LX-98 manufacture in Jan/2017; whereas legal requirement is to retain the sample for one year after it expires.*
*5. The retention samples were found of yellow colored.*
*6. The Hi-tech lab contained FTIR, HPLC, TOC and UV-Vis Spectrophotometer (single beam and double beam).*
*7. The analysis method is In-house using Spectrophotometer, the assay record for Batch No.LX-283 was missing in Log Book.*
*8. Method Validation has been conducted in Jan/2013. In case of Oxyclozanide Validation; the diluents used was methanol instead of acidified methanol as per standard analytical procedure. Moreover, Linearity, Accuracy, Specificity, LOo, LOD were also missing from Validation Documents. For Levamisole, the linearity curve was not straight (non-linear).*
*9. Identification of raw material is done by FTIR against the standard built-in-library of Agilent.*
*10. Accelerated and on-going stability studies have not been conducted for the batches in question.*
*11. The pharmacopeia I reference standards were not available and working standards were used instead.*
***Batch Processing Record***
*1. SMR Record is available.*
*2. Testing Method is available but not validated.*
*3. QC retention samples are available (one unit only) for each batch.*
*4. Tartrazine is on yellow color; 0.600kg/2000Litre.*
*5. Batch mixing, Filling line and packing line clearances records are available.*
*6. In-Process QC tests performed.*
*7. Batch size 2000 Liter.*
***Conclusion:***
*Based upon the observation noted, record/BMR review and stability Study data observations, the panel is of the opinion that change in color was might be due to primary packaging material; as the firm is using inferior quality PET bottle (Polyethylene terephthalate) for government supply. Also, the plastic of varying kind and quality is employed for commercial market and government supply, and the firm has also not established stability studies for that packing material (PET).*
*Therefore, the panel recommends that the matter should be forwarded to the Registration board of DRAP for cancellation/Suspension of registration of drugs on violation of condition of registration of drug.*

Personal hearing notice(s) issued to accused person(s).

**PROCEEDINGS & DECISION BY THE BOARD:**

Case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its 194th meeting held on 18.10.2018. Drug Inspector briefed the Board about facts of the case and requested for the permission for prosecution against the accused persons. Counsel for the firm argued that the drug samples were declared substandard merely on the basis of physical specification i.e. change in color while drug was complying to its chemical specification. He added that tartrazine was being used as coloring agent in the formulation which is light sensitive and should be protected from light. The change in color of liquid may be due to effect of light, but there was not chemical degradation of product as assay of the product was within official limits. He requested the Board for lenient view.

The Board, after detailed scrutiny of the record, inspection report of the firm, due deliberation and detailed discussion observed that change in color might be due to primary packaging material; as the firm was using plastic bottles of varying kind and quality for packaging. The drug was supplied to government in inferior quality PET bottle (Polyethylene terephthalate). Moreover, the firm has also not established stability studies for that packing material (PET). Keeping in the view of foregoing facts of the case the Board decided to grant permission for prosecution against the following accused persons in the Drug Court.

i. M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura through its Chief Executive Ashfaq Ahmad Khan.

ii. Ashfaq Ahmad Khan Chief Executive
iii. M Qasim Aziz Production Incharge/Warrantor
iv. Manzoor Hussain Quality Control Incharge/Warrantor

Of M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road Sheikhupura for the offences of

**a. Manufacturing for sale/sale of substandard drugs.**
**b. issuance of its false warranty.**

The board further decided to recommended registration board, Drug Regulatory Authority of Pakistan for cancellation of registration of Levaox liquid for veterinary 1 liter manufactures M/s Intervac Pvt. Ltd., 18-KM Lahore Sheikhupura Road, Sheikhupura.

## Proceeding and Decision of the 288th Meeting of Registration Board.

The case was presented before the Registration Board in its 288th meeting on 15th February, 2019 and the Board after perusing the record/ document of the instant case deliberated the matter in depth and decided as under:

**"to issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore for manufacturing and selling of substandard Levaox Liquid 1 liter mg tablets, with different batch numbers , manufactured by M/s Intervac Pvt Ltd 18Km Lahore Sheikhupura Road, Sheikhupura."**

## Additional Agenda

| ITEM No. | Detail of Item |
|---|---|
| **I** | Pharmaceutical Evaluation Cell |
| **II** | Division of Biological Evaluation & Reserach |
| **III** | Registration-I section |
| **IV** | Registration-II section |
| **V** | Post registration-I section |
| **VI** | Post registration-II section |
| **VII** | Import & Vetrinary section |

**Item No.I: Pharmaceutical Evaluation Cell**

| S.No. | Detail |
|---|---|
| **Case No.01** | **Registration applications for local manufacturing of (Human) drugs** |
| | a. New cases |
| | b. Deferred cases |
| **Case No.02** | **Registration applications of newly granted DML or New section (Human)** |
| | a. New DML |
| | b. New/Additional section(s) |
| | c. Remaining products of new section |
| **Case No.03** | **Registration applications of drugs for which stability study data is submitted** |
| | a. Deferred cases |
| | b. Onsite Verification of stability study data |
| **Case No.04** | **Registration applications for local manufacturing of (veterinary) drugs** |
| | a. New Cases |
| **Case No.05** | **Registration applications of newly granted DML or New section (Veterinary)** |
| | a. New DML /section |
| **Case No.06** | **Registration applications of categories to be considered on priority** |
| | a. Export Facilitation |
| | b. Import applications of priority categories defined by Registration Board in its 257th meeting |
| **Case No.07** | **Registration applications of import cases** |
| | a. Deferred cases |
| | i. Human |
| **Case No.08** | **Miscellaneous cases** |

**Case No.: 01 Registration applications for local manufacturing of (Human) drugs**

**a. New cases**

**Evaluator PEC-V**

| | | |
|---|---|---|
| **1.** | Name and address of manufacturer / Applicant | M/s Titlis Pharma.528-A, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Diary No. Date of R& I & fee | Dy.No 2991 dated 22-01-2018 Rs. 20,000 Dated 22-01-2018 |
| | Brand Name +Dosage Form + Strength | Titrazole 40mg Capsule |
| | Composition | "Each Capsule Contains:<br>Omeprazole Enteric Coated Pellets Eq. to Omeprazole…40mg" |
| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 2x7's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved. |
| | Me-too status | 080404<br>Calsic-40 Capsules by Caliph Pharmaceuticals, (Pvt) Ltd., Plot No. 17 S.I.Z. Risalpur, Nowshera |
| | GMP status | Certificate is based upon evaluation conducted on 11-07-2018. |
| | Remarks of the Evaluator. | Capsule Section Approval.<br>Source: M/s Titlis Pharma |
| | **Decision: Approved.** | |
| **2.** | Name and address of manufacturer / Applicant | M/s Titlis Pharma.528-A, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Diary No. Date of R& I & fee | Dy.No 2990 dated 22-01-2018 Rs. 20,000 Dated 22-01-2018 |
| | Brand Name +Dosage Form + Strength | Pain-Nil 50mg Tablet |
| | Composition | "Each film coated tablet Contains:<br>Diclofenac Potassium…50mg" |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 2x10's, As per SRO. |
| | Approval status of product in Reference Regulatory Authorities. | MHRA approved |
| | Me-too status | 079985<br>Pngo 50mg Tablet<br>M/s Innvotek Pharmaceuticals, Islamabad |
| | GMP status | Certificate is based upon evaluation conducted on 11-07-2018. |
| | Remarks of the Evaluator. | Tablet Section Approval. |
| | **Decision: Approved.** | |
| **3.** | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | Estela Tablet 5mg |
| | Composition | Each film coated tablet contains:<br>Escitalopram as oxalate…..5mg |
| | Diary No. Date of R& I & fee | Dy.No 6257 dated 20-02-2018 Rs. 20,000/- 20-02-2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitor(SSRI) |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 10's, 14's<br>Price: As per SRO |
| | Approval status of product in | Lexapro |

| | | |
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| | Reference Regulatory Authorities. | USFDA approved |
| | Me-too status | 077829<br>Gentle 5mg Tablet<br>By Wilson's Pharmaceuticals, 387-388, I-9, Sector, Industrial Area, Islamabad. |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and<br>The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Approved in USFDA with box warning.<br>Master formulation mentions Escitalopram as oxalate…..6.35mg wheras applied formulation is Escitalopram as oxalate…..5mg. |
| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| **4.** | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | Estela Tablet 10mg |
| | Composition | Each film coated tablet contains:<br>Escitalopram as oxalate…..10mg |
| | Diary No. Date of R& I & fee | Dy.No 6258 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitor(SSRI) |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 7's, 10's, 14's<br>Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lexapro<br>USFDA approved |
| | Me-too status | 082033<br>Flotella 10mg Tablets<br>M/s Candid Pharmaceuticals, Opposite Pasrur Sugar Mills, Sialkot Road, Pasrur . |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and<br>The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Approved in USFDA with box warning.<br>Master formulation mentions Escitalopram as oxalate…..12.70mg wheras applied formulation is Escitalopram as oxalate…..10mg. |
| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| **5.** | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | SOLFENA Tablet 10mg |
| | Composition | Each film-coated tablet contains:<br>Solifenacin Succinate …..10mg |
| | Diary No. Date of R& I & fee | Dy.No 6255 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018 |
| | Pharmacological Group | Muscarinic Antagonists, Urological Agents |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size:10's<br>Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | VESIcare<br>USFDA Approved. |
| | Me-too status | 081959<br>Solfine Tablet 10 mg<br>M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad |

| | | |
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| | GMP status | Last GMP inspection is conducted on 08/11/2018 and<br>The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | |
| | **Decision: Deferred for submission of revised lavbel claim in terms of equivalency of Solifenacin as per reference product.** | |
| **6.** | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | PRESTO Tablet 145mg |
| | Composition | Each tablets contains:<br>Fenofibrate…….145mg |
| | Diary No. Date of R& I & fee | Dy.No 6255 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018 |
| | Pharmacological Group | Fibrates, Lipid Modifying Agents |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 10's<br>Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | TRICOR (fenofibrate) Tablet, for oral use |
| | Me-too status | 058480<br>Fenoget 145mg Tablet<br>Getz Pharma (Pvt.) Ltd, Karachi |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and<br>The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Present in USP.<br>The master formulation mentions enteric coating material. Clarify.<br>Evidence of uncoated tablets in international reference agencies. |
| | **Decision: Deferred for clarification/Justification from the firm regarding mentioning of enteric coating material in master formulation as the innovators product is uncoated tablets.** | |
| **7.** | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | Mucox Tablet 600mg |
| | Composition | Each film coated tablets contains:<br>Guaifenesin …….600mg |
| | Diary No. Date of R& I & fee | Dy.No 6254 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018 |
| | Pharmacological Group | Expectorant |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 10's<br>Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Mucinex (Guaifenesin) Tablet, Extended Release; Oral |
| | Me-too status | Could not be confirmed. |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | Applied formulation is film coated tablets while the provided international availability is Extended Release; bilayer tablet. |
| | **Decision: Registration board deferred the case for following reasons:**<br>**a. The product approved by reference regulatory authorities is Extended Release; bilayer tablet while the applied product is film coated tablets**<br>**b. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

| | | |
|---|---|---|
| **8.** | Name and address of manufacturer / Applicant | M/s Wimits Pharmaceuticals Pvt. Ltd.<br>Plot 129 Sunder Industrial Estate Raiwind Lahore |
| | Brand Name + Dosage Form + Strength | Aquit Water for Injection |
| | Composition | Each amp. contains:<br>Sterile water for injection …..5ml |
| | Diary No. Date of R& I & fee | Dy.No 6250 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018 |
| | Pharmacological Group | Diluent/vehicle for reconstitution |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | Pack Size: 100's<br>Price: As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | MHRA Approved. |
| | Me-too status | 075933; Water for Injection<br>M/s City Pharma, Karachi . . |
| | GMP status | Last GMP inspection is conducted on 08/11/2018 and<br>The report concludes that firm was found to be operating at good level of GMP compliance. |
| | Remarks of the Evaluator | |
| **Decision: Approved with innovator's specification** | | |

**Evaluator PEC-VIII**

| | | |
|---|---|---|
| **9.** | Name and address of Manufacturer / Applicant | M/s Winthrox Laboratories, K-219-A, SITE, Superhighway, Phase-II, Karachi. |
| | Brand Name + Dosage Form + Strength | Janvia Tablet 50mg/500mg |
| | Composition | Each film coated tablet contains:<br>Sitagliptin (as phosphate monohydrate)…50mg<br>Metformin hydrochloride…. 500mg |
| | Diary No. Date of R&I & fee | Dy.No.3787; 30-01-18: Rs. 20,000 |
| | Pharmacological Group | Anti-Diabetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Janumet Tablets of M/s. Wilshire Laboratories (Pvt) Ltd |
| | GMP status | Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year. |
| | Remarks of Evaluator | Cutting on fee challan from 850mg to 1000mg. |
| | **Decision: Deferred for the verification of fee challan as per decision of 285th meeting of Registration Board.** | |
| **10.** | Name and address of Manufacturer / Applicant | M/s Winthrox Laboratories, K-219-A, SITE, Superhighway, Phase-II, Karachi. |
| | Brand Name+DosageForm+Strength | Spasgo Tablet 80mg/62.333mg/80mg |
| | Composition | Each sugar coated tablet contains:<br>Phloroglucinol hydrate…80mg<br>Trimethyl Phloroglucinol…80mg |
| | Diary No. Date of R&I & fee | Dy.No.3782; 30-01-18: Rs. 20,000 |
| | Pharmacological Group | Gastrointestinal Anticholinergic/ Para-sympatholytic |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's Specifications |
| | Pack Size & Demanded Price | 30's: Rs.450/- |
| | Approval status of product in Reference Regulatory Authorities | Approved in ANSM |
| | Me-too status | Spasfon tablets of M/s Himont |
| | GMP status | Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year. |

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| | Remarks of Evaluator | ---- |
| | **Decision: Approved with innovator's specification** | |

**Evaluator PEC-IX**

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| **11.** | Name and address of manufacturer / Applicant | Berlex Lab. International, 10 Km Nangshah Chowk Karachi Road, Multan |
| | Brand Name +Dosage Form + Strength | Parolex Tablet 20mg |
| | Composition | Each film-coated tablet contains:<br>Paroxetine as HCl…….20mg |
| | Diary No. Date of R& I & fee | Dy No. 33094: 04.10.2018<br>PKR 20,000/-: 29.03.2017 (Duplicate Dossier) |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Paroxetine 20 mg Film-coated tablets. MHRA approved |
| | Me-too status | Frais Tablet 20mg. Reg. No. 82658 (Does not depict hemihydrate) |
| | GMP status | The firm was inspected on 05.07.2018, wherein the panel recommended renewal of DML |
| | Remarks of the Evaluator. | • The firm was asked to revise the label claim in Form 5 to "Each film-coated tablet contains" with submission of applicable fee. The firm revised the label claim without submission of fee.<br>• The reference product contains Paroxetine as HCl hemihydrate. Correct the label claim to Paroxetine as HCl hemihydrate and master formula to Paroxetine HCl hemihydrate. However, the firm did not revise the same. |
| | **Decision: Deferred for revision of salt forms of the API in the formulation as per the reference product along with submission of fee for revision of formulation.** | |
| **12.** | Name and address of manufacturer / Applicant | Berlex Lab. International, 10 Km Nangshah Chowk Karachi Road, Multan |
| | Brand Name +Dosage Form + Strength | Para Forte Tablet |
| | Composition | Each tablet contains:<br>Paracetamol…….650mg<br>Orphenadrine citrate……50mg |
| | Diary No. Date of R& I & fee | Dy No. 33095: 04.10.2018<br>PKR 20,000/-: 29.03.2017 (**Duplicate Dossier**) |
| | Pharmacological Group | Orphenadrine, combinations |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications. |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Could not be confirmed |
| | Me-too status | Nuberol Forte Tablet. Reg No. 27196 |
| | GMP status | The firm was inspected on 05.07.2018, wherein the panel recommended renewal of DML |
| | Remarks of the Evaluator. | • The firm was asked to provide complete finished product specification and testing method including dissolution test and content uniformity test. However, the firm did not submit the same. |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**<br>• **Submission of complete finished product specification and testing method including dissolution test and content uniformity test.** | |

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| **13.** | Name and address of manufacturer / Applicant | Berlex Lab. International, 10 Km Nangshah Chowk Karachi Road, Multan |
| | Brand Name +Dosage Form + Strength | Tramalex Plus Tablet |
| | Composition | Each film-coated tablet contains:<br>Tramadol HCl……37.5<br>Paracetamol……..325 |
| | Diary No. Date of R& I & fee | Dy No. 33096: 04.10.2018<br>PKR 20,000/-: 29.03.2017 (**Duplicate Dossier**) |
| | Pharmacological Group | Opioids in combination with non-opioid analgesics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2x5's; Rs. 100/- |
| | Approval status of product in Reference Regulatory Authorities. | ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms **US-FDA** approved |
| | Me-too status | Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181 |
| | GMP status | The firm was inspected on 05.07.2018, wherein the panel recommended renewal of DML |
| | Remarks of the Evaluator. | • The firm was asked to revise the formulation to film-coated tablet along with correction in label claim, Master Formula and manufacturing outlines and submission of applicable fee. However, the firm only revised label claim in Form 5 and did not submit any fee. |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| **14.** | Name and address of manufacturer / Applicant | M/s ZAFA Pharmaceutical Laboratories (Private) Limited L1/B Block-22 Federal B Industrial Area, Karachi |
| | Brand Name +Dosage Form + Strength | Trimezat Oral Suspension 24mg/5ml |
| | Composition | Each 5 ml contain:<br>Trimebutine…….24mg |
| | Diary No. Date of R& I & fee | Dy No. NIL: 21.05.2011<br>PKR 8,000/-: 21.05.2011 (**Duplicate Dossier**)<br>PKR 12,000/-: 09.01.2019 |
| | Pharmacological Group | Synthetic anticholinergics, esters with tertiary amino group |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specifications |
| | Pack size & Demanded Price | 120 ml; Rs. 93.21 |
| | Approval status of product in Reference Regulatory Authorities. | MODULON CHILD AND INFANT 4.8 mg / ml, granulated (granules composition per 100 g > trimebutine: 0.7870 g) for oral suspension in vial. **ANSM** approved |
| | Me-too status | Tributine Suspension (trimebutine maleate). Reg. No. 54584 |
| | GMP status | The firm was last inspected on 06.10.2017, wherein the panel concluded the GMP compliance as FAIR |
| | Remarks of the Evaluator. | • The me-too product contains trimebutine maleate, while the international product contains trimebutine.<br>• The firm revised the formulation from 'powder for suspension' to 'granules for suspension'.<br>• The firm was asked to provide complete finished product specification and testing method. However, the firm did not submit the same. |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Submission of complete finished product specification and testing method including dissolution test and content uniformity test**<br>• **Submission of fee for revision of formulation.**<br>• **Consideration on its turn.** | |
| **15.** | Name and address of manufacturer / Applicant | Mission Pharmaceuticals (Pvt.) Ltd., Plot No. A-94, SITE Super Highway, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Vorenac-K Tablet 50mg |

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|---|---|---|
| | Composition | Each film-coated tablet contains:<br>Diclofenac potassium……..50mg |
| | Diary No. Date of R& I & fee | Dy No. 6830: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Acetic acid derivatives and related substances |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2 x 10's; Rs. 160.66 |
| | Approval status of product in Reference Regulatory Authorities. | Diclofenac Potassium 50 mg Tablets. **MHRA** approved |
| | Me-too status | Pngo 50 mg film-coated Tablet. Reg. No. 79985 |
| | GMP status | The firm was inspected on 10.10.2017, wherein the GMP level was rated as GOOD.<br>The firm was advised to purchase TOC analyzer and one climatic chamber, and to hire more persons, especially in QA department. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **16.** | Name and address of manufacturer / Applicant | Mission Pharmaceuticals (Pvt.) Ltd., Plot No. A-94, SITE Super Highway, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Merzole Capsule 20mg |
| | Composition | Each capsule contains:<br>Esomeprazole (enteric coated pellets)……..20mg |
| | Diary No. Date of R& I & fee | Dy No. 6831: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Proton pump inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 7's x2; Rs. 170/- |
| | Approval status of product in Reference Regulatory Authorities. | NEXIUM® (esomeprazole magnesium) 20mg delayed-release capsules, for oral use. US-FDA approved |
| | Me-too status | Obpra Capsule 20mg by Obson Pharma. Reg. No. 54165 |
| | GMP status | The firm was inspected on 10.10.2017, wherein the GMP level was rated as GOOD.<br>The firm was advised to purchase TOC analyzer and one climatic chamber, and to hire more persons, especially in QA department. |
| | Remarks of the Evaluator. | • The firm was asked for correction in label claim as per reference product (with respect to salt form) along with submission of applicable fee is required. However, the firm neither submitted revised Form 5 nor the applicable fee.<br>• The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under evaluation. |
| | **Decision: Deferred for revision of label claim and submission of fee for revision of formulation.** | |
| **17.** | Name and address of manufacturer / Applicant | Mission Pharmaceuticals (Pvt.) Ltd., Plot No. A-94, SITE Super Highway, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Vorenac-K Tablet 50mg |
| | Composition | Each film-coated tablet contains:<br>Diclofenac potassium……..50mg |
| | Diary No. Date of R& I & fee | Dy No. 6830: 22.02.2018 PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Acetic acid derivatives and related substances |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 2 x 10's; Rs. 160.66 |
| | Approval status of product in Reference Regulatory Authorities. | Diclofenac Potassium 50 mg Tablets. **MHRA** approved |
| | Me-too status | Pngo 50 mg film-coated Tablet. Reg. No. 79985 |
| | GMP status | The firm was inspected on 10.10.2017, wherein the GMP level was rated as GOOD.<br>The firm was advised to purchase TOC analyzer and one |

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| | | climatic chamber, and to hire more persons, especially in QA department. |
| | Remarks of the Evaluator. | |
| | **Decision:Approved** | |
| **18.** | Name and address of manufacturer / Applicant | Mission Pharmaceuticals (Pvt.) Ltd., Plot No. A-94, SITE Super Highway, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Mefacid Tablet 500mg |
| | Composition | Each film-coated tablet contains:<br>Mefenamic acid……..500mg |
| | Diary No. Date of R& I & fee | Dy No. 6829: 22.02.2018<br>PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Fenamates |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 10 x10's; Rs. 220.70 (blister) 1 x 200's; Rs. 432.12 (jar) |
| | Approval status of product in Reference Regulatory Authorities. | Meflam 500 film-coated. **MHRA** approved |
| | Me-too status | Fortagesic 500mg Tablet. Reg. No. 85207 |
| | GMP status | The firm was inspected on 10.10.2017, wherein the GMP level was rated as GOOD.<br>The firm was advised to purchase TOC analyzer and one climatic chamber, and to hire more persons, especially in QA department. |
| | Remarks of the Evaluator. | • The firm revised the formulation to film-coated tablet (composition and manufacturing outlines). Correction in Form 5 is required along with submission of applicable fee. |
| | **Decision: Deferred for revision of Form 5 as per the reference product along with submission of fee for revision of formulation.** | |
| **19.** | Name and address of manufacturer / Applicant | Mission Pharmaceuticals (Pvt.) Ltd., Plot No. A-94, SITE Super Highway, Karachi, Pakistan |
| | Brand Name +Dosage Form + Strength | Mefacid Tablet 250mg |
| | Composition | Each tablet contains:<br>Mefenamic acid……..250mg |
| | Diary No. Date of R& I & fee | Dy No. 6834: 22.02.2018<br>PKR 20,000/-: 22.02.2018 |
| | Pharmacological Group | Fenamates |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 60 x10's; Rs. 710.0 (blister)<br>1 x 1000's; Rs. 1183.33 (jar) |
| | Approval status of product in Reference Regulatory Authorities. | Meflam 250 film-coated. **MHRA** approved |
| | Me-too status | MF- 250 film-coated Tablet. Reg. No. 76585 |
| | GMP status | The firm was inspected on 10.10.2017, wherein the GMP level was rated as GOOD.<br>The firm was advised to purchase TOC analyzer and one climatic chamber, and to hire more persons, especially in QA department. |
| | Remarks of the Evaluator. | • The firm was asked to provide proof of International availability of same dosage form (plain tablet) with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board, or revise the formulation to film-coated tablet (label claim, composition and manufacturing outlines) along with submission of applicable fee. The firm did reply to the query. |
| | **Decision: Deferred for revision of the appied formulation as film coated as per the reference product along with submission of fee for revision of formulation.** | |

**Evaluator PEC-XIII**

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| **20.** | Name and address of manufacturer / Applicant | M/s Polyfine Chem Pharma, 51- Industrial Estate, Hayatabad, Peshawar |
| | Brand Name +Dosage Form + Strength | Tier Eye Drop 2mg/ ml (0.2%) |
| | Composition | Each ml contains:<br>Purified Sodium Hyaluronate …..2mg |
| | Diary No. Date of R& I & fee | Dy. No. 352;03-01-2018; Rs.20,000/- (03-01-2018) |
| | Pharmacological Group | Ophthalmic surgical agents |
| | Type of Form | Form- 5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Could **not** be confirmed in the applied strength (1mg/ ml is approved in TGA, Australia) |
| | Me-too status | Hylo Eye Drop 2mg/ ml of M/s Helix (Reg. # 067031) |
| | GMP status | Last GMP inspection was conducted on 07-02-2018 and report concludes an acceptable level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | • General eye drops section is available in the firm as mentioned in the GMP inspection report.<br>• International availability could **not** be confirmed in the applied strength as 1mg/ ml is approved in TGA, Australia. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| **21.** | Name and address of manufacturer / Applicant | M/s Medisave Pharmaceuticals, Plot # 578-579, Sunder Industrial Estate, Raiwind Road, Lahore. |
| | Brand Name +Dosage Form + Strength | Ciprozan Infusion 400mg/ 100ml |
| | Composition | Each ml contains:<br>Ciprofloxacin as Lactate……4mg |
| | Diary No. Date of R& I & fee | Dy.No.16973;08-05-2018; Rs.20,000 DUPLICATE (21-05-2018) |
| | Pharmacological Group | Quinolone Antibiotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Not claimed |
| | Pack size & Demanded Price | 1's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Could not be confirmed |
| | Me-too status | Novidate DS 400mg/100ml Infusion of M/s Sami (Reg.#042270) |
| | GMP status | Last GMP inspection was conducted on 11-12-2017 & 10-01-2018 and GMP Certificate was issued on 15-03-2018. |
| | Remarks of the Evaluator [XIII] | • Firm has General Liquid Infusion (SVP) section.<br>• The official monograph for the applied formulation is available in USP.<br>• Internationally, the applied strength could **not** be confirmed. Available strength is 2mg/ml. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |

**Evaluator PEC-VII**

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| **22.** | Name and address of manufacturer / Applicant | M /s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, |
| | Brand Name +Dosage Form + Strength | Zegrid 40 mg capsule |
| | Composition | Each capsule contains:-<br>Omeprazole enteric coated pellets eq. to omeprazole……40mg |
| | Diary No. Date of R& I & fee | Dy. No.624; 6-1-2017; Rs. 20,000/- |
| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 14's/ As per SRO |

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| | Approval status of product in Reference Regulatory Authorities | Losec 40 mg hard gastro-resistant capsules by Astra Zeneca UK Ltd.(MHRA approved) |
| | Me-too status | Losec 40mg capsule by M/s Barrett Hodgson |
| | GMP status | Last GMP inspection was conducted on 6-aug-2018 and the report concludes issuance of GMP |
| | Remarks of Evaluator [VII] | • Source of pellets and related documents of M/S RA Chem pharma Ltd (Plot # A-19-C, A-23A & A-23-B road No. 18, IDA Nacharam Medchal-Malkajgiri district 5000076 telangana india). GMP is issued by Drug control administration gov of Telangana valid up to 2-4-2019.<br>• Stability data of pellets for 3 batches was provided |
| | **Decision: Deferred for submission of differential fee in case of import of pellets.** | |
| **23.** | Name and address of manufacturer / Applicant | M /s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, |
| | Brand Name +Dosage Form + Strength | Zegrid 20 capsule |
| | Composition | Each capsule contains:-<br>Omeprazole……20mg |
| | Diary No. Date of R& I & fee | Dy. No.623; 6-1-2017; Rs. 20,000/- |
| | Pharmacological Group | Proton Pump Inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 14's / As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Losec 20 mg hard gastro-resistant capsules 20mg by Astra Zeneca UK Ltd.(MHRA approved) |
| | Me-too status | Losec 20mg capsule by M/s Barrett Hodgson |
| | GMP status | Last GMP inspection was conducted on 6-aug-2018 and the report concludes issuance of GMP |
| | Remarks of Evaluator [VII] | • Source of pellets and related documents of M/S RA Chem pharma Ltd (Plot # A-19-C, A-23A & A-23-B road No. 18, IDA Nacharam Medchal-Malkajgiri district 5000076 telangana india). GMP is issued by Drug control administration gov of Telangana valid up to 2-4-2019.<br>• Stability data of pellets for 3 batches was provided |
| | **Decision: Deferred for submission of differential fee in case of import of pellets.** | |

**Evaluator PEC-XIV**

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| **24.** | Name and address of manufacturer / Applicant | M/s The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd, Kalawala Stop, 20Km Lahore Jaranwala Road, District Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | RAMIT 2.5mg Tablets |
| | Composition | Each tablet contains:<br>Ramipril ……2.5mg |
| | Diary No. Date of R& I & fee | 164, 20-07-2005, Rs.8000/-,(09-07-2005, photocopy), Rs.8000/-, 08-02-2019, Rs. 12,000/-, 07-05-2015 |
| | Pharmacological Group | ACE inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | BP specifications |
| | Pack size & Demanded Price | 3 × 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Tritace 2.5 mg (uncoated) Tablets by Aventis Pharma (MHRA Approved) |
| | Me-too status | Ramoril Tablets 2.5mg by Werrick Pharma (Reg# 027038) |
| | GMP status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | The firm has submitted duplicate dossier and as per record retrieved from R & I section forwarded by Reg-V section dated 12-02-2019 (attached with dossier) initial submission date of dossier has been verified as 20-07-2005. Moreover |

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| | | firm has submitted undertaking that the submitted fee challans/deposit slips willnot be misused. |
| | **Decision: Approved. Registration Board further decided to verify fee challan of Rs. 12,000/- as per decision of 285th meeting of Registration Board.** | |
| **25.** | Name and address of manufacturer / Applicant | M/s The Schazoo Pharmaceutical Laboratories (Pvt.) Ltd, Kalawala Stop, 20Km Lahore Jaranwala Road, District Sheikhupura, Pakistan |
| | Brand Name +Dosage Form + Strength | RAMIT 5mg Tablets |
| | Composition | Each tablet contains:<br>Ramipril ……5mg |
| | Diary No. Date of R& I & fee | 170, 20-07-2005, Rs.8000/-,(09-07-2005, photocopy), Rs.12,000/-, 07-05-2015, Rs.8000, 08-02-2019. |
| | Pharmacological Group | ACE inhibitor |
| | Type of Form | Form-5 |
| | Finished product Specification | BP specifications |
| | Pack size & Demanded Price | 3 × 10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Tritace 5 mg (uncoated) Tablets by Aventis Pharma (MHRA Approved) |
| | Me-too status | Hyperace Tablets 5mg by Werrick Pharm (Reg#015230) |
| | GMP status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | The firm has submitted duplicate dossier and as per record retrieved from R & I section forwarded by Reg-V section dated 12-02-2019 (attached with dossier) initial submission date of dossier has been verified as 20-07-2005. Moreover firm has submitted undertaking that the submitted fee challans/deposit slips willnot be misused. |
| | **Decision: Approved. Registration Board further decided to verify fee challan of Rs. 12,000/- as per decision of 285th meeting of Registration Board.** | |
| **26.** | Name and address of manufacturer / Applicant | M/s NOA HEMIS Pharmaceuticals, Plot No.154, Sector-23, Korangi Industrial Area Karachi |
| | Brand Name +Dosage Form + Strength | TEVOSOL-D TABLET |
| | Composition | Each tablet contains:<br>Levosulpiride …… 100mg |
| | Diary No. Date of R& I & fee | 32941, 03-10-2018, Rs.20,000/-, 17-08-2018 |
| | Pharmacological Group | Antipsychotic |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 10's; 20's, 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | LEVOPRAID 100mg tablet (AIFA Italy Approved) |
| | Me-too status | Evosol 100mg Tablets of M/s Bio labs (Reg # 054757) |
| | GMP status | Last GMP Inspection dated 17-11-16 with conclusive remarks of cGMP compliance. |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board was apprised that the same formulation applied by firm with brand name of "Evox tablet" was previously rejected in 251st meeting of Registration Board since formulation is not approved by reference regulatory authority as per decision of 250th Meeting Registration Board. Later the Registration Board approved the "Levosulpride 25mg tablets" on the basis of reference product approved by AIFA of Italy, hence the above application is considered on priority.**<br>**Approved with innovator's specification.** | |
| **27.** | Name and address of manufacturer / Applicant | M/s NOA HEMIS Pharmaceuticals, Plot No.154, Sector-23, Korangi Industrial Area Karachi |
| | Brand Name +Dosage Form + Strength | TEVOSOL TABLET |
| | Composition | Each tablet contains:<br>Levosulpiride……50mg |
| | Diary No. Date of R& I & fee | 32940, 03-10-2018, Rs.20,000/-, 17-08-2018 |
| | Pharmacological Group | Antipsychotic |

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| | Type of Form | Form-5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 10's; 20's, 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | LEVOPRAID 50mg tablet (AIFA Italy Approved) |
| | Me-too status | Sulvoric 50mg Tablet of High-Q (Reg # 070485) |
| | GMP status | Last GMP Inspection dated 17-11-16 with conclusive remarks of cGMP compliance. |
| | Remarks of the Evaluator. | Registration Board Rejected the formulation since formulation is not approved by reference regulatory authority as per decision of 250th Meeting Registration Board **(M-251).** |
| | **Decision: Registration Board was apprised that the same formulation applied by firm with brand name of "Evox tablet" was previously rejected in 251st meeting of Registration Board since formulation is not approved by reference regulatory authority as per decision of 250th Meeting Registration Board. Later the Registration Board approved the "Levosulpride 25mg tablets" on the basis of reference product approved by AIFA of Italy, hence the above application is considered on priority.**<br>**Approved with innovator's specification.** | |
| **28.** | Name and address of manufacturer / Applicant | M/s Lahore Chemical and Pharmaceutical Works (Pvt.) Ltd., 137-Ferozepur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | MEERA TABLET 25mg |
| | Composition | Each extended release tablet contains: Mirabegron…….25mg |
| | Diary No. Date of R& I & fee | Duplicate, 10-02-2016, 20,000/-, 10-02-2016 |
| | Pharmacological Group | Beta-3 adrenergic agonist |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specs |
| | Pack size & Demanded Price | Rs. 100 per tablet Rs. 3000 per pack of 30 tablets |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA(as extended release tablet ) |
| | Me-too status | Could not be confirmed. |
| | GMP status | • GMP inspection dated 26-06-2018 concluded as:<br>• The panel visited the premises of M/s. Lahore Chemical & Pharmaceutical works (Pvt.) Lahore and discussed the matter in detail with the management. The management agreed that the production of cephalosporin capsule and dry powder suspension will remain stopped till the development of self-contained and segregated facilities, as the management has already submitted the revised layout plan to the DRAP.<br>• The management informed that they had not got any quota of narcotic substance for manufacturing of their registered injectable. Hence they agreed that till the development of narcotic injectable area, they will not start the production. The management also agreed to discontinue the production of steroidal/hormonal injectable drugs, which were registered in their favour, till the development of new steroidal/hormonal injectable areas, as they were in the process of development thereof.<br>• Keeping in view the other proceedings of the inspection with regard to the areas inspected, building, documentation, testing facilities, sanitation, hygiene of the workers, storage facilities etc., the panel of inspectors is of the opinion that the firm was operating at the satisfactory level of GMP as per Drugs Act, 1976 and rules framed there under. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith 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 278th meeting of Registration Board.** | |

| | | |
|---|---|---|
| **29.** | Name and address of manufacturer / Applicant | M/s Lahore Chemical and Pharmaceutical Works (Pvt.) Ltd., 137-Ferozepur Road, Lahore. |
| | Brand Name +Dosage Form + Strength | MEERA TABLET 50mg |
| | Composition | Each extended release tablet contains: Mirabegron…….50mg |
| | Diary No. Date of R& I & fee | Duplicate, 10-02-2016, 20,000/-, 10-02-2016 |
| | Pharmacological Group | Beta-3 adrenergic agonist |
| | Type of Form | Form-5 |
| | Finished product Specification | In-house specs |
| | Pack size & Demanded Price | Rs. 166.66 per tablet Rs. 5000 per pack of 30 tablets |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA(as extended release tablet ) |
| | Me-too status | Could not be confirmed. |
| | GMP status | • GMP inspection dated 26-06-2018 concluded as:<br>• The panel visited the premises of M/s. Lahore Chemical & Pharmaceutical works (Pvt.) Lahore and discussed the matter in detail with the management. The management agreed that the production of cephalosporin capsule and dry powder suspension will remain stopped till the development of self-contained and segregated facilities, as the management has already submitted the revised layout plan to the DRAP.<br>• The management informed that they had not got any quota of narcotic substance for manufacturing of their registered injectable. Hence they agreed that till the development of narcotic injectable area, they will not start the production. The management also agreed to discontinue the production of steroidal/hormonal injectable drugs, which were registered in their favour, till the development of new steroidal/hormonal injectable areas, as they were in the process of development thereof.<br>• Keeping in view the other proceedings of the inspection with regard to the areas inspected, building, documentation, testing facilities, sanitation, hygiene of the workers, storage facilities etc., the panel of inspectors is of the opinion that the firm was operating at the satisfactory level of GMP as per Drugs Act, 1976 and rules framed there under. |
| | Remarks of the Evaluator. | |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith 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 278th meeting of Registration Board.** | |
| **30.** | Name and address of manufacturer / Applicant | M/s Benson Pharmaceuticals, Plot 3 (Main Road), National Industrial Zone, Rawat |
| | Brand Name +Dosage Form + Strength | ORS Powder |
| | Composition | Each sachet contains:<br>Potassium chloride…….1.50g<br>Sodium chloride……....2.69g<br>Dextrose anhydrous……9.91g<br>Tri-sodium citrate……..2.90g |
| | Diary No. Date of R& I & fee | 310, 02-01-2019, 20,000/-, 02-01-2019 |
| | Pharmacological Group | Oral Rehydration Therapy |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | WHO approved formulation |
| | Me-too status | Peditral Low Sachet of Searle Pakistan<br>Each Sachet contains:<br>Anhydrous Glucose……..13.5g |

| | | |
|---|---|---|
| | | Tri sodium citrate dihydrate……..2.9g<br>Sodium chloride…….2.6g<br>Potassium chloride…….1.5g<br>Me-too is different in quantity of Dextrose anhydrous. |
| | GMP status | Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance. |
| | Remarks of the Evaluator. | • The firm hs been granted new Sachet section under re-grant of DML at new manufacturing site.<br>• The firm has submitted duplicate dossier and record retrieved from R & I section via receiving register. |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |

## b. Deferred cases

**Evaluator PEC-IX**

| | | |
|---|---|---|
| **31.** | Name and address of manufacturer / Applicant | M/s Fozan Pharmaceutical. 36-A, Industrial Estate, Hayatabad, Peshsawar. Contract Manufacturing by: M/s Welwrd Pharmaceuticals, Plot # 3, Block_A, PhaseI-II, Hattar Industrial Estate, Hattar |
| | Brand Name +Dosage Form + Strength | KORS Injection 2g |
| | Composition | Each vial contains:<br>Cefoperazone as sodium…1g<br>Sulbactam as sodium…..1g |
| | Diary No. Date of R& I & fee | Dy No. 26824: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins and beta-lactamase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia |
| | Me-too status | Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027 |
| | GMP status | Inspection of M/s Wellwrd Pharma was conducted on 12.11.2018, wherein the following sections of the firm were considered to be operating at satisfactory level of GMP.<br>i) Tablet Section (General/antibiotics)<br>ii) Liquid injectable section (General/antibiotics)<br>iii) Dry injectable section (General/antibiotics)<br>iv) Dry powder injectable (cephalosporins)<br>While the remaining sections viz Capsule general, dry powder suspension general and Sachet sections were observed with certain shortcomings that need to be rectified. |
| | Remarks of the Evaluator. | • The firm has submitted list of six (**06**) approved products for contract manufacturing.<br>• The firm has submitted list of eleven (**11**) products applied for contract manufacturing.<br>• Latest GMP inspection report of manufacturer, M/s Fozan Pharmaceutical shows that the firm has seven (**07**) approved section. |
| | Previous decision | • The Board in its 287th meeting deferred the case for correction of label claim. |
| | Evaluation by PEC | • The firm submitted revised Form 5 with corrected label claim; however, Form 5 has been signed by Managing Director of M/s Welwrd Pharmaceuticals (Manufacturer) rather than M/s Fozan Pharma (the applicant). |
| | • **Decision: Deferred for correction of Form-5 as Form 5 has been signed by Managing Director of M/s Welwrd Pharmaceuticals (Manufacturer) rather than M/s Fozan Pharma (the applicant).** | |

**Evaluator PEC-XIII**

| | | |
|---|---|---|
| **32.** | Name and address of manufacturer / Applicant | M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad |
| | Brand Name +Dosage Form + Strength | Ensulid tablet 100mg |
| | Composition | Each film-coated tablet contains:<br>Nimesulide……...100mg |
| | Diary No. Date of R& I & fee | Dy.No.26661; 29-12-2017;Rs.20,000/(29-12-2017) |
| | Pharmacological Group | Selective Cox-2 Inhibitor |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 2 x 10's & as per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in Italy as uncoated tablet |
| | Me-too status | Nims uncoated tablet of M/s Sami Pharma (Reg. # 026657) |
| | GMP status | Last GMP inspection was conducted on 07-12-2017 and the report concludes good compliance. |
| | Previous remarks of the Evaluator | • The firm has applied film-coated while it is approved in reference regulatory authority (Italy) as uncoated tablet.<br>• No USP or BP monograph is available for the applied formulation. |
| | Previous decision | Deferred in 286th meeting for submission of evidence of approval of applied formulation as "film-coated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee. |
| | Evaluation by PEC | • Firm has submitted its reference as Aulin 100mg film-coated tablet of M/s CSC Pharma (Austria) which could not be verified as film-coated formulation.<br>• Instead the applied formulation is approved as uncoated in ANSM (France), Italy, EMA and Austria. |
| | **Decision: Registration board deferred the case for further deliberation since the product approved by reference regulatory authorities is uncoated while the applied formulation is film coated tablet** | |

**Evaluator PEC-XIV**

| **Fresh application applied as replacement** | | |
|---|---|---|
| **33.** | Name and address of manufacturer / Applicant | M/s Delta Pharma (Pvt) Ltd 9-Nowshera Industrial Estate, (SIZ) Risalpur |
| | Brand Name +Dosage Form + Strength | Dardnil 50mg Tablet |
| | Composition | Each film coated tablet contains:<br>Diclofenac potassium……...50mg |
| | Diary No. Date of R& I & fee | 5447, 07-02-2019, 20,000/-, 07-02-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Dicota 50 Tablet of M/s Linz Karachi, (Reg.# 073524) |
| | GMP status | CLB in its 256th meeting held on 9th-10th November 2017 has considered and approved the grant of DML (Afresh) by way of formulation. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Registration Board deferred the case for submission of evidence of approval status in Reference Regulatory Authorities. (M-278) |
| | Evaluation by PEC | |
| | **Decision: Approved.** | |

| | | |
|---|---|---|
| **Previously Deferred case (M-278)** | | |
| | Name and address of manufacturer / Applicant | M/s Delta Pharma (Pvt) Ltd 9-Nowshera Industrial Estate, (SIZ) Risalpur |
| | Brand Name +Dosage Form + Strength | Dardnil 75mg Tablet |
| | Composition | Each film coated tablet contains:<br>Diclofenac potassium……..75mg |
| | Diary No. Date of R& I & fee | Dy.No.98, 23-01-18, 20,000/-, 22-01-2018 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form-5 |
| | Finished product Specification | USP specifications |
| | Pack size & Demanded Price | Rs.100/20's |
| | Approval status of product in Reference Regulatory Authorities. | TGA approved. |
| | Me-too status | Caflam by M/s. Novartis Pharma |
| | GMP status | Provided reference could not be verified. |
| | Decision: **Registration Board acceded the firm's request and decided to reject Dardnil 75mg Tablet** | |
| **Fresh application Applied as Replacement** | | |
| **34.** | Name and address of manufacturer / Applicant | M/s Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-k Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | RAKADINE TABLET |
| | Composition | Each tablet contains:<br>Paracetamol……500mg<br>Codeine Phosphate……15mg |
| | Diary No. Date of R& I & fee | 40285, 05-12-2018, 20,000/-, 04-12-2018, |
| | Pharmacological Group | Opioid analgesic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 100's in Blister pack provided in box ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Codipar 15mg/500mg Tablets by M/s Mercury Pharmaceuticals Ltd (MHRA Approved) |
| | Me-too status | Freingesic Tablet 15mg/500mg by M/s Friends Pharma (Pvt.) Ltd. (Reg#060315) |
| | GMP status | The firm was conducted panel inspection dated 19-09-2018 which recommended the grant of cGMP certificate to firm. |
| | Remarks of Evaluator | |
| | Previous Decision | Registered Board deferred the application since applied formulation is not Psychotropic, and firm has applied to manufacture it in Tablet section (Psychotropic) Section **(M-287).** |
| | Evaluation by PEC | • |
| | **Decision: Approved.** | |
| **Previously Deferred Case (M-287)** | | |
| | Name and address of manufacturer / Applicant | M/s Rakaposhi Pharmaceutical (Pvt.) Ltd. 97-k Industrial Estate, Hayatabad, Peshawar, Pakistan |
| | Brand Name +Dosage Form + Strength | Rakanac Forte 400/60 mg Tablet |
| | Composition | Form-5 Dy.#38937 (27-11-2018) Rs.20,000/- Dated 27-11-2018 |
| | Diary No. Date of R& I & fee | Each Uncoated Tablet Contains:<br>Ibuprofen…400mg<br>Pseudoephedrine HCl…60mg |
| | Pharmacological Group | Analgesic/Antihistamine |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 2x10's/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Lasynac Max Strength 400mg/60mg film coated tablets (MHRA) |
| | Me-too status | Panadol CF Tablet by M/s GSK (Reg#013113) |

| | | |
|---|---|---|
| | GMP status | The firm was conducted panel inspection dated 19-09-2018 which recommended the grant of cGMP certificate to firm. |
| | Decision: **Registration Board aceeded the firm's request and decided to reject Rakanac Forte 400/60 mg Tablet.** | |
| **35.** | Name and address of manufacturer / Applicant | M/s NabiQasim Industries (Private) Limited, 17/24, Korangi Industrial Area, Korangi, Karachi |
| | Brand Name +Dosage Form + Strength | Loprot Insta Sachet |
| | Composition | Each sachet contains:<br>Omeprazole ……..20 mg<br>Sodium Bicarbonate (as Buffer)……1680 mg |
| | Diary No. Date of R& I & fee | Dy.No.1332, 14-7-2010 Rs.8000/- + Rs 12,000/- (14-5-2013) (Photo copy) |
| | Pharmacological Group | Anti Ulcerant |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 7's, 10's; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Zegerid (USFDA Approved) |
| | Me-too status | Omega rapid (Ferozesons) |
| | GMP status | GMP status Last inspection conducted on 03-08-2017 and 02-11-2017 reports conclude that firm is found GMP compliant. . |
| | Previous remarks of the Evaluator. | Firm has submitted copy of inspection report conducted on 03-08-2017 concluding acceptable of GMP compliance. |
| | Previous decision(s) | Deferred for following: (M-273)<br>Registration Board was apprised of the observations related to GMP made by panel of inspection for the product SOVIR-C 400mg tablet and as recorded in inspection report (dated: 01-04-2017). The observations in the GMP inspection report of area FID, dated 03.08.2017 was also considered. Registration Board deferred the case for clarification from QA< Division regarding GMP status of the firm in the light of observations made by the panel of inspection for the product SOVIR-C 400mg tablet and those recorded by area FID in inspection report dated 03-08-2017. Moreover, clarification shall be obtained from firm regarding use of sodium bicarbonate as buffer.<br>Deferred for clarification of use of Sodium bicarbonate as buffer in the applied formulation (M-278) |
| | Evaluation by PEC | The firm has submitted following:<br>Loprot Insta contains an immediate release formulation of Omeprazole combined with antacid buffer (sodium bicarbonate), which neutralizes gastric acid and protects Omeprazole from gastric acid degradation. At neutral pH, Omeprazole is chemically stable. Omeprazole is acid labile and destroy rapidly as pH falls (e. g., by gastric acid) thus, it is important that drug should not be exposed to low pH gastric acid prior to absorption. Wherein the dosage form, Omeprazole is not enteric coated and is devoid of any delayed-release or sustained release delivery mechanism thus Omeprazole will exposed to degradation by gastric acid in the stomach.<br>Sodium bicarbonate is an antacid that raises the pH in stomach by reducing gastric acid to keep the Omeprazole from breaking down in stomach and helps Omeprazole to work better |
| | **Decision: Approved with innovator's specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| **36.** | Name and address of manufacturer / Applicant | M/s NabiQasim Industries (Private) Limited, 17/24, Korangi Industrial Area, Korangi, Karachi |
| | Brand Name +Dosage Form + Strength | Loprot Insta Sachet |
| | Composition | Each sachet contains:<br>Omeprazole ……..40 mg Sodium |

| | | |
|---|---|---|
| | | Bicarbonate (as Buffer)….1680 mg |
| | Diary No. Date of R& I & fee | Dy.#1331 (14-7-2010) Rs.8000/-+Rs.12,000/- (14-5-2013) (Photo copy) |
| | Pharmacological Group | Anti Ulcerant |
| | Type of Form | Form 5 |
| | Finished product Specification | Manufacturer specifications |
| | Pack size & Demanded Price | 7‘s, 10‘s; As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Zegerid (USFDA Approved) |
| | Me-too status | Omega Rapid (Ferozsons) |
| | GMP status | GMP status Last inspection conducted on 03-08-2017 and 02-11-2017 reports conclude that firm is found GMP compliant. . |
| | Previous remarks of the Evaluator. | Firm has submitted copy of inspection report conducted on 03-08-2017 concluding acceptable of GMP compliance. |
| | Previous decision(s) | Deferred for following: **(M-273)**<br>Registration Board was apprised of the observations related to GMP made by panel of inspection for the product SOVIR-C 400mg tablet and as recorded in inspection report (dated: 01-04-2017). The observations in the GMP inspection report of area FID, dated 03.08.2017 was also considered. Registration Board deferred the case for clarification from QA< Division regarding GMP status of the firm in the light of observations made by the panel of inspection for the product SOVIR-C 400mg tablet and those recorded by area FID in inspection report dated 03-08-2017. Moreover, clarification shall be obtained from firm regarding use of sodium bicarbonate as buffer.<br>Deferred for clarification of use of Sodium bicarbonate as buffer in the applied formulation **(M-278)** |
| | Evaluation by PEC | The firm has submitted following:<br>**Loprot Insta** contains an immediate release formulation of Omeprazole combined with antacid buffer (sodium bicarbonate), which neutralizes gastric acid and protects Omeprazole from gastric acid degradation. At neutral pH, Omeprazole is chemically stable. Omeprazole is acid labile and destroy rapidly as pH falls (e. g., by gastric acid) thus, it is important that drug should not be exposed to low pH gastric acid prior to absorption. Wherein the dosage form, Omeprazole is not enteric coated and is devoid of any delayed-release or sustained release delivery mechanism thus Omeprazole will exposed to degradation by gastric acid in the stomach.<br>Sodium bicarbonate is an antacid that raises the pH in stomach by reducing gastric acid to keep the Omeprazole from breaking down in stomach and helps Omeprazole to work better |
| | **Decision: Approved with innovator’s specification. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.** | |
| **37.** | Name and address of manufacturer / Applicant | "M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi" |
| | Brand Name +Dosage Form + Strength | Kay Gone 10gm Sachet |
| | Composition | Each Sachet Contains:<br>Sodium Polystyrene Sulfonate…10gm |
| | Diary No. Date of R& I & fee | Dy.No 24563 (16-07-2018) Rs.20,000/- Dated 16-07-2018 |
| | Pharmacological Group | Ion-exchange resin |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer’s specifications |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA as 454gm per bottle |
| | Me-too status | - |

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|---|---|---|
| | GMP status | Last GMP inspection report dated 23-02-2018 concluding as under:<br>"Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Pharm Evo Pvt. Ltd. Karachi was considered to be operating at acceptable level of compliance with GMP standards as today." |
| | Remarks of the Evaluator[2] | Evidence of Me-too status required. |
| | Previous Decision of 286th 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 or else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board. |
| | Evaluation by PEC | • Firm has submitted 36 months long term & 6 months accelerated stability study reports of three batches of "Polystyrene Sulphonate" from the supplier i.e., M/s Phaex polymers Pvt. Ltd., Maharashtra, India.<br>• Moreover firm has submitted following undertaking:<br>"We, PharmEvo (Pvt) Limited do hereby undertake that we will provide real time stability studies of (Sodium Polystyrene Sulphonate USP according to stability protocol till assigned shelf life of the product." |
| | **Decision: Deferred for application on Form 5-D along with submission of differential fee and stability study data by the finished product manufacturer as per the requirements of 278th meeting of Registration Board.** | |
| **38.** | Name and address of manufacturer / Applicant | M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi |
| | Brand Name +Dosage Form + Strength | K-Plus 10% Oral Solution |
| | Composition | "Each 5ml Solution for Oral Administration Contains:<br>Potassium Chloride…500mg" |
| | Diary No. Date of R& I & fee | Dy.#24565 dated 16-07-2018 Rs.20,000/- Dated 16-07-2018 |
| | Pharmacological Group | Electrolyte |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | As per PRC |
| | Approval status of product in Reference Regulatory Authorities. | |
| | Me-too status | |
| | GMP status | Last GMP inspection report dated 23-02-2018 concluding as under:<br>"Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Pharm Evo Pvt. Ltd. Karachi was considered to be operating at acceptable level of compliance with GMP standards as today." |
| | Remarks of the Evaluator[2] | Firm has submitted revised form 5 with following composition:<br>"K-Plus syrup 1gm/5ml<br>Each 5 ml syrup contains:<br>Potassium Chloride …. 1gm".<br>Following me too reference has been verified against revised formulation:<br>Potassium chloride syrup of M/s Specific Karachi (Reg.#003198)<br>Firm has submitted reference of Kay-CEE –L Syrup approved by MHRA of UK against revised composition which is of different strength i.e. 0.3727gm per 5ml. |
| | Previous Decision of 286th meeting: | Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting. |

| | | |
|---|---|---|
| | Evaluation by PEC | **Firm has submitted as under:**<br>"With reference to our submitted product **POTASSIUM CHLORIDE**, we would like to draw your kind attention towards the fact that the 10% strength will supply 20 mEq of Potassium Chloride whereas 20% strength will supply 40 mEq of Potassium Chloride; it may be diluted with water or any other liquid. The usual dietary intake of Potassium Chloride is 50 to 100 mEq per day.<br><br>We understand that there is no safety or efficacy concern with respect the concentration of dilution as both the dilution supply Potassium Chloride less than usual daily intake. The product may be registered either with 10% or 20% Solution. Furthermore, internationally, it is available in both 10% and 20% dilutions.\|" |
| | **Decision: Deferred for following:**<br>• **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** | |

## Case No.: 02 Registration applications of newly granted DML or New section (Human)

### a. New DML

**Evaluator PEC-XII**

**Case. No. M/s Avensis Pharmaceuticals, Karachi. (New Licence)**

CLB in its 267th meeting held on 31st Dec, 2018 has considered and approved the grant of DML to Avensis Pharmaceuticals by way of Formulation with following nine sections:
i. Capsule (General) Section
ii. Sachet (General) Section
iii. Liquid Ampoule & Vial (General) Section
iv. SVP Infusion (General) Section
v. Dry Powder Injection (Cephalosporin) Section
vi. Tablet (Psychotropic) Section
vii. Liquid Ampoule (Psychotropic) Section
viii. Dry Powder Suspension (Cephalosporin) Section
ix. Capsule (Cephalosporin) Section
Accordingly DML has been issue by secretary CLB vide letter no. F.2-6/2017-Lic. Dated 08-01-2019. Number of DML: 000894
Following applications applied by firm are hereby presented for consideration of Board.

| Sr. No | Section | No. of products | No. of molecules |
|---|---|---|---|
| 1 | Capsule (General) Section | 0 | 0 |
| 2 | Sachet (General) Section | 0 | 0 |
| 3 | Liquid Ampoule & Vial (General) Section | 6 | 3 |
| 4 | SVP Infusion (General) Section | 1 | 1 |
| 5 | Dry Powder Injection (Cephalosporin) Section | 4 | 1 |
| 6 | Tablet (Psychotropic) Section | 20 | 8 |
| 7 | Liquid Ampoule (Psychotropic) Section | 5 | 5 |
| 8 | Dry Powder Suspension (Cephalosporin) Section | 2 | 1 |
| 9 | Capsule (Cephalosporin) Section | 0 | 0 |

**Liquid Ampoule & Vial (General) Section:**
**06 product/ 03 molecule**

| | | |
|---|---|---|
| **39.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Water For Injection 5ml |
| | Diary No. Date of R & I & fee | Dy No. 5748: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 5ml ampoule contains:<br>Sterile Water For injection …5ml |
| | Pharmacological Group | Diluent |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Pfizer (Perth) WATER FOR INJECTION 10mL BP ampoule by M/s Pfizer Australia Pty Ltd (TGA Approved) |
| | Me-too Status | Aqua Pro Injection 5ml (ampoule) by Mass Pharma (Reg#020875) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **40.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Water For Injection 10ml |
| | Diary No. Date of R & I & fee | Dy No. 5752: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 10ml ampoule contains:<br>Sterile Water For injection …10ml |
| | Pharmacological Group | Diluent |
| | Type of Form | Form 5 |

| | | |
|---|---|---|
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Pfizer (Perth) WATER FOR INJECTION 10mL BP ampoule by M/s Pfizer Australia Pty Ltd (TGA Approved) |
| | Me-too Status | Water for Injection 10ml (ampoule) by Healthtek Karachi (Reg#076482) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **41.** | Name and Address of Manufacturer / Applicant | **M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi** |
| | Brand Name + Dosage Form + Strength | **Avevil Injection 45.4mg/2ml** |
| | Diary No. Date of R & I & fee | Dy No. 5808: 11-02-2019 PKR 20,000/-: 11-02-2019 |
| | Composition | Each 2ml ampoule contains:<br>Pheniramine maleate…45.4ml |
| | Pharmacological Group | Antihistamine |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 50's, 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Not confirmed |
| | Me-too Status | Zafvil Injection of Zafa Pharmaceuticals (Reg#030637) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Approval Status of Product in Reference Regulatory Authorities not confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| **42.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Xylosis 1%w/v injection 2ml |
| | Diary No. Date of R & I & fee | Dy No. 5807: 11-02-2019 PKR 20,000/-: 11-02-2019 |
| | Composition | Each 2ml ampoule contains:<br>Lidocaine hydrochloride…1%w/v |
| | Pharmacological Group | Anesthetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Lidocaine Hydrochloride solution for Injection 1% w/v of M/s Accord Health Care, UK (MHRA Approved) |
| | Me-too Status | Lidocaine 1% Injection of M/s Zafa Pharmaceuticals (Reg. # 030216) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **43.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Xylosis 2%w/v injection 2ml |
| | Diary No. Date of R & I & fee | Dy No. 5806: 11-02-2019 PKR 20,000/-: 11-02-2019 |
| | Composition | Each 2ml ampoule contains:<br>Lidocaine hydrochloride…40mg (2%w/v) |
| | Pharmacological Group | Anesthetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |

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| | Approval Status of Product in Reference Regulatory Authorities. | Lignocaine-Claris lidocaine (lignocaine) hydrochloride 40 mg/2 mL solution for injection, ampoule of M/s Baxter Healthcare Pty Ltd (TGA Approved) |
| | Me-too Status | Lignox 2% Injection (2ml) of M/s Novamed (Reg. # 076968) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **44.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Xylosis 2%w/v injection 10ml |
| | Diary No. Date of R & I & fee | Dy No. 5807: 11-02-2019 PKR 20,000/-: 11-02-2019 |
| | Composition | Each 10ml ampoule contains:<br>Lidocaine hydrochloride…200mg (2%w/v) |
| | Pharmacological Group | Anesthetic |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Lignocaine-Claris lidocaine (lignocaine) hydrochloride 40 mg/2 mL solution for injection, ampoule of M/s Baxter Healthcare Pty Ltd (TGA Approved) |
| | Me-too Status | Adcaine 2% Injection (10ml) of M/s Ameer & Adnan Pharmaceuticals (Reg. # 78638) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **SVP Infusion (General) Section:<br>01 product/ 01 molecule** | | |
| **45.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Avedol Infusion 1000mg/100ml |
| | Diary No. Date of R & I & fee | Dy No. 5151: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 100ml vial contains:<br>Paracetamol …1000mg |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 1'Ss/As per DRAP Policy |
| | Approval Status of Product in Reference Regulatory Authorities. | PERFALGAN 10 mg/ml solution for infusion (Vial) by M/s Bristol-Myers Squibb Pharmaceuticals Ltd (MHRA approved) |
| | Me-too Status | Panam Infusion 1gm by M/s English Pharma. (Reg.# 067999) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovator's specifications.** | |
| **Dry Powder Injection (Cephalosporin) Section:<br>04 product/ 01 molecule** | | |
| **46.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Axis 2g IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 4626: 01-02-2019 PKR 20,000/-: 01-02-2019 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …2gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1's /As per DRAP policy |

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|---|---|---|
| | Approval Status of Product in Reference Regulatory Authorities. | Ceftriaxone 2 g Powder for Solution for Injection/Infusion (IV) by Sandoz Limited (MHRA Approved) |
| | Me-too Status | Cesod 2000mg IV Injection by M/s Amson (Reg#052403) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **47.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | Axis 1g IV Injection |
| | Diary No. Date of R & I & fee | Dy No. 4628: 01-02-2019 PKR 20,000/-: 01-02-2019 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …1gm |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IV 1 g Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 1000mg IV Injection by M/s ROCHE (Reg#008436) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **48.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Axis 500mg IV Injection** |
| | Diary No. Date of R & I & fee | Dy No. 4630: 01-02-2019 PKR 20,000/-: 01-02-2019 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …500mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IV 500 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 500mg IV Injection by M/s ROCHE (Reg#008435) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **49.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Axis 250mg IV Injection** |
| | Diary No. Date of R & I & fee | Dy No. 4627: 01-02-2019 PKR 20,000/-: 01-02-2019 |
| | Composition | Each Vial contains:<br>Ceftriaxone (as sodium) …250mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 1's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Rocephin IV 250 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved) |
| | Me-too Status | Rocphin 250mg IV Injection by M/s ROCHE (Reg#008433) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

| Tablet (Psychotropic) Section: 20 product/ 08 molecule | | |
|---|---|---|
| **50.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Xalax 0.25 mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4151: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Alprazolam …0.25mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Xanax 250 microgram Tablets by M/s Pfizer Limited (MHRA Approved) |
| | Me-too Status | Alprazolam 0.25mg Tablets by M/s Heal Pharmaceuticals (Reg#079390) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **51.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Xalax 0.5 mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4150: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Alprazolam …0.5mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Xanax 500 microgram Tablets by M/s Pfizer Limited (MHRA Approved) |
| | Me-too Status | Alprazolam 0.5mg Tablets by M/s Heal Pharmaceuticals (Reg. # 079391) |
| | GMP Status | 28-11-2018<br>Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **52.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Xalax 1mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4152: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Alprazolam …1mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Alprazolam Mylan 1 mg, tablet by M/s Mylan Sas (ANSM France Approved) |
| | Me-too Status | Alprazolam 1 mg Tablets by M/s Heal Pharmaceuticals (Reg.# 079392) |
| | GMP Status | 28-11-2018<br>Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |

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| **53.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Xalax 2mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4153: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Alprazolam …2mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | ALPRAZOLAM 2 mg TABLETS, USP by M/s JAMP Pharma Corporation (Health Canada Approved) |
| | Me-too Status | Pranax 2 mg Tablets by M/s Aries Pharma (Reg#079370) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **54.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Lexotil 1.5mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4145: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Bromazepam …1.5mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 30's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | APO-BROMAZEPAM - TAB 1.5MG by APOTEX INC. (Health Canada approved.) |
| | Me-too Status | Lexilium 1.5mg tablet by SAMI |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with Innovators specifications.** | |
| **55.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Lexotil 3mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4144: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Bromazepam …3mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 30's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | LEXOTAN bromazepam 3mg tablet by Roche. (TGA approved.) |
| | Me-too Status | Broma 3mg tablet of M/s Pharmacare (Reg. # 015610) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| **56.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Lexotil 6mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4146: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Bromazepam …6mg |
| | Pharmacological Group | Benzodiazepine Derivative |

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| | Type of Form | Form-5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 30's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | LEXOTAN bromazepam 6mg tablet by Roche. (TGA approved.) |
| | Me-too Status | Mazimax 6mg tablet of M/s Nova Med (Reg. # 054139) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| **57.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **RIVO 0.5mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4162: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Clonazepam …0.5mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's, 50's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Clonazepam Auden 500mcg Tablets by M/s Auden Mckenzie (Pharma Division) Ltd (MHRA Approved) |
| | Me-too Status | Tovir 0.5mg Tablet by M/s Adamjee (Reg#080335) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **58.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **RIVO 1mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4161: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Clonazepam …1mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's, 50's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Klonopin Tablets 1mg by M/s Roche (USFDA Approved) |
| | Me-too Status | Curo 1mg Tablets by M/Wilshire Laboratories (Pvt) Ltd (Reg#065700) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **59.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **RIVO 2mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4149: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Clonazepam …2mg |
| | Pharmacological Group | Benzodiazepine Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30's, 50's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Clonazepam Auden 2mg Tablets by M/s Auden Mckenzie (Pharma Division) Ltd (MHRA Approved) |
| | Me-too Status | Tovir 2mg Tablet by M/s Adamjee (Reg#080336) |

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| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **60.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **D.PAM 2mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4159: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Diazepam …2mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 30's, 1000's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Diazepam 2 mg Tablets by M/s TEVA UK Limited (MHRA Approved) |
| | Me-too Status | DIAZEPAM 2mg Tablet by M/s Heal Pharmaceutical (Reg#079395) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **61.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **D.PAM 5mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4158: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Diazepam …5mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 30's, 1000's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Diazepam 5 mg Tablets by M/s TEVA UK Limited (MHRA Approved) |
| | Me-too Status | Dipam tablet 5mg by M/s Leads Pharma Pvt Ltd (Reg#065299) |
| | GMP Status | 28-11-2018<br>Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **62.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **D.PAM 10mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4160: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Diazepam …10mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 30's, 1000's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Diazepam 10mg Tablets by M/s TEVA UK Limited (MHRA Approved) |
| | Me-too Status | Dipam tablet 10mg by M/s Leads Pharma Pvt Ltd (Reg#065300) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

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| **63.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | AVENAC 200mg/30mg Tablet |
| | Diary No. Date of R & I & fee | Dy No. 4147: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each film-coated tablet contain:<br>Ibuprofen …200mg<br>Pseudoephedrine hydrochloride …30mg |
| | Pharmacological Group | NSAID in combination with Sympathomimetic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | SOUL Pattinson Decongestant and Sinus Pain Relief tablet by Soul Pattinson Manufacturing Pty Ltd. (TGA approved) |
| | Me-too Status | Dolocol Tablets by Semos Pharmaceuticals (Reg#028203) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board rejected the application since firm does not have required section i.e Tablet (General) Section.** | |
| **64.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **AVENAC Forte 400mg/60mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4148: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each film-coated tablet contain:<br>Ibuprofen …400mg<br>Pseudoephedrine hydrochloride …60mg |
| | Pharmacological Group | NSAID in combination with sympathomimetic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Lasynac Max Strength 400mg/60mg film coated tablets (MHRA approved) |
| | Me-too Status | Irofen Forte Tablets of M/Searle Pakistan (Reg.#042233) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board rejected the application since firm does not have required section i.e Tablet (General) Section.** | |
| **65.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Lomosis 2.5mg/0.025mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4632: 01-02-2019 PKR 20,000/-: 01-02-2019 |
| | Composition | Each tablet contain:<br>Diphenoxylate hydrochloride …2.5mg<br>Atropine sulfate …0.025mg |
| | Pharmacological Group | Antipropulsive in combination with Anticholinergic (Antidiarrheal) |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 500's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Lomotil 2.5mg/0.025mg Tablets by M/s iNova Pharmaceutical (Australia) Pty Ltd (TGA Approved) |
| | Me-too Status | Distop Tables 2.5mg/0.025mg by M/s Webros Pharmaceuticals (Reg#043347) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Registration Board rejected the application since firm does not have required section i.e Tablet (General) Section.** | |

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| **66.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Phenosis 30mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4154: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Phenobarbital …30mg |
| | Pharmacological Group | Barbiturates and derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 60's, 1000's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Phenobarbital 30mg Tablets by M/s Relonchem Limited (MHRA Approved) |
| | Me-too Status | Phenobarbitone Tablet 30mg by M/s Bayer (Reg# 000033) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **67.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **ATIPAM 0.5mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4157: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Lorazepam …0.5mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Ativan (lorazepam) 0.5mg Tablet by MEDA Manufacturing. (USFDA approved) |
| | Me-too Status | Veniti 0.5mg Tablet by WILSHIRE (Reg#071220) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **68.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **ATIPAM 1mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4155: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Lorazepam …1mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Ativan (lorazepam) 1mg Tablet by MEDA Manufacturing. (USFDA approved) |
| | Me-too Status | Razepam Tablet 1mg by Mediate Pharmaceutical (Reg#061954) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **69.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **ATIPAM 2mg Tablet** |
| | Diary No. Date of R & I & fee | Dy No. 4156: 30-01-2019 PKR 20,000/-: 30-01-2019 |
| | Composition | Each tablet contains:<br>Lorazepam …2mg |

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| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Ativan (lorazepam) 2mg Tablet by MEDA Manufacturing. (USFDA approved) |
| | Me-too Status | Razepam Tablet 2mg by Mediate Pharma (Reg#061937) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **Liquid Ampoule (Psychotropic) Section: 05 product/ 05 molecule** | | |
| **70.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **D.Pam Injection 10mg/2ml** |
| | Diary No. Date of R & I & fee | Dy No. 5146: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 2ml ampoule contain:<br>Diazepam …10mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 5's, 25's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | DBL DIAZEPAM 10mg/2ml injection (ampoule) by Pfizer Australia.(TGA Approved) |
| | Me-too Status | Relaxipam 10mg/2ml Injection by EPLA (Reg#003368) |
| | GMP Status | 28-11-2018<br>Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **71.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Phenosis Injection 200mg/ml** |
| | Diary No. Date of R & I & fee | Dy No. 5147: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 1ml ampoule contain:<br>Phenobarbital Sodium …200mg |
| | Pharmacological Group | Barbiturates and derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 5's, 25's, 100's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Phenobarbital Sodium 200mg/ml Injection (ampoule) by M/s Macarthys Laboratories Ltd (MHRA approved) |
| | Me-too Status | P-Bar Injection 200mg/ml by Saydon Pharmaceuticals (Reg#079731) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **72.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **TimeGesic Injection 0.3mg/ml** |
| | Diary No. Date of R & I & fee | Dy No. 5149: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 1ml ampoule contain:<br>Buprenorphine (as hydrochloride) …0.3mg |
| | Pharmacological Group | Oripavine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | BP |

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| | Pack Size & Demanded Price | 5's/As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Temgesic Injection 0.3mg/ml (ampoule) By M/s Indivior UK Limited (MHRA approved) |
| | Me-too Status | Segesic Injection 0.3mg/ml of Saydon Pharmaceuticals Industries.(Reg#079729) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **73.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Soseget Injection 30mg/ml** |
| | Diary No. Date of R & I & fee | Dy No. 5150: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 1ml ampoule contain:<br>Pentazocine …30mg |
| | Pharmacological Group | Benzomorphan derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 5's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | Discontinued in USFDA |
| | Me-too Status | Omsis 30mg/ml injection by SAMI Pharma (Reg#50746) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | • Approval Status of Product in Reference Regulatory Authorities not confirmed. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| **74.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Dormilam Injection 5mg/5ml** |
| | Diary No. Date of R & I & fee | Dy No. 5148: 06-02-2019 PKR 20,000/-: 06-02-2019 |
| | Composition | Each 5ml ampoule contain:<br>Midazolam (as hydrochloride) …5mg |
| | Pharmacological Group | Benzodiazepine derivatives |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 5's /As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | MIDAZOLAM SANDOZ midazolam 5mg/5mL injection ampoule by M/s Sandoz Pty Ltd (TGA Approved) |
| | Me-too Status | Dormicum 5mg/5ml injection by Martin Dow (Reg#014929) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **Dry Powder Suspension (Cephalosporin) Section :<br>02 product/ 01 molecule** | | |
| **75.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Novacef 100mg/5ml powder for suspension** |
| | Diary No. Date of R & I & fee | Dy No. 4630: 01-02-2019 PKR 20,000/-: 01-02-2019 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefixime (as trihydrate) …100 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml / As per DRAP policy |

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|---|---|---|
| | Approval Status of Product in Reference Regulatory Authorities. | SUPRAX® (cefixime) for oral suspension 100mg/5ml by M/ Lupin Pharmaceuticals, Inc. (USFDA Approved) |
| | Me-too Status | Bestar dry Suspension 100mg/5ml by M/s Elko (Reg#073247) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |
| **76.** | Name and Address of Manufacturer / Applicant | M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi |
| | Brand Name + Dosage Form + Strength | **Novacef DS 200mg/5ml powder for suspension** |
| | Diary No. Date of R & I & fee | Dy No. 4631: 01-02-2019 PKR 20,000/-: 01-02-2019 |
| | Composition | Each 5ml suspension after reconstitution contains:<br>Cefixime (as trihydrate) …200 mg |
| | Pharmacological Group | 3rd Generation Cephalosporin Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 30ml / As per DRAP policy |
| | Approval Status of Product in Reference Regulatory Authorities. | SUPRAX® (cefixime) for oral suspension 200mg/5ml by M/ Lupin Pharmaceuticals, Inc. (USFDA Approved) |
| | Me-too Status | Bestar DS dry Suspension 200mg/5ml by M/s Elko (Reg#037036) |
| | GMP Status | 28-11-2018; Grant of DML<br>Panel recommends Grant of DML |
| | Remarks of the Evaluator. | |
| | **Decision: Approved.** | |

### b. New/Additional section(s)

**Evaluator PEC-VIII**

**M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI,**
**National Industrial Zone, Rawat, Islamabad.**

CLB in its 266th meeting dated 24th October, 2018, has granted New Section Dry Powder Vial Injection (Ceph). The details of products applied for each section is provided below;

| **Dry Powder Vial Injection (Ceph): Molecules: 05, Product ;13** | | |
|---|---|---|
| **77.** | Na me and address of manufacturer / Applicant | M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad |
| | Brand Name +Dosage Form + Strength | CEFME 250mg Dry powder injectable |
| | Composition | Each vial contains<br>Cefotaxime (as sodium)…….250mg |
| | Diary No. Date of R& I & fee | Dy No. 43518; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.126.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Baxim Injection by Nabiqasim |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **78.** | Brand Name +Dosage Form + Strength | CEFME 500mg Dry powder injectable |
| | Composition | Each vial contains<br>Cefotaxime (as Sodium)…… 500mg |
| | Diary No. Date of R& I & fee | Dy No. 43515; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.192.00 |

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| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Baxim Injection by Nabiqasim |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **79.** | Brand Name +Dosage Form + Strength | CEFME 1g Dry powder injectable |
| | Composition | Each vial contains<br>Cefotaxime (as Sodium) …… 1g |
| | Diary No. Date of R& I & fee | Dy No. 43516; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.317.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Baxim Injection by Nabiqasim |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **80.** | Brand Name +Dosage Form + Strength | CEFZONE 250mg IV, Dry powder injectable |
| | Composition | Each vial contains<br>Ceftriaxone (as Sodium) …… 250mg |
| | Diary No. Date of R& I & fee | Dy No. 43517; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.133.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Rocphin 250mg IV Injection by M/s ROCHE (Reg#008433) |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **81.** | Brand Name +Dosage Form + Strength | CEFZONE 500mg IV, Dry powder injectable |
| | Composition | Each vial contains<br>Ceftriaxone (as Sodium) …… 500mg |
| | Diary No. Date of R& I & fee | Dy No. 43519; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.253.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Rocphin 500mg IV Injection by M/s ROCHE (Reg#008435) |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **82.** | Brand Name +Dosage Form + Strength | CEFZONE 1g IV, Dry powder injectable |
| | Composition | Each vial contains<br>Ceftriaxone (as Sodium) …… 1g |
| | Diary No. Date of R& I & fee | Dy No. 43521; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.414.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |

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| | Me-too status | Rocphin 1000mg IV Injection by M/s ROCHE (Reg#008436) |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **83.** | Brand Name +Dosage Form + Strength | CEFZONE 250mg IM, Dry powder injectable |
| | Composition | Each vial contains<br>Ceftriaxone (as Sodium) …… 250mg |
| | Diary No. Date of R& I & fee | Dy No. 43518; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.133.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Rocphin 250mg IM Injection by M/s ROCHE (Reg#008432) |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **84.** | Brand Name +Dosage Form + Strength | CEFZONE 500mg IM, Dry powder injectable |
| | Composition | Each vial contains<br>Ceftriaxone (as Sodium) …… 500mg |
| | Diary No. Date of R& I & fee | Dy No. 43520; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.253.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Rocphin 500mg IM Injection by M/s ROCHE (Reg#008434) |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **85.** | Brand Name +Dosage Form + Strength | EPIVEL 500mg , Dry powder injectable |
| | Composition | Each vial contains<br>Cefepime (as hydrochloride) …… 500mg |
| | Diary No. Date of R& I & fee | Dy No. 43512; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs. 512.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Uspime Injection by Usawa Pharmaceuticals |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | Apply in-line with Reference product containing L-arginine. |
| | **Decision: Deferred for revision formulation as per the reference product along with submission of fee for revision of formulation.** | |
| **86.** | Brand Name +Dosage Form + Strength | EPIVEL 1g , Dry powder injectable |
| | Composition | Each vial contains<br>Cefepime (as hydrochloride) …… 1g |
| | Diary No. Date of R& I & fee | Dy No. 43518; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.966.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in US-FDA |
| | Me-too status | Uspime Injection by Usawa Pharmaceuticals |

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| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | Apply in-line with Reference product containing L-arginine. |
| | **Decision: Deferred for revision formulation as per the reference product along with submission of fee for revision of formulation.** | |
| **87.** | Brand Name +Dosage Form + Strength | CEFRAVEL 1g , Dry powder injectable |
| | Composition | Each vial contains<br>Cefoperazone (as Sodium) …… 1g |
| | Diary No. Date of R& I & fee | Dy No. 43509; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 1's : Rs.310.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in Czech, Slovakia, Poland |
| | Me-too status | Bezone Injection by Medisave |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved.** | |
| **88.** | Brand Name +Dosage Form + Strength | CEFATAM 1g , Dry powder injectable |
| | Composition | Each vial contains<br>Cefoperazone (as Sodium) …… 500mg<br>Sulbactam (as Sodium) …. 500 mg |
| | Diary No. Date of R& I & fee | Dy No. 43510; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1's : Rs.460.00 |
| | Approval status of product in Reference Regulatory Authorities. | PMDA Japan Approved |
| | Me-too status | Cebac Injection by Bosch Pharma |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved with JP specification.** | |
| **89.** | Brand Name +Dosage Form + Strength | CEFATAM 2g , Dry powder injectable |
| | Composition | Each vial contains<br>Cefoperazone (as Sodium) …… 1000mg<br>Sulbactam (as Sodium) …. 1000 mg |
| | Diary No. Date of R& I & fee | Dy No. 43511; 20-12-18 Rs. 20,000 |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack size & Demanded Price | 1's : Rs.782.00 |
| | Approval status of product in Reference Regulatory Authorities. | Approved in three European Union |
| | Me-too status | Suzone Injection of M/s Fynk Pharmaceuticals |
| | GMP status | New section( Letter Issuance Date: 3rd December 2018) |
| | Remarks of the Evaluator | |
| | **Decision: Approved with JP specification.** | |

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| The firm has been granted new section on the basis of inspection dated 19.09.2018. The firm has applied for 10 generics (26 products) in the tablet section. | | |
| **90.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | T-Lap 100mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Topiramate…100mg |
| | Diary No. Date of R& I & fee | Dy No. 41601: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 3x10's, 6x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Topamax® 100 mg film-coated tablets. **MHRA** approved |
| | Me-too status | Topister Tablet 100mg. Reg. No. 82549 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **91.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | T-Lap 50mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Topiramate…50mg |
| | Diary No. Date of R& I & fee | Dy No. 41604: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 3x10's, 6x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Topamax® 50 mg film-coated tablets. **MHRA** approved |
| | Me-too status | Topister Tablet 50mg. Reg. No. 82548 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **92.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | T-Lap 200mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Topiramate…200mg |
| | Diary No. Date of R& I & fee | Dy No. 41585: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 3x10's, 6x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Topamax® 200 mg film-coated tablets. **MHRA** approved |
| | Me-too status | Epik 200mg Tablets. Reg. No. 48560 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **93.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | T-Lap 25mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Topiramate…25mg |
| | Diary No. Date of R& I & fee | Dy No. 41546: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |

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| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 3x10's, 6x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Topamax® 25 mg film-coated tablets. **MHRA** approved |
| | Me-too status | Erbro 25mg Tablet Tablet. Reg. No. 80384 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **94.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Rison 1mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Risperidone…1mg |
| | Diary No. Date of R& I & fee | Dy No. 41567: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 5x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | RISPERDAL 1 mg film-coated tablet. **MHRA** approved |
| | Me-too status | Neo-Risp Tablet 1mg. Reg. No. 85184 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **95.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Rison 2mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Risperidone…2mg |
| | Diary No. Date of R& I & fee | Dy No. 41541: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 5x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | RISPERDAL 2 mg film-coated tablet. **MHRA** approved |
| | Me-too status | Neo-Risp Tablet 2mg. Reg. No. 85185 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **96.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Rison 3mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Risperidone…3mg |
| | Diary No. Date of R& I & fee | Dy No. 41590: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 5x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | RISPERDAL 3 mg film-coated tablet. **MHRA** approved |
| | Me-too status | Neo-Risp Tablet 3mg. Reg. No. 85186 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved.** | |

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| **97.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Rison 4mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Risperidone…4mg |
| | Diary No. Date of R& I & fee | Dy No. 41595: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 5x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | RISPERDAL 4 mg film-coated tablet. **MHRA** approved |
| | Me-too status | Neo-Risp Tablet 4mg. Reg. No. 85187 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **98.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Flumet 100mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Fluvoxamine Maleate…100mg |
| | Diary No. Date of R& I & fee | Dy No. 41550: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 60's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | FLUVOXAMINE MALEATE film-coated 100mg Tablets for oral administration. **USFDA** approved |
| | Me-too status | Revilife 100mg tablets. Reg. No. 82526 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **99.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Flumet 50mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Fluvoxamine Maleate…50mg |
| | Diary No. Date of R& I & fee | Dy No. 41550: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 60's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | FLUVOXAMINE MALEATE film-coated 50mg Tablets for oral administration. **USFDA** approved |
| | Me-too status | B-Vert Tablets 50mg. Reg.#66546 (does not depict film-coating) |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **100.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Venlax ER 100mg Tablet |
| | Composition | Each extended release tablet contains:<br>Desvenlafaxine (as succinate monohydrate) …100mg |
| | Diary No. Date of R& I & fee | Dy No. 41606: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specification |
| | Pack size & Demanded Price | 10's, 14's, 28's; As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | Pristiq extended release tablets 100mg (film-coated). **USFDA** approved |
| | Me-too status | Denla XR 100mg Tablet. Reg.#70434 (Does not depict coating) |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| **101.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Venlax ER 50mg Tablet |
| | Composition | Each extended release tablet contains:<br>Desvenlafaxine (as succinate monohydrate) …50mg |
| | Diary No. Date of R& I & fee | Dy No. 41607: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Other antidepressants |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer's specification |
| | Pack size & Demanded Price | 10's, 14's, 28's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Pristiq extended release tablets 50mg (film-coated). **USFDA** approved |
| | Me-too status | Denla XR 50mg Tablet. Reg.#70433 (Does not depict coating) |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| **102.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Depnil 100mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Sertraline (as hydrochloride)…100mg |
| | Diary No. Date of R& I & fee | Dy No. 41583: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 20's, 30's, 50's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ZOLOFT (sertraline hydrochloride) 100mg film-coated tablets, for oral use. **USFDA** approved |
| | Me-too status | Lowtral 100mg Tablets. Reg. No. 50993 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **103.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Depnil 50mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Sertraline (as hydrochloride)…50mg |
| | Diary No. Date of R& I & fee | Dy No. 41605: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 50's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ZOLOFT (sertraline hydrochloride) 50mg film-coated tablets, for oral use. **USFDA** approved |
| | Me-too status | Lowtral 50mg Tablets. Reg. No. 51000 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved.** | |
| **104.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Velpro 500mg Tablet |

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| | Composition | Each enteric-coated tablet contains:<br>Divalproex sodium eq. to Valproic acid……500mg |
| | Diary No. Date of R& I & fee | Dy No. 41511: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 3x10, 10x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Depakote 500mg Gastro-resistant Tablets. **MHRA** approved |
| | Me-too status | Uni-Val enteric coated Tablets. Reg. No. 79240 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **105.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Velpro 250mg Tablet |
| | Composition | Each enteric-coated tablet contains:<br>Divalproex sodium eq. to Valproic acid……250mg |
| | Diary No. Date of R& I & fee | Dy No. 41512: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antiepileptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 2x10's, 3x10, 10x10's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Depakote 250mg Gastro-resistant Tablets. **MHRA** approved |
| | Me-too status | Zalprocid Tablets 250mg. Reg. No. 41643 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **106.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Panamol-T Tablet |
| | Composition | Each film-coated tablet contains:<br>Tramadol HCl…..37.5mg<br>Paracetamol….325mg |
| | Diary No. Date of R& I & fee | Dy No. 41547: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Opioids in combination with non-opioid analgesics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30, 50's, 100's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms **USFDA** approved |
| | Me-too status | Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **107.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Etox CR 25mg Tablet |
| | Composition | Each enteric, film-coated, controlled release tablet contains:<br>Paroxetine (as HCl hemihydrate)……25mg |
| | Diary No. Date of R& I & fee | Dy No. 41547: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 14's, 20's, 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PAXILCR enteric, film-coated tablet 25mg. **USFDA** approved |

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| | Me-too status | Panox CR Tablet 25 mg. Reg. No. 81954 (does not depict enteric, film coating and hemihydrate form). |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • The firm revised the formulation from controlled release tablet" to "enteric, film-coated, controlled release tablet" without submission of any fee. |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| **108.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Etox CR 12.5mg Tablet |
| | Composition | Each enteric, film-coated, controlled release tablet contains:<br>Paroxetine (as HCl hemihydrate)……12.5mg |
| | Diary No. Date of R& I & fee | Dy No. 41554: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 14's, 20's, 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | PAXILCR enteric, film-coated tablet 12.5mg. **USFDA** approved |
| | Me-too status | Jurox CR 12.5 Tablet. Reg. No. 81929 (does not depict enteric, film coating and hemihydrate form). |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • The firm revised the formulation from controlled release tablet" to "enteric, film-coated, controlled release tablet" without submission of any fee. |
| | **Decision: Deferred for submission of fee for revision of formulation** | |
| **109.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Etox 20mg Tablet |
| | Composition | Each film-coated tablet contains:<br>Paroxetine (as HCl hemihydrate)……20mg |
| | Diary No. Date of R& I & fee | Dy No. 41554: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Selective serotonin reuptake inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 14's, 20's, 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Paroxetine 20 mg Film-coated tablets. **MHRA** approved |
| | Me-too status | Frais Tablet 20mg. Reg.#82658 (Does not depict hemihydrate) |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **110.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | QTR XR Tablet 300mg |
| | Composition | Each extended release tablet contains:<br>Quetiapine fumarate eq. to Quetiapine……300mg |
| | Diary No. Date of R& I & fee | Dy No. 41531: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antipsychotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 50's, 100's, 500's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Alaquet XL 300 mg prolonged-release tablets. **MHRA** approved |
| | Me-too status | Angepine XR 300mg Tablets. Reg. No. 78826 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |

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| **111.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | QTR Tablet 300mg |
| | Composition | Each film-coated tablet contains:<br>Quetiapine fumarate eq. to Quetiapine……300mg |
| | Diary No. Date of R& I & fee | Dy No. 41563: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antipsychotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 50's, 100's, 500's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Seroquel 300 mg film-coated tablets. **MHRA** approved |
| | Me-too status | Pine Tablet. Reg. No. 82048 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **112.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | QTR XR Tablet 150mg |
| | Composition | Each extended release tablet contains:<br>Quetiapine fumarate eq. to Quetiapine……150mg |
| | Diary No. Date of R& I & fee | Dy No. 41532: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antipsychotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's, 50's, 100's, 500's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Alaquet XL 150 mg prolonged-release tablets. **MHRA** approved |
| | Me-too status | Ziapine XR150mg Oral Tablets . Reg. No. 78755 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **113.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Befine Tablet 24mg |
| | Composition | Each tablet contains:<br>Betahistine dihydrochloride……24mg |
| | Diary No. Date of R& I & fee | Dy No. 41510: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antivertigo preparations |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Betahistine 24 mg uncoated tablets. **MHRA** approved |
| | Me-too status | Statobex 24mg Tablet. Reg. No. 58432 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **114.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Befine Tablet 16mg |
| | Composition | Each tablet contains:<br>Betahistine dihydrochloride……16mg |
| | Diary No. Date of R& I & fee | Dy No. 41578: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antivertigo preparations |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 30's; As per SRO |

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| | Approval status of product in Reference Regulatory Authorities. | Betahistine 16 mg uncoated tablets. **MHRA** approved |
| | Me-too status | Histogen 16mg Tablets. Reg. No. 56092 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |
| **115.** | Name and address of manufacturer / Applicant | Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad Pakistan |
| | Brand Name +Dosage Form + Strength | Befine Tablet 8mg |
| | Composition | Each tablet contains:<br>Betahistine dihydrochloride……8mg |
| | Diary No. Date of R& I & fee | Dy No. 41580: 07.12..2018 PKR 20,000/-: 07.12..2018 |
| | Pharmacological Group | Antivertigo preparations |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack size & Demanded Price | 30's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Betahistine 8 mg uncoated tablets. **MHRA** approved |
| | Me-too status | Histogen 8mg Tablets. Reg. No. 56090 |
| | GMP status | New section granted on the basis of inspection dated 19.09.2018 |
| | Remarks of the Evaluator. | • |
| | **Decision: Approved** | |

### c. Remaining products of New DML/New section

**Evaluator PEC-IV**

CLB in its 259th meeting held on 29th & 30th March 2018, has approved the following 3 additional sections of M/s Medisure Laboratories Pakistan.

Capsule (Cephalosporin)

Dry Powder Suspension(Cephalosporin)

Dry Powder Injection(Cephalosporin)Section

| Sr. No | Section | Already considered molecule/products | Balance Molecules |
|---|---|---|---|
| 1 | Dry Powder Injection (Cephalosporin) Section | 03 Molecules/09 Products in 283rd RB meeting<br>&<br>2 Molecules/03 Products in 285rd RB meeting | 5 |

| | | |
|---|---|---|
| **Dry Powder Injection (Cephalosporin) Section<br>02Molecules/04 Products<br>03 products of 1 Molecule in 283rd RB meeting Ceftriaxon IV** | | |
| **116.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A- 115, S.I.T.E, Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | TAZICEF 250mg Injection |
| | Composition | Each vial contains:<br>Ceftazidime (as pentahydrate) ..……250mg |
| | Diary No. Date of R& I & fee | Dy.No;42672 13-12-2018 Rs. 20,000-(11-12-2018) |
| | Pharmacological Group | AntiBiotic |
| | Type of Form | Form-5 |
| | Finished product SDry Powder Injection (Cephalosporin) Sectionpecifications | USP |
| | Pack size & Demanded Price | 1's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Fortum injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Tazinig injection of M/s Honig Pharmaceutic |
| | GMP status | New section (Letter issuance date: 12th April 2018) |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |

| | | |
|---|---|---|
| **117.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E, Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | TAZICEF 500mg Injection |
| | Composition | Each vial contains:<br>Ceftazidime (as pentahydrate) ..……500mg |
| | Diary No. Date of R& I & fee | Dy.No;42673 13-12-2018 Rs. 20,000-(11-12-2018) |
| | Pharmacological Group | AntiBiotic |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Fortum injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Dayfort injection of M/s High- Q |
| | GMP status | New section (Letter issuance date: 12th April 2018) |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| **118.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E, Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | TAZICEF 1g Injection |
| | Composition | Each vial contains:<br>Ceftazidime (as pentahydrate) ..……1g |
| | Diary No. Date of R& I & fee | Dy.No;42674 13-12-2018 Rs. 20,000-(11-12-2018) |
| | Pharmacological Group | AntiBiotic |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Fortum injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Astedime injection of M/s Astellas Pharmaceuticals, |
| | GMP status | New section (Letter issuance date: 12th April 2018) |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| **119.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E, Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | TAZICEF 2g Injection |
| | Composition | Each vial contains:<br>Ceftazidime (as pentahydrate) ..……2g |
| | Diary No. Date of R& I & fee | Dy.No;42675 13-12-2018 Rs. 20,000-(11-12-2018) |
| | Pharmacological Group | AntiBiotic |
| | Type of Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Fortum injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Not found |
| | GMP status | New section (Letter issuance date: 12th April 2018) |
| | Remarks of the Evaluator[4] | |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| **120.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E, Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | ARMASURE 250mg IM Injection |
| | Composition | Each vial contains:<br>Ceftriaxone (as Sodium)……250mg |

| | | |
|---|---|---|
| | Diary No. Date of R& I & fee | Dy.No;24304 12-07-2018 Rs. 20,000-(12-07-2018) |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Rocephin I.M injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Accucef 250 mg IM Injection M/s Wel Wink Pharmaceuticals, |
| | GMP status | New section (Letter issuance date: 12th April 2018) |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| **121.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E, Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | ARMASURE 500mg IM Injection |
| | Composition | Each vial contains:<br>Ceftriaxone (as Sodium)……500mg |
| | Diary No. Date of R& I & fee | Dy.No;20220 04-06-2018 Rs. 20,000-(04-06-2018) |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Rocephin I.M injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Wixone 500 mg Injection IM M/s Wise Pharmaceuticals, |
| | GMP status | New section (Letter issuance date: 12th April 2018) |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |
| **122.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories Pakistan (Pvt.) Ltd. A-115, S.I.T.E, Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | ARMASURE 1g IM Injection |
| | Composition | Each vial contains:<br>Ceftriaxone (as Sodium)……1g |
| | Diary No. Date of R& I & fee | Dy.No;24876 18-07-2018 Rs. 20,000-(17-07-2018) |
| | Pharmacological Group | Cephalosporin |
| | Type of Form | Form 5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 1's ; As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Rocephin I.M injection of (MHRA approved) |
| | Me-too status (with strength and dosage form) | Accucef 1gm IM Injection M/s Wel Wink Pharmaceuticals |
| | GMP status | New section (Letter issuance date: 12th April 2018) |
| | Remarks of the Evaluator[4] | |
| | **Decision: Approved** | |

**Evaluator PEC-VIII**

| | | |
|---|---|---|
| **Lyophilized Vials Injectable (General): Previously considered Molecules; 07 (M-275)** | | |
| **Now applied: Molecules: 01 Products: 02** | | |
| **123.** | Name and address of Manufacturer / Applicant | M/s MTI Medical Pvt Ltd.<br>586-587, Sundar Industrial Estate, Lahore, Pakistan" |
| | Brand Name + Dosage Form + Strength | Tagagy 50mg Lyophilized Injection |
| | Composition | Each Vial Contains:<br>Tigecycline …..50mg |
| | Diary No. Date of R&I & fee | DyNo.18445; 21-05-2018; Rs. 20,000/- |
| | Pharmacological Group | Antibiotic |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 1's:As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in US-FDA |
| | Me-too status | Tilane 50mg injection of M/s S.J.&G. Fazul Ellahie |
| | GMP status | NEW SECTION (Letter Issuance date: 11th April, 2017)<br>Lyophilized Vials Injectables(general) |
| | Remarks of Evaluator | |
| | **Decision: Approved** | |
| **124.** | Name and address of Manufacturer / Applicant | M/s MTI Medical Pvt Ltd.<br>586-587, Sundar Industrial Estate, Lahore, Pakistan" |
| | Brand Name + Dosage Form + Strength | Tinkar Lyophilized 1gm Injection |
| | Composition | Each Vial Contains:<br>L-Carnitine…1gm |
| | Diary No. Date of R&I & fee | DyNo.18444; 21-05-2018; Rs. 20,000/- |
| | Pharmacological Group | Amino-Acid Derivative |
| | Type of Form | Form-5 |
| | Finished Product Specification | USP Specifications |
| | Pack Size & Demanded Price | 1's:As per SRO |
| | Approval status of product in Reference Regulatory Authorities | Approved in Italy(as provided by firm ) |
| | Me-too status | Kefei injection of R.G. Pharmaceutica (Pvt) Ltd., Karachi |
| | GMP status | NEW SECTION (Letter Issuance date: 11th April, 2017)<br>Lyophilized Vials Injectables(general) |
| | Remarks of Evaluator | |
| | **Decision: Approved** | |

**Evaluator PEC-XIII**

| | | |
|---|---|---|
| Central Licensing Board in its 266th meeting held on 24th October, 2018 has considered and approved the various sections including "Soft gel capsule" and accordingly secretary CLB has issued letter for "Grant of Additional Section" dated 03-12-2018. | | |
| **125.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Cosmin-C soft gelatin capsule 5mg |
| | Composition | Each soft gelatin capsule contains:<br>Isotretinoin ……..……5mg |
| | Diary No. Date of R& I & fee | Dy.No.38947;27-11-2018; Rs.20,000 (26-11-2018) |
| | Pharmacological Group | Anti-Acne Preparations |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 10's & 30's; Rs. 500 & Rs. 3400 |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Could not be confirmed in the applied strength (Available strengths are 10mg and 20mg) |

| | | |
|---|---|---|
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and the report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>• Firm has claimed BP specifications while its monograph is available in USP not in BP.<br>• Me- too could not be confirmed in the applied strength. (Available strengths are 10mg and 20mg). |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| **126.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Cosmin- C soft gelatin capsule 10mg |
| | Composition | Each soft gelatin capsule contains:<br>Isotretinoin …….10mg |
| | Diary No. Date of R& I & fee | Dy.No.38948;27-11-2018; Rs.20,000 (26-11-2018) |
| | Pharmacological Group | Anti-Acne Preparations |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 10's & 30's; Rs. 500 & Rs. 3400 |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Roaccutane 10mg capsule of M/s Roche (023612) |
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and the report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>• Firm has claimed BP specifications while its monograph is available in USP not in BP. |
| | **Decision: Approved.** | |
| **127.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Cosmin- C soft gelatin capsule 20mg |
| | Composition | Each soft gelatin capsule contains:<br>Isotretinoin …….20mg |
| | Diary No. Date of R& I & fee | Dy.No.38949;27-11-2018; Rs.20,000 (26-11-2018) |
| | Pharmacological Group | Anti-Acne Preparations |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 10's & 30's Rs. 500 & Rs. 3400 |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Roaccutane 20mg capsule of M/s Roche (023613) |
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>• Firm has claimed BP specifications while its monograph is available in USP not in BP. |
| | **Decision: Approved.** | |
| **128.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Cosmin- C soft gelatin capsule 40mg |
| | Composition | Each soft gelatin capsule contains:<br>Isotretinoin ……..……..40mg |
| | Diary No. Date of R& I & fee | Dy. No.38950;27-11-2018; Rs.20,000 (26-11-2018) |

| | | |
|---|---|---|
| | Pharmacological Group | Anti-Acne Preparations |
| | Type of Form | Form-5 |
| | Finished product Specification | BP |
| | Pack size & Demanded Price | 10's & 30's ; Rs. 500 & Rs. 3400 |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Could not be confirmed in the applied strength (Available strengths are 10mg and 20mg) |
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>• Firm has claimed BP specifications while its monograph is available in USP not in BP.<br>• Me- too could not be confirmed in the applied strength. (Available strengths are 10mg and 20mg). |
| | **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| **129.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Enew 200mg Soft Gelatin Capsule |
| | Composition | Each soft gelatin capsule contains:<br>Vitamin E……200mg |
| | Diary No. Date of R& I & fee | Dy.No.38944;27-11-2018; Rs.20,000 (26-11-2018) |
| | Pharmacological Group | Vitamins |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 30's & 100's Rs. 200 & Rs. 400 |
| | Approval status of product in Reference Regulatory Authorities | Applied strength could not be confirmed |
| | Me-too status | Evion 200mg Cap of M/s Ad Marker<br>(Reg. # 008753) |
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>• The official monograph for the applied formulation is available in USP.<br>• The applied strength could not be confirmed internationally. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| **130.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Enew 400mg Soft Gelatin Capsule |
| | Composition | Each soft gelatin capsule contains:<br>Vitamin E……400mg |
| | Diary No. Date of R& I & fee | Dy.No.38945;27-11-2018; Rs.20,000 (26-11-2018) |
| | Pharmacological Group | Vitamins |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 30's & 100's Rs. 300 & Rs. 600 |
| | Approval status of product in Reference Regulatory Authorities | **Applied strength could not be confirmed** |
| | Me-too status | Evion 400mg Cap of M/s Ad Marker (Reg. # 008754) |
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | • The official monograph for the applied formulation is available in USP. |

| | | |
|---|---|---|
| | | • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>• The applied strength could not be confirmed internationally. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| **131.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Enew 600mg Soft Gelatin Capsule |
| | Composition | Each soft gelatin capsule contains:<br>Vitamin E……600mg |
| | Diary No. Date of R& I & fee | Dy.No.38946;27-11-2018; Rs.20,000 (26-11-2018) |
| | Pharmacological Group | Vitamins |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 30's & 100's Rs. 400 & Rs. 800/- |
| | Approval status of product in Reference Regulatory Authorities | Applied strength could not be confirmed |
| | Me-too status | Could not be confirmed |
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | •The official monograph for the applied formulation is available in USP.<br>•Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>•The applied formulation could not be confirmed locally and internationally. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| **132.** | Name and address of manufacturer / Applicant | M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad. |
| | Brand Name +Dosage Form + Strength | Nedil Soft Gelatin capsule 10mg |
| | Composition | Each soft gelatin capsule contains:<br>Nifedipine…….10mg |
| | Diary No. Date of R& I & fee | Dy.No.38943;27-11-2018; Rs.20,000 (26-11-2018) |
| | Pharmacological Group | Calcium Antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 30's & Rs. 200.00 |
| | Approval status of product in Reference Regulatory Authorities | Adalat 10 mg soft capsules of M/s Bayer Plc<br>(Approved in MHRA) |
| | Me-too status | Nifed Soft Gelatin capsules of M/s Unimark Pharma (Reg.#021977) |
| | GMP status | Last GMP inspection was conducted on 13.10.2018 and report concludes good compliance with grant of GMP certificate. |
| | Remarks of the Evaluator [XIII] | • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter.<br>• The official monograph for the applied formulation is available in USP. |
| | **Decision: Approved with innovator's specification.** | |

**Case No. Dynatis Pakistan Pvt Ltd..,** Lahore**. (Remaining products)**

CLB in its 267th meeting held on 31st December, 2018 has considered and approved the grant the Drug Manufacturing License (DML) by way of formulation to M/ s Dynatis Pakistan (Pvt.) Ltd, Plot No. 710, Sunder Industrial Estate, Lahore with six sections.

| Sr. no | Section | No. of P/M already considered by RB | New products | New molecules |
|---|---|---|---|---|
| 1 | Capsule Section (General) | 5 Molecules/8 Products | 05 | 04 |

**Capsule Section**
**05 olecules/05 Products**

| | | |
|---|---|---|
| **133.** | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | Zolonaf Capsule 50mg |
| | Diary No. Date of R & I & fee | Dy.No 4840 dated 04-02-2019 Rs.20,000/- 01-02-2019 |
| | Composition | Each hard gelatin capsule contains:<br>Fluconazole …50mg |
| | Pharmacological Group | Antimycotics for systemic use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 7's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Azocan 50mg Capsules by FDC International Ltd. (MHRA Approved) |
| | Me-too Status | Fungon Capsules 50mg by Dyson Research Laboratories. (Reg#55352) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **134.** | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | **Zolonaf Capsule 150mg** |
| | Diary No. Date of R & I & fee | Dy.No 4841 dated 04-02-2019 Rs.20,000/- 01-02-2019 |
| | Composition | Each hard gelatin capsule contains:<br>Fluconazole …150mg |
| | Pharmacological Group | Antimycotics for systemic use |
| | Type of Form | Form 5 |
| | Finished Product Specification | BP |
| | Pack Size & Demanded Price | 1's, 2's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Fluconazole 150mg capsule by Bristol Laboratories Limited. (MHRA Approved) |
| | Me-too Status | Fungon Capsules 150mg by Dyson Research Laboratories. (Reg#55353) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **135.** | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | **Co Flexine Capsules 6mg/25mg** |
| | Diary No. Date of R & I & fee | Dy.No 4839 dated 04-02-2019 Rs.20,000/- 01-02-2019 |
| | Composition | Each hard gelatin capsule contains:<br>Olanzapine …6 mg<br>Fluoxetine (as hydrochloride) …25mg |
| | Pharmacological Group | Antidepressants in combination with psycholeptics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 10's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Symbyax 6mg/25mg capsule by Eli Lilly (USFDA Approved) |
| | Me-too Status | Co-Depricap 6/25mg Capsule by M/s NabiQasim Industries Pvt.Ltd. (Reg#076135) |

| | | |
|---|---|---|
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |
| **136.** | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | **Dyzole Capsules 100mg** |
| | Diary No. Date of R & I & fee | Dy.No 3903 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Composition | Each hard gelatin capsule contains:<br>Itraconazole (as immediate release pellets 22%w/w) …100mg |
| | Pharmacological Group | Triazole derivatives |
| | Type of Form | Form 5 |
| | Finished Product Specification | Manufacturer's specifications |
| | Pack Size & Demanded Price | 4's / As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Itraconazole 100 mg capsules, hard by M/s Sandoz Limited (MHRA Approved) |
| | Me-too Status | Mukil Capsule 100mg of M/s. Dyson Research Laboratories (Pvt) Ltd (Reg.# 055356) |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | • Source of pellets: M/s Murli Krishna Pharma (Pvt) Ltd., D-98, Ranjangaon MIDC, Ranjangaon, Taluka-Shirur, Pune Mahrashtra State, India<br>• Firm has submitted GMP certificate of M/s Murli Krishna issued by FDA Mahrashtra valid till 07-03-2019. |
| | **Decision: Approved with innovator's specification.** | |
| **137.** | Name and Address of Manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name + Dosage Form + Strength | **Dyamide Capsules 2mg** |
| | Diary No. Date of R & I & fee | Dy.No 4842 dated 04-02-2019 Rs.20,000/- 01-02-2019 |
| | Composition | Each hard gelatin capsule contains:<br>Loperamide hydrochloride …2mg |
| | Pharmacological Group | Antipropulsives |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack Size & Demanded Price | 6's/ As per SRO |
| | Approval Status of Product in Reference Regulatory Authorities. | Diafix 2mg capsule by Galpharm (MHRA Approved) |
| | Me-too Status | Molin 2mg Capsule of Asian Continental (Pvt.) Ltd. |
| | GMP Status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved** | |

| Sr. no | Section | No. of P/M already considered by RB | New products | New molecules |
|---|---|---|---|---|
| 1 | Tablet Section (General) | 5 Molecules/12 Products | 10 | 05 |

**Tablet section (General) 10 products/ 5 molecules**

| | | |
|---|---|---|
| **138.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynasaid 50mg Tablets |
| | Composition | "Each Film Coated Tablet Contains:<br>Flurbiprofen .....50mg" |
| | Diary No. Date of R& I & fee | Dy.No 3904 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; as per DPC |
| | Approval status of product in Reference | Approved by USFDA |

| | | |
|---|---|---|
| | Regulatory Authorities. | |
| | Me-too status | Froben Tablets 50mg by M/s Abbott Laboratories Pakistan Ltd. Karachi (Reg. No. 005888) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |
| **139.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynasaid 100mg Tablets |
| | Composition | "Each Film Coated Tablet Contains:<br>Flurbiprofen ….100mg" |
| | Diary No. Date of R& I & fee | Dy.No 3905 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | NSAID |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 30's and 100's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Froben Tablets 100mg by M/s Abbott Laboratories Pakistan Ltd. Karachi (Reg. No. 006904) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |
| **140.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynasil 125mg Tablets |
| | Composition | "Each Tablet Contains:<br>Terbinafine as Hydrochloride …125mg" |
| | Diary No. Date of R& I & fee | Dy.No 3906 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Logirid Tablet 125mg by Lowitt Pharmaceutical (Pvt) Ltd, Plot.No.24 Industrial Estate, Peshawar.(Reg.# 080846) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |
| **141.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynasil 250mg Tablets |
| | Composition | "Each Tablet Contains:<br>Terbinafine as Hydrochloride…250mg" |
| | Diary No. Date of R& I & fee | Dy.No 3907 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | Antifungal |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Lamisil Tablets 250mg by M/s Novartis Pakistan Ltd, Karachi (Reg. No. 013209) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |

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| **142.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Solicin 10mg Tablets |
| | Composition | "Each Film Coated Tablet Contains:<br>Solifenacin Succinate…10mg" |
| | Diary No. Date of R& I & fee | Dy.No 3909 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | Anticholinergic/Anti Spasmodic Agent |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 10's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Solifen Tablets 10mg by M/s Getz,Karachi(Reg. No. 061203) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| **143.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dyvol 250mg Tablets |
| | Composition | "Each Tablet Contains:<br>Valproate Semisodium …250mg" |
| | Diary No. Date of R& I & fee | Dy.No 4837 dated 04-02-2019 Rs.20,000/- 01-02-2019 |
| | Pharmacological Group | Anti convulsant |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 100's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Epival Tablets 250mg by M/s Abbott Pakistan Ltd, Karachi (Reg. No. 007160) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | • In contrary to reference product which contains 269.10 mg of valproate semisodium per tablet (equivalent to 250 mg of valproic acid), firm has applied for valproate semisodium equal to 250mg.<br>• In contrary to reference product which is available as gastor-resistant tablet, firm has applied otherwise. |
| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| **144.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dyvol 500mg Tablets |
| | Composition | "Each Tablet Contains:<br>Valproate Semisodium …500mg" |
| | Diary No. Date of R& I & fee | Dy.No 4837 dated 04-02-2019 Rs.20,000/- 01-02-2019 |
| | Pharmacological Group | Anti convulsant |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 100's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Epival Tablets 500mg by M/s Abbott Pakistan Ltd, Karachi (Reg. No. 007161) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | • In contrary to reference product which contains 538.20 mg of valproate semisodium per tablet (equivalent to 500 mg of valproic acid), firm has applied for valproate semisodium equal to 250mg.<br>• In contrary to reference product which is available as |

| | | |
|---|---|---|
| | | gastor-resistant tablet, firm has applied otherwise. |
| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| **145.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynol 2.5mg Tablets |
| | Composition | "Each Tablet Contains:<br>Nebivolol as hydrochloride …..2.5mg" |
| | Diary No. Date of R& I & fee | Dy.No 3910 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | Anti Hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 14's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Biscard Tablets (Nebivolol Hydrochloride) 2.5mg by M/s Searle Pakistan Ltd, Karachi (Reg. No. 071104) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | • |
| | **Decision: Approved with innovator's specification.** | |
| **146.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynol 5mg Tablets |
| | Composition | "Each Tablet Contains:<br>Nebivolol as hydrochloride …….5mg" |
| | Diary No. Date of R& I & fee | Dy.No 3912 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | Anti Hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 14's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Nebil Tablets (Nebivolol Hydrochloride) 5mg by M/s Getz Pharma (Pvt.) Ltd, Karachi (Reg. No. 061345) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| **147.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynol 10mg Tablets |
| | Composition | "Each Tablet Contains:<br>Nebivolol as hydrochloride …….10mg" |
| | Diary No. Date of R& I & fee | Dy. No 3911 dated 29-01-2019 Rs.20,000/- 29-01-2019 |
| | Pharmacological Group | Anti Hypertensive |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 14's; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Nebil Tablets (Nebivolol Hydrochloride) 10mg by M/s Getz Pharma (Pvt.) Ltd, Karachi (Reg. No. 061346) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |

**Lotion Section (General)**

| Sr.No | No. of P/M already considered by RB | M-288th (Current meeting) |
|---|---|---|
| 1 | 3-Molecules/ 3-Products | 3-Molecules/ 3-Products |

| | | |
|---|---|---|
| **148.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dytasone 0.1% Lotion |
| | Composition | Each gram contains:<br>Mometasone Furoate….0.1% |
| | Diary No. Date of R& I & fee | Dy. No 5579 dated 08-2-2019 Rs.20,000/- Dated 7-2-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 20ml; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Hivate Cream by Saffron Pharma reg # 46432 |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | Firm did not specify whether the formulation is w/w or w/v.<br>The pack size in USFDA approved product is 30ml whereas firm has applied in 20ml.<br>Firm has Lotion Section (general) |
| | **Decision: Deferred for the clarification whether the applied formulation is w/w or w/v.** | |
| **149.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dyac (Clindamycin) 1 % Lotion |
| | Composition | Each gm contains:<br>Clindamycin phosphate …… 1 % |
| | Diary No. Date of R& I & fee | Dy. No 5577 dated 07-2-2019 Rs.20,000/- Dated 7- 2-2019 |
| | Pharmacological Group | Bacteroistatic |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 30ml; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Austaclin T Lotion by Bloom Pharmaceuticals Reg # 063077 |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | Salt factor is incorrect.<br>Firm has Lotion Section (general) |
| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| **150.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Scabnil (Permethrin) 5% Lotion |
| | Composition | "Each gm contains:<br>Permethrin ……5%" |
| | Diary No. Date of R& I & fee | Dy. No 5578 dated 07-2-2019 Rs.20,000/- Dated 7- 2-2019 |
| | Pharmacological Group | Synthetic Pyrethyroid/ scabicide |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 60ml, 120ml; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Permilot Lotion 5% by M/S Semos reg # 076033 |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | Firm has Lotion Section (general) |

| | | |
|---|---|---|
| | | Firm did not specify whether the formulation is w/w or w/v. |
| | **Decision: Deferred for the clarification whether the applied formulation is w/w or w/v.** | |

**Non-Steroidal Cream & Ointment**

| Sr.No | No. of P/M already considered by RB | M-288th (Current meeting) |
|---|---|---|
| 1 | 4-Molecules/ 6-Products | 6-Molecules/ 6-Products |

| | | |
|---|---|---|
| **151.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Scabnil (Permethrin) 5% Cream |
| | Composition | Each gm contains:<br>Permethrin ……5% |
| | Diary No. Date of R& I & fee | Dy. No 5577 dated 07-2-2019 Rs.20,000/- Dated 7- 2-2019 |
| | Pharmacological Group | Synthetic Pyrethyroid/ scabicide |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 30gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Bioscab Cream reg # 074773 |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML.<br>Firm has Cream Section (Steroid) |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| **152.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynazin (Silver sulphadizine) 1% Cream |
| | Composition | Each gm contains:<br>Silver sulphadizine ……1% |
| | Diary No. Date of R& I & fee | Dy. No 5574 dated 08-2-2019 Rs.20,000/- Dated 7- 2-2019 |
| | Pharmacological Group | Anti-bacterial |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 15gm, 25gm, 50gm & 250gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by USFDA |
| | Me-too status | Flamoff 1% Cream Reg # 030940 |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |
| **153.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dylene (Adapalene) 0.1% Cream |
| | Composition | "Each gm contains:<br>Adapalene……0.1%" |
| | Diary No. Date of R& I & fee | Dy. No 4850 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Retinoids |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 15gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Adapco Cream "Each gm contains:<br>Adapalene…0.1%" by M/s ATCO Laboratories (Reg# 050526) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |

| | | |
|---|---|---|
| **154.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynasil (Terbinafine) 1% Cream |
| | Composition | "Each gm contains:<br>Terbinafine hydrochloride USP ……1%" |
| | Diary No. Date of R& I & fee | Dy. No 4849 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Anti-fungal |
| | Type of Form | Form 5 |
| | Finished product Specification | JP |
| | Pack size & Demanded Price | 10gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Lamisil Cream "Each gm contains:<br>Terbinafine hydrochloride USP ……1%""<br>by M/s GSK Pakistan (Reg. # 084005) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML.<br>Firm has Cream Section (Steroid) |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |
| **155.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynoren (Azelaic acid) 20% Cream |
| | Composition | "Each gm contains:<br>Azelaic acid ……20%" |
| | Diary No. Date of R& I & fee | Dy. No 4846 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Anti-bacterial |
| | Type of Form | Form 5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 10gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Skinoren Cream "Each gm contains:<br>Azelaic acid ……20%" by M/s Bayer Pharma. |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| **156.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dylene (Adapalene) 0.1% Gel |
| | Composition | "Each gm contains:<br>Adapalene……0.1%" |
| | Diary No. Date of R& I & fee | Dy. No 4843 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Retinoids |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 15gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | USFDA Approved |
| | Me-too status | Adapco Gel "Each gm contains:<br>Adapalene……0.1%" by M/s ATCO Laboratories. |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |

**Steroidal Cream & Ointment:**

| Sr.No | No. of P/M already considered by RB | M-288th (Current meeting) |
|---|---|---|
| 1 | 3-Molecules/ 4-Products | 6-Molecules/ 6-Products |

| | | |
|---|---|---|
| **157.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynovate N (Betamethasone Valerate + Neomycin) 1.22mg + 5mg cream |
| | Composition | "Each gm contains:<br>Betamethasone Valerate USP …….....1.22mg<br>Neomycin Sulphate USP ……5mg" |
| | Diary No. Date of R& I & fee | Dy. No 4847 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished product Specification | In-House |
| | Pack size & Demanded Price | 10gm, 15gm & 20gm ; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Betnovate-N Cream<br>"Each gm contains:<br>Betamethasone Valerate USP …….....1.22mg<br>Neomycin Sulphate USP ……5mg"<br>by M/s GSK Pakistan. |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML.<br>Firm has Cream Section (Steroid) |
| | Remarks of the Evaluator | On Fee challan Neomycin is written 10mg instead of 5mg. |
| | **Decision: Deferred for submission of relevant fee challan.** | |
| **158.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Vantan (Methyl Prednisolone aceponate) 0.1% Cream |
| | Composition | "Each gm contains:<br>Methyl Prednisolone aceponate ……0.1% |
| | Diary No. Date of R& I & fee | Dy. No 4846 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 5gm & 10gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | TGA Approved |
| | Me-too status | Advantan 0.1 % cream<br>"Each gm contains:<br>Methyl Prednisolone aceponate ……0.1%<br>by M/s Bayer Pakistan. |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML.<br>Firm has Cream Section (Steroid) |
| | Remarks of the Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| **159.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynovate (Betamethasone Valerate) 0.1 % cream |
| | Composition | "Each gm contains:<br>Betamethasone Valerate USP …….....0.1 %" |
| | Diary No. Date of R& I & fee | Dy. No 4848 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |

| | | |
|---|---|---|
| | Pack size & Demanded Price | 10gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Betvonate Cream 0.1 %<br>"Each gm contains:<br>Betamethasone Valerate USP …….....0.1 %"<br>by M/s GSK Pakistan. |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | Salt factor is incorrect<br>Firm has Cream Section (Steroid) |
| | **Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.** | |
| **160.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dyquin Plus (Tretinoin + Hydroquinone + Flucinolone acetonide Permethrin) 0.05% + 4% + 0.01% Cream |
| | Composition | "Each gm contains:<br>Tretinoin USP……0.05%<br>Hydroquinone USP…4%<br>Flucinolone acetonide USP……. 0.01%" |
| | Diary No. Date of R& I & fee | Dy. No 4843 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Retinoid + Depigmenting agent + Corticosteroid |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 15gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved By USFDA |
| | Me-too status | Hyderquin Plus Cream<br>"Each gm contains:<br>Tretinoin ……0.05%<br>Hydroquinone …4%<br>Flucinolone acetonide ……. 0.01%".<br>by M/s Atco Laboratories (Pvt.) Ltd. |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML. |
| | Remarks of the Evaluator | Firm has Cream Section (Steroid) |
| | **Decision: Approved** | |
| **161.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynaderm-NN (clobetasol+neomycin+nystatin) 0.05%+0.5 % 100000IU /gm Ointment |
| | Composition | "Each gm contains:<br>Clobetasol propionate USP ……0.05%<br>Neomycin sulphate USP ……..0.5%<br>Nystatin USP …….....100, 000 IU" |
| | Diary No. Date of R& I & fee | Dy. No 4843 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished product Specification | In House |
| | Pack size & Demanded Price | 10gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA |
| | Me-too status | Dermovat-NN Ointment<br>"Each gm contains:<br>Clobetasol propionate USP ……0.05%<br>Neomycin sulphate USP ……..0.5%<br>Nystatin USP …….....100000 IU"<br>by M/s GSK Pakistan. |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML.<br>Firm has Cream Section (Steroid) |

| | | |
|---|---|---|
| | Remarks of the Evaluator | Firm has Cream/Ointment Section(Steroidal) |
| | **Decision: Approved with innovator's specification.** | |
| **162.** | Name and address of manufacturer / Applicant | Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore |
| | Brand Name +Dosage Form + Strength | Dynacute (Fluticasone propionate) 0.05% Cream |
| | Composition | "Each gm contains:<br>Fluticasone propionate USP ……0.05%" |
| | Diary No. Date of R& I & fee | Dy. No 4845 dated 07-2-2019 Rs.20,000/- Dated 7- 2-2019 |
| | Pharmacological Group | Corticosteroid |
| | Type of Form | Form 5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10gm; as per DPC |
| | Approval status of product in Reference Regulatory Authorities. | Approved by MHRA of UK |
| | Me-too status | Cutivate M Cream "Each gm contains:<br>Fluticasone propionate……0.05%" by M/s GSK. (Reg. # 058448) |
| | GMP status | Inspection dated 04-12-2018 recommends grant of DML.<br>Firm has Cream Section (Steroid) |
| | Remarks of the Evaluator | |
| | **Decision: Approved** | |

## Case No.: 03 Registration applications of drugs for which stability study data is submitted

### a. Deferred 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| **163.** | M/s Scilife Pharma (Pvt.) Ltd., Karachi. | B-Form Rotacaps 400mcg+12mcg<br>Each capsule contains:-<br>Budesonide…400mcg<br>Formoterol fumarate dihydrate……. 12 mcg<br>(Glucocorticosteroid/Selective β2 adrenoceptor agonist) | Form 5 dated 07-04-2017<br>Rs. 20,000/-<br>30's, As per Drug pricing policy | Symbicort Turbuhaler approved by Health Canada<br><br>Venticort Rotacaps by M/s Macter Pharma, Karachi |
| | **Evaluation by PEC:**<br>• Evidence of approval of applied formulation in similar dosage form as applied, by reference regulatory authorities/agencies, which were adopted by the Registration Board in its 275th meeting.<br>• Budesonide is a glucocorticoid.<br>Details of submitted data are as under:<br>(Dy.# 34006 dated 12-10-2018) | | | |

| **STABILITY STUDY DATA** | |
|---|---|
| Drug | B-Form Rotacaps 400mcg+12mcg |
| Name of Manufacturer | M/s Scilife Pharma (Pvt.) Ltd., Karachi. |
| Manufacturer of APIs | M/s Vamsi labs Ltd., Maharashtra, India |
| API Lot No. | Formoterol fumarate dihydrate: FF-0030317<br>Budesonide: BDS-0100517 |
| Description of Pack (Container closure system) | Alu –Alu blister with unit carton |

| | | | |
|---|---|---|---|
| Stability Storage Condition | Real time : 30°C ± 2°C / 75% ± 5%RH<br>Accelerated: 40°C ± 2°C / 75% ± 5%RH | | |
| Time Period | Real time: 6 months Accelerated: 6 months | | |
| Frequency | Accelerated: 0,3,6 month Real Time: 0,3,6 month | | |
| Batch No. | 210B17 | 211B17 | 212B17 |
| Batch Size | 26000 rotacaps | 26000 rotacaps | 26000 rotacaps |
| Manufacturing Date | 28-12-2017 | 28-12-2017 | 28-12-2017 |
| Date of Initiation | 19-01-2018 | 19-01-2018 | 19-01-2018 |
| No. of Batches | 03 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COAS of API | Yes. |
| 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. | Copy of GMP certificate (certificate# NEW-WHO-GMP/CERT/PD/75003/2018/1/25587) issued by Food and Drug Administration Maharashtra to M/s Vamsi labs Ltd., Maharashtra, India valid till 02-11-2021 |
| 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. | Copy of Form 6 & commercial invoice has been submitted attested by ADC DRAP, Karachi |
| 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**

| Sr.# | Observation | Firm's Response |
|---|---|---|
| **i.** | Evidence of approval of applied formulation in similar dosage form as applied, by reference regulatory authorities/agencies, which were adopted by the Registration Board in its 275th meeting. | Firm has referred to product "Venticort" with similar composition of Macter International Karachi, approved by Registration Board in its 275th meeting.<br>Moreover firm has referred that applied dosage form is a cost effective approach as compared to reference product. |
| **ii.** | Label claim for delivered dose shall be submitted, based upon the performance tests identified by USP in its general chapter <601>. | Firm has submitted results for "Uniformity of delivered dose" by Dose Uniformity Sampling Apparatus at 9th month long term stability time point.<br>On the basis of above performance test firm has submitted following label claim:<br>**"Each delivered dose (the dose that leaves the mouthpiece) contains:**<br>**"Budesonide ……. 320mcg**<br>**Formoterol fumarate dehydrate….. 9mcg"** |
| **iii.** | Following performance quality & specific tests as identified by USP in its general chapter <5> & <601> have not been performed during stability studies:<br>• Aerodynamic size distribution.<br>• Microbial Enumeration test<br>• Test for specified microorganisms<br>• Foreign particulate matter.<br>• Uniformity of delivered dose | Firm has submitted results for following tests at 9th month long term stability time point:<br>• Aerodynamic size distribution.<br>• Microbial Enumeration test<br>• Test for specified microorganisms<br>• Foreign particulate matter.<br>• Uniformity of delivered dose |

**Decision of 287th meeting:** Deferred for further deliberation upon required manufacturing facility for applied formulation.

**Firm's reply:** Firm has submitted as under:

"In reference to a concern raised during 287th Registration Board meeting on subject product registration case where the case been deferred for clarification on dedicated section for oral steroidal preparation, please find below is a clarification on concerned objection point wise for your review and kind perusal.

1. Please note that Scilife Pharma Manufacturing facility have two dispensing areas and thus we can dedicate one dispensing booth along with dedicated utensils and gowning to ensure proper segregation avoiding mix-up and cross contamination.
2. We also dedicate a mixer/blender for products containing steroids including the above combination, nullifying the chances of mix-up and /or cross contamination during this stage of process too.
3. Capsule filling process to be executed on a dedicate change parts of steroidal products, nullifying the chances of mix-up and/or cross contamination during this stage of process too.
4. In compliance to International guidelines to avoid the mix-up and cross contamination, we have taken following preventive measures in our manufacturing facility.
   - All powder generated areas (Where the products are exposed), the airflow is negative, hence no any room air goes outside the corridor.
   - In HVAC (het Ventilation Air Conditioning System), design of primary manufacturing the corridor of each processing room is called clean corridor means no air of any room is came in to the corridor.
   - The contaminated air is return to Air handling units where the filtration series is installed.
     - Bag Filter F6 (65% Efficiency)
     - Bag Filter F9 (95% Efficiency)
     - HEPA Filter H13 (99.97% Efficiency)
     - Return Grill G4 (35% Efficiency)
       - The room air changes were designed more than 30 ACH (Air Changes per hour) which given the more air sweeping effects and help to maintain the cleaning of rooms.
       - All process machines were cleaned with validated cleaning agent and approved cleaning procedures.
       - After each equipment cleaning, Quality Assurance and quality Control do the cleaning verification.

| |
|---|
| After reviewing the above clarification, you will realize that the company has taken all necessary precautions to avoid mix-up and cross contamination by dedicating equipments and utensils for products containing steroids verified by an effective robust validated cleaning procedure.<br>On above stated clarification, its humbly requested to consider the product registration case for onward process of registration in applied general oral capsule section." |
| **Decision: Deferred for further deliberation** |

**Evaluator PEC-XIV**

| | | |
|---|---|---|
| **164.** | Name and address of manufacturer / Applicant | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| | Brand Name +Dosage Form + Strength | Milri Injection 10 mg/10ml |
| | Composition | Each 10 ml contains<br>Milrinone (as lactate)……..10mg |
| | Diary No. Date of R& I & fee | Diary No:5251, 08/06/2017, Rs: 20,000/- |
| | Pharmacological Group | Inotropic agent & vasodilator |
| | Type of Form | Form-5 |
| | Finished product Specification | Innovator's specifications |
| | Pack size & Demanded Price | 1's x 10ml/As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Milrinone 1 mg/ml concentrate for solution for infusion by M/s Stragen UK Limited (MHRA Approved) |
| | Me-too status | Milrone 10mg/10ml Injection by M/s ATCO (Reg#053459) |
| | GMP status | 03-05-17; Inspection of Additional Sections.<br>Panel recommends grant of additional sections. |
| | Previous remarks of the Evaluator. | • **In MHRA:**<br>Nature and contents of container Type 1 colourless glass ampoules of 10 ml and 20 ml packed in boxes of 10.<br>• Firm has claimed USP specification but product monograph is not confirmed from available pharmacopoeias. |
| | Previous decision(s) | Registration Board was apprised that applied formulation is available in glass ampoules, both in Reference Regulatory Authorities and as generics approved by DRAP, whereas, firm has applied for formulation in polyethylene ampoules.<br>Registration Board deliberated that difference in packaging material is not considered as New Drug. So, no need to be applied on Form 5D and such applications shall be treated as Me-too/Generic, while stability studies data, as per guidelines decided by Registration Board in its 251st meeting, shall be submitted to establish shelf life with applied packaging material. Hence Registration Board deferred the case for submission of stability studies data, as per guidelines decided by Registration Board in its 251st meeting **(M-274)**. |
| | Evaluation by PEC | The firm has submitted details of stability study data which are as follows: |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Milri Injection 10 mg/10ml | | |
| Name of Manufacturer | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore | | |
| Manufacturer of API | M/s Kinfon Pharmachem Co., Limited, 32F, Duhe Plaza, Lijiatuo Street, Banan Dist, Chongqing, China.<br>**Indentor**: Fine Gas company Limited, 130, Industrial Estate, Kot Lakhpat, Lahore. | | |
| API Lot No. | 20170312A01 | | |
| Description of Pack (Container closure system) | LDPE ampoule 10ml in a box of 1's × 10ml | | |
| Stability Storage Condition | Accelerated: 40°C ± 2°C/25%RH | | |
| Time Period | Accelerated: 06 months | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (months) | | |
| Batch No. | MITB/001 | MITB/002 | MITB/003 |
| Batch Size | 500ampoules | 500ampoules | 500ampoules |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |

| | | | |
|---|---|---|---|
| Date of Initiation | --------- | --------- | --------- |
| No. of Batches | 03 | | |
| Date of Submission | 42480 (12-12-2018) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s Kinfon PharmaChem Co., Limited, China has been 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. | Not submitted. |
| 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. | Not submitted |
| 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 6 months accelerated stability study data for 3 batches.
- Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.
- GMP certificate of API manufacturer is required to be submitted.
- Commitments as per 278th meeting of Registration Board need to be submitted.
- Date of initiation of & implementation is not mentioned in Stability study data sheet.
- The firm has not performed water loss test.
- The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH.

**Decision: Deferred for following:**

- **Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.**
- **GMP certificate of API manufacturer is required to be submitted.**
- **Commitments as per 278th meeting of Registration Board need to be submitted.**
- **Date of initiation of & implementation is not mentioned in Stability study data sheet.**
- **The firm has not performed water loss test.**
- **The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH, with similar results.**

| | | |
|---|---|---|
| **165.** | Name and address of manufacturer / Applicant | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| | Brand Name +Dosage Form + Strength | ONDERON 2mg/ml injection |
| | Composition | Each ml contains:<br>Ondansetron (as hydrochloride dehydrate)…2mg |
| | Diary No. Date of R& I & fee | Diary No:5253, 08/06/2017, Rs: 20,000/- |
| | Pharmacological Group | Serotonin (5HT3) antagonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 5's x 4ml/As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Zofran Flexi-amp injection 2 mg/ml by M/s Novartis Pharmaceuticals UK Ltd, (MHRA Approved) |
| | Me-too status | Setrox Injection by M/s Regal Pharmaceuticals (Reg#082003) |
| | GMP status | 03-05-17; Inspection of Additional Sections. |

| | | |
|---|---|---|
| | | Panel recommends grant of additional sections. |
| | Previous remarks of the Evaluator. | • |
| | Previous decision(s) | Registration Board was apprised that applied formulation is available in glass ampoules, both in Reference Regulatory Authorities and as generics approved by DRAP, whereas, firm has applied for formulation in polyethylene ampoules.<br>Registration Board deliberated that difference in packaging material is not considered as New Drug. So, no need to be applied on Form 5D and such applications shall be treated as Me-too/Generic, while stability studies data, as per guidelines decided by Registration Board in its 251st meeting, shall be submitted to establish shelf life with applied packaging material. Hence Registration Board deferred the case for submission of stability studies data, as per guidelines decided by Registration Board in its 251st meeting **(M-274)**. |
| | Evaluation by PEC | The firm has submitted details of stability study data which are as follows: |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | ONDERON 2mg/ml injection | | |
| Name of Manufacturer | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore | | |
| Manufacturer of API | M/s SYMED LABS LIMITED (UNIT-VI), Telangana, India | | |
| API Lot No. | 7DON0060517 | | |
| Description of Pack (Container closure system) | LDPE ampoule 4ml in a box of 4ml × 5 | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/25% RH<br>Real time: | | |
| Time Period | Accelerated: 06 months<br>Real time: | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (months)<br>Real time: | | |
| Batch No. | Ond 001 | Ond 002 | Ond 003 |
| Batch Size | 500ampoules | 500ampoules | 500ampoules |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | --------- | --------- | --------- |
| No. of Batches | 03 | | |
| Date of Submission | 2039 (16-01-2019) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s SYMED LABS LIMITED (UNIT-VI), Telangana, India 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. | Copy of GMP of M/s SYMED LABS LIMITED (UNIT-VI), Telangana, India issued by Drug Control Administration, Government of Telangana, India has been submitted. |
| 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. | Not submitted |
| 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 6 months accelerated stability study data for 3 batches.
- Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.
- Commitments as per 278th meeting of Registration Board need to be submitted.
- Date of initiation of & implementation is not mentioned in Stability study data sheet.
- The firm has not performed water loss test.
- The firm had initially submitted stability data with storage conditions of 40°C± 2°C/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40°C± 2°C/NMT 25%RH. Justification/clarification is required.

**Decision: Deferred for following:**

- **Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.**
- **GMP certificate of API manufacturer is required to be submitted.**
- **Commitments as per 278th meeting of Registration Board need to be submitted.**
- **Date of initiation of & implementation is not mentioned in Stability study data sheet.**
- **The firm has not performed water loss test.**
- **The firm had initially submitted stability data with storage conditions of 40°C± 2°C/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40°C± 2°C/NMT 25%RH, with similar results.**

| | | |
|---|---|---|
| **166.** | Name and address of manufacturer / Applicant | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| | Brand Name +Dosage Form + Strength | NUSPASNIL plus injection |
| | Composition | Each ampoule contains<br>Phloroglucinol Hydrate……..40mg<br>Trimethyl phloroglucinol……...0.04mg |
| | Diary No. Date of R& I & fee | Diary No:5270, 08/06/2017, Rs: 20,000/- |
| | Pharmacological Group | Anti-spasmodic |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer's Specifications |
| | Pack size & Demanded Price | 6's x 4ml/As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | SPASFON, solution for injection in ampoule 4ml by M/s TEVA HEALTH, (ANSM Approved) |
| | Me-too status | Spasfon Injection 4ml by M/s Himont (Reg#018530) |
| | GMP status | 03-05-17; Inspection of Additional Sections.<br>Panel recommends grant of additional sections. |
| | Previous remarks of the Evaluator. | In ANSM<br>Glass ampoule (s) of 4 ml |
| | Previous decision(s) | Registration Board was apprised that applied formulation is available in glass ampoules, both in Reference Regulatory Authorities and as generics approved by DRAP, whereas, firm has applied for formulation in polyethylene ampoules.<br>Registration Board deliberated that difference in packaging material is not considered as New Drug. So, no need to be applied on Form 5D and such applications shall be treated as Me-too/Generic, while stability studies data, as per guidelines decided by Registration Board in its 251st meeting, shall be submitted to establish shelf life with applied packaging material. Hence Registration Board deferred the case for submission of stability studies data, as per guidelines decided by Registration Board in its 251st meeting **(M-274)**. |
| | Evaluation by PEC | The firm has submitted details of stability study data which are as follows: |

| **STABILITY STUDY DATA** | |
|---|---|
| Drug | NUSPASNIL plus injection |
| Name of Manufacturer | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| Manufacturer of API | M/s TAIXING YINXIN CHEMICAL Co., Ltd, TAIXING CITY, China |
| API Lot No. | Phloroglucinol Dihydrate: TX20170606<br>Trimethyl Phloroglucinol: TMB20170401 |

| | | | |
|---|---|---|---|
| Description of Pack (Container closure system) | LDPE ampoule 4ml in a box of 4ml × 5 | | |
| Stability Storage Condition | Accelerated: 40°C ± 2°C/25% RH<br>Real time: | | |
| Time Period | Accelerated: 06 months<br>Real time: | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (months)<br>Real time: | | |
| Batch No. | PHTP 001 | PHTP 002 | PHTP 003 |
| Batch Size | 500ampoules | 500ampoules | 500ampoules |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | --------- | --------- | --------- |
| No. of Batches | 03 | | |
| Date of Submission | 2039 (16-01-2019) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s TAIXING YINXIN CHEMICAL Co., Ltd, TAIXING CITY, 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. | Copy of GMP of M/s Kaifeng Mingren Pharmaceutical Co., Ltd China issued by China Food and Drug Administration has been submitted. |
| 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. | Not submitted |
| 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 6 months accelerated stability study data for 3 batches.
- Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.
- Commitments as per 278th meeting of Registration Board need to be submitted.
- API manufacturer mentioned on GMP certificate is different from that mentioned on COA.
- The firm has not performed water loss test.
- Date of initiation of & implementation is not mentioned in Stability study data sheet.
- The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH. Justification/clarification is required.

**Decision: Deferred for following:**

- **Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.**
- **GMP certificate of API manufacturer is required to be submitted.**
- **Commitments as per 278th meeting of Registration Board need to be submitted.**
- **Date of initiation of & implementation is not mentioned in Stability study data sheet.**
- **The firm has not performed water loss test.**
- **The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH, with similar results.**

| | | |
|---|---|---|
| **167.** | Name and address of manufacturer / Applicant | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| | Brand Name +Dosage Form + Strength | DOMIN 250mg/20ml injection |
| | Composition | Each ml contains:<br>Dobutamine (as hydrochloride)…12.5 mg |
| | Diary No. Date of R& I & fee | Diary No:5277, 08/06/2017, Rs: 20,000/- |
| | Pharmacological Group | Beta 1-agonist |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1's x20ml/As Per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Dobutamine 12.5 mg/ml, concentrate for solution for infusion by M/s Hameln Pharma plus gmbh (MHRA Approved) |
| | Me-too status | Dobutrex solution 250mg/20ml by M/s Ali Gohar & Co (Reg#012912) |
| | GMP status | 03-05-17; Inspection of Additional Sections.<br>Panel recommends grant of additional sections. |
| | Previous remarks of the Evaluator. | • **In MHRA:**<br>Nature and contents of container<br>20 ml clear glass ampoule (type I) |
| | Previous decision(s) | Registration Board was apprised that applied formulation is available in glass ampoules, both in Reference Regulatory Authorities and as generics approved by DRAP, whereas, firm has applied for formulation in polyethylene ampoules.<br>Registration Board deliberated that difference in packaging material is not considered as New Drug. So, no need to be applied on Form 5D and such applications shall be treated as Me-too/Generic, while stability studies data, as per guidelines decided by Registration Board in its 251st meeting, shall be submitted to establish shelf life with applied packaging material. Hence Registration Board deferred the case for submission of stability studies data, as per guidelines decided by Registration Board in its 251st meeting **(M-274)**. |
| | Evaluation by PEC | The firm has submitted details of stability study data which are as follows: |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | DOMIN 250mg/20ml injection | | |
| Name of Manufacturer | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore | | |
| Manufacturer of API | M/s ARIHANTANAM LIFE CARE PVT. Ltd, India | | |
| API Lot No. | | | |
| Description of Pack (Container closure system) | LDPE ampoule 20ml in a box of 1's × 20ml | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/25%RH<br>Real time: | | |
| Time Period | Accelerated: 06 months<br>Real time: | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (months)<br>Real time: | | |
| Batch No. | DBTN 001 | DBTN 002 | DBTN 003 |
| Batch Size | 500ampoules | 500ampoules | 500ampoules |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | --------- | --------- | --------- |
| No. of Batches | 03 | | |
| Date of Submission | 2039 (16-01-2019) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| **Sr.** | **Documents To Be Provided** | **Status** |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s ARIHANTANAM LIFE CARE PVT. Ltd, India 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. | Copy of GMP of M/s ARIHANTANAM LIFE CARE PVT. Ltd, India issued by Food and Drug Control Administration, India has been submitted. |
| 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. | Not submitted |
| 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 6 months accelerated stability study data for 3 batches.
- Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.
- Commitments as per 278th meeting of Registration Board need to be submitted.
- Certificate of analysis of API is not submitted.
- Date of initiation of & implementation is not mentioned in Stability study data sheet.
- The firm has not performed water loss test.
- The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH. Justification/clarification is required.

**Decision: Deferred for following:**

- **Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.**
- **GMP certificate of API manufacturer is required to be submitted.**
- **Commitments as per 278th meeting of Registration Board need to be submitted.**
- **Date of initiation of & implementation is not mentioned in Stability study data sheet.**
- **The firm has not performed water loss test.**
- **The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH, with similar results.**

| | | |
|---|---|---|
| **168.** | Name and address of manufacturer / Applicant | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| | Brand Name +Dosage Form + Strength | Neudopamit Injection 5ml |
| | Composition | Each ml contains:<br>Dopamine hydrochloride…40mg |
| | Diary No. Date of R& I & fee | Diary No:20652, 10/11/2017, Rs. 20,000/- |
| | Pharmacological Group | Adrenergic and dopaminergic agents |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 10's x 5ml/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Dopamine Hydrochloride 40mg/ml Concentrate for Solution for Infusion by M/s Mercury Pharma International Ltd (MHRA Approved) |
| | Me-too status | Dalpam 200mg/5ml Injection by M/s Safe Pharmaceuticals (Pvt.) Limited (Reg# 058225) |
| | GMP status | 03-05-17; Inspection of Additional Sections.<br>Panel recommends grant of additional sections. |
| | Previous remarks of the Evaluator. | • **<u>In MHRA:</u>**<br>• **Nature and Content of Container**<br>5 ml clear glass one point-cut (OPC) ampoules, glass Type I Ph |

| | | |
|---|---|---|
| | | Eur. |
| | Previous decision(s) | Registration Board was apprised that applied formulation is available in glass ampoules, both in Reference Regulatory Authorities and as generics approved by DRAP, whereas, firm has applied for formulation in polyethylene ampoules.<br>Registration Board deliberated that difference in packaging material is not considered as New Drug. So, no need to be applied on Form 5D and such applications shall be treated as Me-too/Generic, while stability studies data, as per guidelines decided by Registration Board in its 251st meeting, shall be submitted to establish shelf life with applied packaging material. Hence Registration Board deferred the case for submission of stability studies data, as per guidelines decided by Registration Board in its 251st meeting **(M-277)**. |
| | Evaluation by PEC | The firm has submitted details of stability study data which are as follows: |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Neudopamit Injection 5ml | | |
| Name of Manufacturer | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore | | |
| Manufacturer of API | M/s DK PHARMA CHEM PVT. LTD, BADLAPUR DISTRICT, BADLAPUR | | |
| API Lot No. | | | |
| Description of Pack (Container closure system) | LDPE ampoule 5ml, Packed as 5ml × 10's | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/25%RH<br>Real time: | | |
| Time Period | Accelerated: 06 months<br>Real time: | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (months)<br>Real time: | | |
| Batch No. | DPN- 001 | DPN- 002 | DPN- 003 |
| Batch Size | 500ampoules | 500ampoules | 500ampoules |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | --------- | --------- | --------- |
| No. of Batches | 03 | | |
| Date of Submission | 2039 (16-01-2019) | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr.** | **Documents To Be Provided** | **Status** |
| 1. | COA of API | Not 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. | Copy of GMP certificate from M/s DK PHARMA CHEM PVT. LTD, BADLAPUR DISTRICT, BADLAPUR issued by Food and Drug Administration, Maharashtra State, India has been submitted. |
| 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. | Not submitted |
| 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 6 months accelerated stability study data for 3 batches.

- Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.
- Commitments as per 278th meeting of Registration Board need to be submitted.
- Certificate of analysis of API is not submitted.
- The firm has not performed water loss test.
- Date of initiation & implementation is not mentioned in Stability study data sheet.
- The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH. Justification/clarification is required.

**Decision: Deferred for following:**

- **Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.**
- **GMP certificate of API manufacturer is required to be submitted.**
- **Commitments as per 278th meeting of Registration Board need to be submitted.**
- **Date of initiation of & implementation is not mentioned in Stability study data sheet.**
- **The firm has not performed water loss test.**
- **The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH, with similar results.**

| **169.** | | |
|---|---|---|
| | Name and address of manufacturer / Applicant | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| | Brand Name +Dosage Form + Strength | P-Vacin Injection 0.5% |
| | Composition | Each ml contains:<br>Bupivacaine hydrochloride…5mg |
| | Diary No. Date of R& I & fee | Diary No:20653, 10/11/2017, Rs. 20,000/- |
| | Pharmacological Group | Local Anesthetic (Amides) |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 5's x 10ml/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Bupivacaine Hydrochloride 5 mg/ml Solution for Injection by M/s Milpharm Limited (MHRA Approved) |
| | Me-too status | Sensocain Injection 5mg/ml by M/s Brookes Pharmaceuticals (Reg# 047396) |
| | GMP status | 03-05-17; Inspection of Additional Sections.<br>Panel recommends grant of additional sections. |
| | Previous remarks of the Evaluator. | • **In MHRA:**<br>**Nature and contents of container**<br>10 ml type I clear glass ampoules. .<br>Each carton contains 1, 5, 10, 20 and 100 ampoules. |
| | Previous decision(s) | Registration Board was apprised that applied formulation is available in glass ampoules, both in Reference Regulatory Authorities and as generics approved by DRAP, whereas, firm has applied for formulation in polyethylene ampoules.<br>Registration Board deliberated that difference in packaging material is not considered as New Drug. So, no need to be applied on Form 5D and such applications shall be treated as Me-too/Generic, while stability studies data, as per guidelines decided by Registration Board in its 251st meeting, shall be submitted to establish shelf life with applied packaging material. Hence Registration Board deferred the case for submission of stability studies data, as per guidelines decided by Registration Board in its 251st meeting **(M-277)**. |
| | Evaluation by PEC | The firm has submitted details of stability study data which are as follows: |

| **STABILITY STUDY DATA** | |
|---|---|
| Drug | P-Vacin Injection 0.5% |
| Name of Manufacturer | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| Manufacturer of API | M/s Dishman Carbogen Amics Ltd., Gujarat, India |
| API Lot No. | |

| | | | |
|---|---|---|---|
| Description of Pack (Container closure system) | LDPE ampoule 10ml, Packed as 4ml × 5's | | |
| Stability Storage Condition | Accelerated: 40°C ± 2°C/25%RH<br>Real time: | | |
| Time Period | Accelerated: 06 months<br>Real time: | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (months)<br>Real time: | | |
| Batch No. | BCN- 001 | BCN- 002 | BCN- 003 |
| Batch Size | 500ampoules | 500ampoules | 500ampoules |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | --------- | --------- | --------- |
| No. of Batches | 03 | | |
| Date of Submission | 2039 (16-01-2019) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of M/s Dishman Carbogen Amics Ltd., Gujarat, India 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. | Copy of GMP certificate from M/s Dishman Carbogen Amics Ltd., Gujarat, India issued by Food and Drug Control Administration, Gujarat State, India has been submitted. |
| 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. | Not submitted |
| 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 6 months accelerated stability study data for 3 batches.
- Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.
- Commitments as per 278th meeting of Registration Board need to be submitted.
- Certificate of analysis of API is not submitted.
- The firm has not performed water loss test.
- Date of initiation & implementation is not mentioned in Stability study data sheet.
- The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH. Justification/clarification is required.

**Decision: Deferred for following:**

- **Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.**
- **GMP certificate of API manufacturer is required to be submitted.**
- **Commitments as per 278th meeting of Registration Board need to be submitted.**
- **Date of initiation of & implementation is not mentioned in Stability study data sheet.**
- **The firm has not performed water loss test.**
- **The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH, with similar results.**

| | | |
|---|---|---|
| **170.** | Name and address of manufacturer / Applicant | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore |
| | Brand Name +Dosage Form + Strength | Neulepil 500mg Injection |
| | Composition | Each 5ml ampoule contains:<br>Levetiracetam …500mg |
| | Diary No. Date of R& I & fee | Diary No:20651, 10/11/2017, Rs. 20,000/- |
| | Pharmacological Group | Antiepileptic |
| | Type of Form | Form-5 |
| | Finished product Specification | USP |
| | Pack size & Demanded Price | 1's x 5ml/ As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Levetiracetam Beacon 100 mg/ml concentrate for solution for infusion by M/s Beacon Pharmaceuticals Ltd (MHRA Approved) |
| | Me-too status | Eplipsa Injection 500mg/5ml by M/s Helix (Reg#075918) |
| | GMP status | 03-05-17; Inspection of Additional Sections.<br>Panel recommends grant of additional sections. |
| | Previous remarks of the Evaluator. | • **In MHRA:**<br>• Nature and contents of container<br>5 ml glass vial (type I) with polytetrafluoroethylene coated bromobutyl rubber stoppers and sealed with an aluminium/polypropylene flip off cap. |
| | Previous decision(s) | Registration Board was apprised that applied formulation is available in glass ampoules, both in Reference Regulatory Authorities and as generics approved by DRAP, whereas, firm has applied for formulation in polyethylene ampoules.<br>Registration Board deliberated that difference in packaging material is not considered as New Drug. So, no need to be applied on Form 5D and such applications shall be treated as Me-too/Generic, while stability studies data, as per guidelines decided by Registration Board in its 251st meeting, shall be submitted to establish shelf life with applied packaging material. Hence Registration Board deferred the case for submission of stability studies data, as per guidelines decided by Registration Board in its 251st meeting **(M-277)**. |
| | Evaluation by PEC | The firm has submitted details of stability study data which are as follows: |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Neulepil 500mg Injection | | |
| Name of Manufacturer | M/s. Neutro pharma (Pvt.) Ltd. 9.5 km Sheikhupura Road Lahore | | |
| Manufacturer of API | M/s Zheijiang Huahai Pharmaceutical Co., Ltd., China | | |
| API Lot No. | | | |
| Description of Pack (Container closure system) | LDPE ampoule 5ml, Packed as 5ml × 1's | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C/25%RH<br>Real time: | | |
| Time Period | Accelerated: 06 months<br>Real time: | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (months)<br>Real time: | | |
| Batch No. | NTPL- 001 | NTPL- 002 | NTPL- 003 |
| Batch Size | 500ampoules | 500ampoules | 500ampoules |
| Manufacturing Date | 01-2018 | 01-2018 | 01-2018 |
| Date of Initiation | --------- | --------- | --------- |
| No. of Batches | 03 | | |
| Date of Submission | 2039 (16-01-2019) | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr.** | **Documents To Be Provided** | **Status** |

| | | |
|---|---|---|
| 1. | COA of API | Copy of M/s Zheijiang Huahai Pharmaceutical 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. | Copy of GMP certificate from M/s Zheijiang Huahai Pharmaceutical Co., Ltd., China issued by Zheijiang Meureine Center for Economic Development has been submitted. It is valid until 22-04-2020 |
| 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. | Not submitted |
| 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 6 months accelerated stability study data for 3 batches.
- Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.
- Commitments as per 278th meeting of Registration Board need to be submitted.
- Certificate of analysis of API is not submitted.
- The firm has not performed water loss test.
- Date of initiation & implementation is not mentioned in Stability study data sheet.
- The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH. Justification/clarification is required.

**Decision: Deferred for following:**

- **Real time stability study data supported by lab reports, raw data sheets and chromatograms are required to be submitted.**
- **GMP certificate of API manufacturer is required to be submitted.**
- **Commitments as per 278th meeting of Registration Board need to be submitted.**
- **Date of initiation of & implementation is not mentioned in Stability study data sheet.**
- **The firm has not performed water loss test.**
- **The firm had initially submitted stability data with storage conditions of 40ºC± 2ºC/75%± 5% RH. Now the firm has submitted data with revised storage conditions of 40ºC± 2ºC/NMT 25%RH, with similar results.**

## b. Onsite Verification of stability study data

**Evaluator PEC-II**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| **171.** | M/s Weather Folds Pharaceuticals, Plot No.62/2, Phase-II Industrial Estate Hattar. | Empaa-M 5/500mg tablet<br>Each film coated tablet contains:-<br>Empagliflozin ….. 5mg<br>Metforimn HCl …… 500mg<br>(Anti-diabetic) | Form 5-D<br>Diary No. 43470 dated 24-12-2018<br>Rs. 50,000/- dated 24-12-2018<br>As per SRO | Synjardy approved by USFDA |
| | **Evaluation by PEC:**<br>The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board.<br>Details of submitted data are as under: | | | |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Empaa-M 5/500mg tablet | | |
| Name of Manufacturer | M/s Weather Folds Pharaceuticals, Plot No.62/2, Phase-II Industrial Estate Hattar. | | |
| Manufacturer of API | **Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd., Zhejiang, China.<br>**Metformin HCl:** M/s IOL Chemicals & Pharmaceuticals Ltd., Village Fatehgarh Channa, Mansa Road, (Trident Complex), Barnala-Punjab-India. | | |
| API Lot No. | **Empagliflozin:** 20170929<br>**Metformin HCl:** 4250/1203/18/A-0028PM | | |
| Description of Pack (Container closure system) | Alu-Alu foil | | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 65% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| Time Period | Real time: 6 months<br>Accelerated: 6 months | | |
| Frequency | Accelerated: 0,1,2,3,4,6 months<br>Real Time: 0,3,6 months | | |
| Batch No. | T16 | T17 | T18 |
| Batch Size | 1200 Tablets | 1200 Tablets | 1200 Tablets |
| Manufacturing Date | 18-05-2018 | 18-05-2018 | 18-05-2018 |
| Date of Initiation | 21-05-2018 | 21-05-2018 | 21-05-2018 |
| No. of Batches | 03 | | |

| **DOCUMENTS / DATA PROVIDED BY THE APPLICANT** | | |
|---|---|---|
| **Sr. No.** | **Documents To Be Provided** | **Status** |
| 1. | COAS of APIs | Yes. |
| 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. | **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180032) issued by China Food & Drug Administration valid upto 14-03-2023.<br>**Metformin HCl:** Copy of GMP certificate |

| | | |
|---|---|---|
| | | (Certificate# 2018/1895) issued by Food and Drug Administration, Pujab for M/s IOL Chemicals & Pharmaceuticals Ltd., Village Fatehgarh Channa, Mansa Road, (Trident Complex), Barnala-Punjab-India valid upto 07-03-2018 has been submitted. |
| 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. | **Empagliflozin:** Copy of commercial invoice (Invoice# ZMI/C/003/2017-18) dated 10-10-2017 has been submitted. (Quantity: 100gm)<br>**Metformin HCl:** Copy of Goods Declaration in the name of M/s Weatherfolds Pharmaceuticals for Metformin HCl. (Quantity 13Kg) |
| 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**

- Submitted commercial invoices for import of both APIs have not been attested by ADC, DRAP. Documents of approval issued by DRAP for import of APIs shall be submitted.

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| **172.** | M/s Weather Folds Pharaceuticals, Plot No.62/2, Phase-II Industrial Estate Hattar. | Empaa-M 12.5/500mg tablet<br>Each film coated tablet contains:-<br>Empagliflozin ….. 12.5mg<br>Metforimn HCl …… 500mg<br>(Anti-diabetic) | Form 5-D<br>Diary No. 43739 dated 24-12-2018<br>Rs. 50,000/- dated 24-12-2018<br>As per SRO | Synjardy approved by USFDA |
| | **Evaluation by PEC:**<br>The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board.<br>Details of submitted data are as under: | | | |

**STABILITY STUDY DATA**

| | |
|---|---|
| Drug | Empaa-M 12.5/500mg tablet |
| Name of Manufacturer | M/s Weather Folds Pharmaceuticals, Plot No.62/2, Phase-II Industrial Estate Hattar. |
| Manufacturer of API | **Empagliflozin:** M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd., Zhejiang, China.<br>**Metformin HCl:** M/s IOL Chemicals & Pharmaceuticals Ltd., Village Fatehgarh Channa, Mansa Road, (Trident Complex), Barnala-Punjab-India. |
| API Lot No. | **Empagliflozin:** 20170929<br>**Metformin HCl:** 4250/1203/18/A-0028PM |

| | | | |
|---|---|---|---|
| Description of Pack (Container closure system) | Alu-Alu foil | | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 65% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| Time Period | Real time: 6 months<br>Accelerated: 6 months | | |
| Frequency | Accelerated: 0,1,2,3,4,6 months<br>Real Time: 0,3,6 months | | |
| Batch No. | T19 | T20 | T21 |
| Batch Size | 1200 Tablets | 1200 Tablets | 1200 Tablets |
| Manufacturing Date | 18-05-2018 | 18-05-2018 | 18-05-2018 |
| Date of Initiation | 21-05-2018 | 21-05-2018 | 21-05-2018 |
| No. of Batches | 03 | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COAS of APIs | Yes. |
| 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. | **Empagliflozin:** Copy of GMP certificate (Certificate# ZJ20180032) issued by China Food & Drug Administration valid upto 14-03-2023.<br>**Metformin HCl:** Copy of GMP certificate (Certificate# 2018/1895) issued by Food and Drug Administration, Pujab for M/s IOL Chemicals & Pharmaceuticals Ltd., Village Fatehgarh Channa, Mansa Road, (Trident Complex), Barnala-Punjab-India valid upto 07-03-2018 has been submitted. |
| 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. | **Empagliflozin:** Copy of commercial invoice (Invoice# ZMI/C/003/2017-18) dated 10-10-2017 has been submitted. (Quantity: 100gm)<br>**Metformin HCl:** Copy of Goods Declaration in the name of M/s Weatherfolds Pharmaceuticals for Metformin HCl. (Quantity 13Kg) |
| 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**

- Submitted commercial invoices for import of both APIs have not been attested by ADC, DRAP. Documents of approval issued by DRAP for import of APIs shall be submitted.

**Audit Format for PSI (Empaa-M 5/500mg and Empaa-M 12.5/500mg Tablets)**

Firm Name& Address: Weatherfolds Pharmaceutical Hattar Plot No 69/2,Phase 2 Industrial Estate Hattar

**Panel members:**

- Director DTL, Peshawar (Member Registration Board)
- Dr. Muhammad Usman (Member CLB)

- Mr. Adnan (Assistamnt Dirctor, DRAP Peshawar)

**Inspection dated 08-02-2019**

| | | |
|---|---|---|
| Q.No.1 | Do you have documents confirming the import of **(Empaa-M 5/500mg. Empaa-M 12.5/500mg Tablets)** APIs? | Invoices, gate passes available (ADC attested invoice not available) |
| Q.No.2 | What was the rationale behind selecting the particular manufacturer of API? | GMP compliant and easy availability. |
| Q.No.3 | Do you have documents confirming the import of Metformin and Empagliflozin reference standard and impurity standards? | Record unavailable for impurities. |
| Q.No.4 | Do you have certificate of Analysis of the API, reference standards and impurity standards? | Yes for API, Impurities not available |
| Q.No.5 | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | Yes GMP certificates for both APIs available |
| Q.No.6 | Do you use API manufacturer method of testing? | Yes |
| Q.No.7 | Do you have stability studies reports on API? | Yes as supplied by manufacturer |
| Q.No.8 | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | Not available |
| Q.No.9 | Do you have method for quantifying the impurities in the API? | Method available |
| Q.No.10 | Do you have some remaining quantities of the API, its reference standard and impurities standards? | Yes for API, No impurities available |
| Q.No.11 | Have you used pharmaceutical grade excipients? | Yes |
| Q.No.12 | Do you have documents confirming the import of the used excipients? | For other registered products |
| Q.No.13 | Do you have test reports and other records on the excipients used? | Yes |
| Q.No.14 | Do you have written and authorized protocols for the development of **Empaa-M 5/500mg. Empaa-M 12.5/500mg Tablets**? | Yes |
| Q.No.15 | Have you performed Drug-excipient compatibility studies? | Record available |
| Q.No.16 | Whether firm has performed comparative dissolution studies? | Record for Synjardy 5mg/1000mg vs EMPAA-M Batch# T-16 available. |
| Q.No.17 | Do you have product development (R&D) section | **No** |
| Q.No.18 | Do you have necessary equipments available in product development section for development of **Empaa-M 5/500mg. Empaa-M 12.5/500mg Tablets?** | Not Applicable |
| Q.No.19 | Are the equipments in product development section qualified? | Not Applicable |
| Q.No.20 | Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section? | Not Applicable |
| Q.No.21 | Do you have qualified staff in product development section with proper knowledge and training in product development? | Yes |
| Q.No.22 | Have you manufactured three stability batches for the stability studies of **Empaa-M 5/500mg. Empaa-M 12.5/500mg Tablets** as required? | Yes |
| Q.No.23 | What was the criteria for fixing the batch size of stability batches? | The criteria for fixing the batch size of the stability batches is the quantity |

| | | |
|---|---|---|
| | | required for testing and number of testing frequencies. |
| Q.No.24 | Do you have complete record of production of stability batches? | Yes |
| Q.No.25 | Do you have protocols for stability testing of stability batches? | Yes |
| Q.No.26 | Do you have developed and validated the method for testing of stability batches? | In-house method developed and validated |
| Q.No.27 | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | Not applicable |
| Q.No.28 | Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug? | Calibration record maintained. |
| Q.No.29 | Do your method of analysis stability indicating? | Yes, method validated |
| Q.No.30 | Do your HPLC software is 21CFR compliant? | Yes |
| Q.No.31 | Can you show Audit Trail reports on **Empaa-M 5/500mg. Empaa-M 12.5/500mg Tablets** testing? | Yes |
| Q.No.32 | Do you have some remaining quantities of degradation products and stability batches? | Degradation products not available<br>Stability batches available |
| Q.No.33 | Do you have commitment batches kept on stability testing? | Yes |
| Q.No.34 | Do you have valid calibration status for the equipments used in **Empaa-M 5/500mg. Empaa-M 12.5/500mg Tablets** production in analysis? | Yes |
| Q.NO.35 | Do proper and continuous monitoring and control are available for stability chamber? | Manual records maintained. |
| Q.No.36 | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | Yes |

(a) Gate passes, (GRN) good receiving notes and Good Declaration (GD) copies of both APIs available.
(b) Record of content uniformity tests available.

**Conclusion:**

On risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of **Empaa-M 5/500mg. Empaa-M 12.5/500mg Tablets** is verifiable to satisfactory level.

**Decision: Registration Board decided to approve registration of "Empaa-M 5/500mg Tablets & Empaa-M 12.5/500mg Tablets" by M/s Weatherfold Pharmaceuticals (Pvt) Ltd., Plot # 62/2, phase II, industrial estate Hattar. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| **173.** | M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K | Sofotun 400 mg tablet<br>Each film coated tablet contains:-<br>Sofosbuvir…….400mg<br>Anti-viral | Form-5-D<br>Dy. No: 758<br>Dated.2-11-2015<br>Rs.20,000/- (29-10-2015)<br>Duplicate<br>10's ; Rs. 3400/-<br>14's; Rs. 4760/- | Sovaldi (FDA Approved).<br>GMP inspection report conducted on Inspection dated 13-02-2018, with good GMP |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Sofotun 400 mg tablet | | |
| Name of Manufacturer | M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K | | |
| Manufacturer of API | **Sofosbuvir:** Zhejiang Warrant Pharmaceutical Co., Ltd.,Xinbin road, Binhai industry zone, Shaoxing county, Zhejiang province, China. | | |
| API Lot No. | **Sofosbuvir:** A1-620161201 | | |
| Description of Pack (Container closure system) | 28 tablets in blister | | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 75% ± 5% RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5% RH | | |
| Time Period | Real time: 6 months<br>Accelerated:6 months | | |
| Frequency | Accelerated: 1, 3,6,8,12,16,20, 24 (weeks)<br>Real Time: 0,1, 2, 3,4, 6,8,12,16,20,24,26 (weeks) | | |
| Batch No. | Sofo T001 | Sofo T002 | Sofo T003 |
| Batch Size | 1800 tablets | 1800 tablets | 1800 tablets |
| Manufacturing Date | 12-2017 | 12-2017 | 12-2017 |
| Date of Initiation | 12-2017 | 12-2017 | 12-2017 |
| No. of Batches | 03 | | |
| Date of Submission | 24-1-2018 (Dy. No. 3164) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. No. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 2. 0 | Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin. | **Sofosbuvir:** Copy of GMP certificate issued to Zhejiang Warrant Pharmaceutical Co., Ltd.,Xinbin road, Binhai industry zone, Shaoxing county, Zhejiang province, China valid till; 2-28-2021 |
| 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. | **Sofosbuvir:** Copy of commercial invoice not submitted. AD Peshawar attested, Form 6 is provided |
| 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**

| Sr.# | Deficiency/Observation | Response by Pharma. |
|---|---|---|
| 1. | GMP of API manufacturer not provided. | Copy of GMP certificate issued to Zhejiang Warrant Pharmaceutical Co., Ltd.,Xinbin road, Binhai industry zone, Shaoxing county, Zhejiang province, China valid till; 2-28-2021was provided however scope of inspection is mentioned as Bulk Drug (Cetirizine HCl). |
| 2. | Master formulation is not provided | Provided |
| 3. | Chromatograms for each time point is not month wise and not in sequence. Chromatograms for week 4 is missing in accelerated stability. | The week 4 was a partial testing interval, so there were no chromatograms however the physical testing reports are provided |
| 4. | On stability data sheet capsule is mentioned instead of tablet. Clarification is required | The capsule is written mistakenly and the correct sheet is now provided |
| 5. | Invoice to import API is not AD attested | Copy of commercial invoice not submitted. AD Peshawar attested, Form 6 is provided |

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Sofotun 400mg Tablet by M/s Aulton Pharmaceuticals Pvt Limited, 84/1, Block A, Phase V, Industrial Estate Hattar**

**Reference No:** F.13-11/ 2017-PEC (Pt) dated 23-1-2019
**Investigation Date and Time:** 12th February 2019 (Afternoon)
**Investigation Site:** Premises of M/s Aulton Pharmaceuticals Pvt Limited, 84/1, Block A, Phase V, Industrial Estate Hattar.

**Background:**

Chairman Registration Board considered the applications of M/s Aulton Pharmaceuticals Pvt Limited, 84/1,Block A, Phase V, Industrial Estate Hattar for registration of Sofotun Tablets 400mg (Sofosbuvir) and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

**Composition of Panel:**

1. Dr. Muhammad Khalid Javed, Director Drug Testing Laboratory Peshawar.
2. *Dr. Muhammad Usman, Dean Faculty of Pharmacy, University of Lahore (Islamabad Campus)
3. Muneeb Ahmed Cheema, Assistant Director DRAP Islamabad

* Initially Dr. Qurban Ali Member Registration Board was the panel member but due to his non-availability, Chairman Registration Board nominated Dr. Muhammad Usman.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation are summarized as under:

| Sr. No. | Description | Observation by panel |
|---|---|---|
| 1. | Do you have documents confirming the import of API including approval from DRAP? | Copy of Import License (Form-6) to import 03Kg Sofosbuvir issued by ADC (Peshawar) vide letter no. 00180/2017-DRAP(PS)/454 dated 06-03-2017 from M/s Zhejiang Warrant Pharmaceuticals Ltd., Xinbin Road Binhai Industry Shaoxing Zhejiang 312073 China is provided. A copy of Goods Declaration Certificate No. P17330604276001 dated 14-02-2017 vide invoice vide No. 20170207WM dated 07-02-2017 for 3Kg Sofosbuvir vide batch No. A1-620161201 from aforesaid manufacturer is also provided. |
| 2. | Do you have any rationale behind selecting the particular manufacturer | Firm has selected the vendor of API i.e. M/s Zhejiang Warrant Pharmaceuticals Ltd., China on the basis of GMP certificate issued by CFDA. A copy of the same has been presented. |
| 3. | Do you have documents confirming the Import of Reference standard and Impurities standards? | Firm has not provided any document regarding the import of reference standard. However they state that 4g of Sofosbuvir working standard was provided along with the API. |
| 4. | Do you have certificate of analysis of the API reference standard and impurities standards? | Firm has provided certificate of analysis of Sofosbuvir claiming it as working standard but the said certificate does not indicate that whether it is reference/ working standard. Details are as under:<br>Batch No: YF20141227<br>Mfg Date: 27-12-2015<br>Retest Date: 26-12-2017<br>Quantity: 4g |
| 5. | Do you have any approval of API or GMP certificate of manufacturer issued by regulatory authority of country of origin? | Firm has provided copy of GMP certificate No. ZJ20160046 dated 29-02-2016 issued by CFDA in name of M/s Zhejiang Warrant Pharmaceuticals Ltd., China. |
| 6. | Do you use API manufacturer method of Testing for testing of API? | The Firm has developed in house method for the analysis of API |
| 7. | Do you have stability Studies Report on API? | The Stability study of the API by M/s Zhejiang Warrant Pharmaceuticals Ltd., China is not conducted as per Zone-IVA. The conditions are :<br>Accelerated: $40\pm2^0$C, RH75±5%<br>Real time: $25\pm2^0$C, RH 60±10% |
| 8. | If Yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | The related substances / impurities are quantified as indicated in stability data of API. |
| 9. | Do you have method for quantifying the impurities in the API? | The firm has no method for quantifying the impurities in the API. |
| 10. | Do you have some remaining quantities of the API, Its reference standard and impurities standard? | Firm has remaining 760gm of Sofosbuvir. Moreover, 4g working standard as mentioned above has been consumed but they have also developed 2gm secondary working standard from the working standard. 1.10gm is remaining for future testing. |

<table>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>Firm has used pharmaceutical grade excipients in the manufacturing of stability batches for Sofotun 400mg tablets.</td></tr>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>Firm has necessary documents for local purchase of used excipients in the formulation for Sofotun 400mg tablets.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients?</td><td>The firm has test reports and other records of the excipients used.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development drug product?</td><td>There is no protocol available for the development of drug product.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-Excipient compatibility studies?</td><td>The firm has not performed Drug-Excipient compatibility studies, they have informed that formulation is developed based on their experience in manufacturing of Tablets.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>Firm has presented Comparative dissolution study report. The details of reference product & Sample product are as follows:
<table>
<tr><td>Feature</td><td>Reference product</td><td>Product of Saffron</td></tr>
<tr><td>Brand name</td><td>Sofiget 400mg Tablet (Getz)</td><td>Sofotun 400mg tablet</td></tr>
<tr><td>Batch No.</td><td>195F86</td><td>T-001</td></tr>
</table>
Comparative dissolution studies have been performed in 0.05 M Monobasic Potassium Phosphate Buffer having pH 6.8, however similarity factor is not provided</td></tr>
<tr><td>17.</td><td>Do you have Product Development / R&D Section?</td><td>The firm has no separate product development (R&D) Section. They have used the product and QC department for manufacturing and analysis. Firm is advised to develop separate R&D Facility.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment's available in product development section for development drug product?</td><td>The firm has necessary equipment available in Production department</td></tr>
<tr><td>19.</td><td>Are the equipment's in product development qualified?</td><td>The available equipment in Production Department are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD?</td><td>There is proper maintenance / calibration program for the equipment used in Production Department.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has proper qualified staff in Production and QC Department.<br>03Pharmacists and 03Chemists 01 Microbiologist.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of drug product?</td><td>The firm has manufactured three stability batches for the stability studies of Sofotun400 mg tablets detailed as under:
<table>
<tr><td>Batch No.</td><td>T-001</td><td>T-002</td><td>T-003</td></tr>
<tr><td>Batch size</td><td>1,800 Tablets</td><td>1,800 Tablets</td><td>1,800 Tablets</td></tr>
<tr><td>Mfg. date</td><td>12-2017</td><td>12-2017</td><td>12-2017</td></tr>
</table></td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability of batches?</td><td>The criteria for fixing the batch size of stability batches is the number of samples required per testing frequency.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has detailed manufacturing record of all the three stability batches of Sofotun 400 mg tablet,</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>Firm has protocols for stability testing of the stability batches, which are based on the criteria as approved by the 251st meeting of Registration Board.</td></tr>
</table>

| | | |
|---|---|---|
| 26. | Do you have developed and validated the method for testing of stability batches? | The firm has developed in-house method for testing of Sofotun 400 mg tablet and validated the method. Analytical method validation report along with relevant chromatograms were presented during inspection. |
| 27. | Do you have method transfer studies in case when the method of testing being used by your firm is by any other lab? | Not applicable |
| 28. | Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of the product's API and drug product? | Firm has complete record of qualification of equipment / instruments used in the test and analysis of API and Sofotun 400 mg tablet |
| 29. | Do your method of analysis Stability indicating? | The firm has performed force degradation study on their product for conformance of its stability indicating method. |
| 30. | Is your HPLC software 21CFR compliant? | The firm has used Waters 600 Quaternary Gradient HPLC with 486 Detector for stability studies. Audit trail logs have been activated. |
| 31. | Can you show audit trail reports on drug product testing? | The firm has audit trail Reports on their testing |
| 32. | Do you have some remaining quantities of degradation products and stability batches? | The firm has remaining quantities of stability batches |
| 33. | Do you have batches kept on stability testing? | The firm has kept the remaining quantities of all batches in stability chamber for on-going real time stability study. |
| 34. | Do you have valid calibration status for the equipment's used in drug product's production and analysis? | The firm has valid calibration status of all equipment used in production and analysis of Sofotun 400 mg tablet. |
| 35. | Do Proper and Continuous monitoring and control are available for stability chamber? | The firm has stability chambers for accelerated and real time stability studies with uninterrupted power supply and however the data logging is being performed manually. |
| 36. | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | Related manufacturing area, equipment, personnel and utilities can be rated as compliant. |

**Conclusions:**
Submitted for consideration of Registration Board in lights of Points as highlighted at Sr. No. 4, 7, 10, 14, 15 and 16

**Decision:**
**Registration Board after thorough discussion decided to reject the stability data on the basis of following reasons:**

- **Firm has provided certificate of analysis of Sofosbuvir claiming it as working standard but the said certificate does not indicate that whether it is reference/ working standard.**
- **The Stability study of the API by M/s Zhejiang Warrant Pharmaceuticals Ltd., China is not conducted as per Zone-IVA. The provided stability was on conditions: Accelerated: 40±20C, RH75±5%, Real time: 25±20C, RH 60±10%.**
- **Firm has remaining 760gm of Sofosbuvir. Moreover, 4g working standard as mentioned above has been consumed but they have also developed 2gm secondary working standard from the working standard. 1.10gm is remaining for future testing.**
- **There is no protocol available for the development of drug product.**
- **The firm has not performed Drug-Excipient compatibility studies, they have informed that formulation is developed based on their experience in manufacturing of Tablets.**
- **Comparative dissolution studies have been performed in 0.05 M Monobasic Potassium Phosphate Buffer having pH 6.8, however similarity factor is not provided**

| 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<br><br>GMP Inspection Report Date & Remarks | Previous DRB Decision / Remarks (if any) |
|---|---|---|---|---|---|
| 174. | M/s Welwrd Pharmaceuticals, plot # 3, Block A, Phase I-II, industrial Estate, Hattar-Pakistan | Weldex 30mg DDR Capsule<br><br>Each capsule contains: Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole (22.5%)……..... 30mg<br><br>Proton Pump inhibitor Innovator's specs | Form-5 Duplicate dossier Rs.20,000/- dated 28-10-2015, Rs. 30,000/- dated 24-05-2016<br><br>As per SRO<br>As per SRO | Dexilant capsule 30mg of Takeda Pharmaceuticals, **USFDA** Last inspection report 12-11-2018 shows that Capsule general, Dry powder suspension general and sachet sections were observed with certain shortcomings which need to be rectified. | |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Weldex 30mg Capsule | | |
| Name of Manufacturer | M/s Welwrd Pharmaceuticals, plot # 3, Block A, Phase I-II, industrial Estate, Hattar-Pakistan | | |
| Manufacturer of API | M/s Vision Pharmaceuticals, Islamabad | | |
| API Lot No. | DLP254 | | |
| Description of Pack (Container closure system) | Alu/Alu Blister in outer unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75%±5%RH<br>Real Time: 30˚C ± 2˚C & 65%±5%RH | | |
| Time Period | Accelerated: 06 Months<br>Real Time: 06 Months | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (Months)<br>Real Time: 0, 3, 6 (Months) | | |
| Batch No. | T001 | T002 | T003 |
| Batch Size | 1650 capsules | 1650 capsules | 1650 capsules |
| Manufacturing Date | March 2018 | March 2018 | March 2018 |
| Date of Initiation | 20-03-2018 | 21-03-3018 | 22-03-3018 |
| No. of Batches | 3 | | |
| Date of Submission | 21-06-2018 (Dy. No. 21689) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s Vision Pharmaceuticals, Islamabad has been 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. | The firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals, Islamabad (Certificate No.F.8-1/2016-DDG (E&M)) issued by Additional Director (QA&LT), DRAP, Islamabad. |
| 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. | N/A |
| 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 provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Batches.

| 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<br><br>GMP Inspection Report Date & Remarks | Previous DRB Decision / Remarks (if any) |
|---|---|---|---|---|---|
| **175.** | M/s Welwrd Pharmaceuticals, plot # 3, Block A, Phase I-II, industrial Estate, Hattar-Pakistan | Weldex 60mg Capsule<br><br>Each capsule contains:<br>Dexlansoprazole Dual Delayed Released Pellets eq. to Dexlansoprazole (22.5%)…….....60mg<br>Proton Pump inhibitor<br>Innovator's specs | Form-5<br>Duplicate dossier<br>Rs.20,000/- dated 28-10-2015,<br>Rs.30,000/- dated 24-05-2016<br><br>As per SRO<br>As per SRO | Dexilant capsule 60mg of Takeda Pharmaceuticals, **USFDA**<br><br>Last inspection report 12-11-2018 shows that Capsule general, Dry powder suspension general and sachet sections were observed with certain shortcomings which need to be rectified. | |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Weldex 60mg Capsule | | |
| Name of Manufacturer | M/s Welwrd Pharmaceuticals, plot # 3, Block A, Phase I-II, industrial Estate, Hattar-Pakistan | | |
| Manufacturer of API | M/s Vision Pharmaceuticals, Islamabad | | |
| API Lot No. | DLP254 | | |
| Description of Pack (Container closure system) | Alu/Alu Blister in outer unit carton | | |
| Stability Storage Condition | Accelerated: 40˚C ± 2˚C & 75±5%RH<br>Real Time: 30˚C ± 2˚C & 65±5%RH | | |
| Time Period | Accelerated: 06 Months<br>Real Time: 06 Months | | |
| Frequency | Accelerated: 0,1,2,3,4,6 (Months)<br>Real Time: 0, 3, 6 (Months) | | |
| Batch No. | T001 | T002 | T003 |
| Batch Size | 1650 Capsules | 1650 Capsules | 1650 Capsules |
| Manufacturing Date | 03-2018 | 03-2018 | 03-2018 |
| Date of Initiation | 27-03-2018 | 28-03-2018 | 29-03-2018 |
| No. of Batches | 3 | | |
| Date of Submission | 21-06-2018 (Dy. No. 21689) | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| Sr. | Documents To Be Provided | Status |
|---|---|---|

| | | |
|---|---|---|
| 1. | COA of API | Copy of COA from M/s Vision Pharmaceuticals, Islamabad has been 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. | The firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals, Islamabad (Certificate No.F.8-1/2016-DDG (E&M)) issued by Additional Director (QA&LT), DRAP, Islamabad. |
| 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. | N/A |
| 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 provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Batches. | | |

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Weldex (Dexlansoprazole) 30mg & 60mg Capsules by M/s Welwrd Pharmaceuticals Plot No. 3 Block A Phase I-II Industrial Estate Hattar**

**Reference No:** F.13-11/ 2017-PEC (Pt) dated 23-1-2019
**Investigation Date and Time:** 12th February 2019 (Afternoon)
**Investigation Site:** Premises of M/s Welwrd Pharmaceuticals Plot No. 3 Block A Phase I-II Industrial Estate Hattar

**Background:**

Chairman Registration Board considered the applications of M/s Welwrd Pharmaceuticals Plot No. 3 Block A Phase I-II Industrial Estate Hattar for registration of Weldex (Dexlansoprazole) 30mg & 60mg Capsules and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

**Composition of Panel:**

1. Dr. Muhammad Khalid Javed, Director Drug Testing Laboratory Peshawar.
2. *Dr. Muhammad Usman, Dean Faculty of Pharmacy, University of Lahore (Islamabad Campus)
3. Muneeb Ahmed Cheema, Assistant Director DRAP Islamabad

* Initially Dr. Qurban Ali Member Registration Board was the panel member but due to his non-availability, Chairman Registration Board nominated Dr. Muhammad Usman.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

<table>
<tr><th>S. No.</th><th>Description</th><th>Observation by panel</th></tr>
<tr><td>1</td><td>Do you have documents confirming the import of API including approval from DRAP?</td><td>The firm has locally procured 2.0 Kg Dexlansoprazole pellets from M/s Vision Pharmaceuticals Pvt Limited Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.</td></tr>
<tr><td>2</td><td>Do you have any rationale behind selecting the particular manufacturer</td><td>The firm has selected the vendor on the basis of authorization for manufacturing of Dexlansoprazole pellets and GMP certificate issued by DRAP.</td></tr>
<tr><td>3</td><td>Do you have documents confirming the Import of Reference standard and Impurities standards?</td><td>Working Standard was provided by M/s Vision M/s Vision Pharmaceuticals Pvt Limited Islamabad. However the impurity standards are not available. Details of working standards are as under:<br><table><tr><td>Batch No.</td><td>Quantity</td></tr><tr><td>DLP/ 1706013</td><td>5gm</td></tr><tr><td>RLP0330718</td><td>1gm</td></tr></table></td></tr>
<tr><td>4</td><td>Do you have certificate of analysis of the API reference standard and impurities standards?</td><td>The firm has certificate of analysis for Dexlansoprazole Pellets and Dexlansoprazole working standard.</td></tr>
<tr><td>5</td><td>Do you have any approval of API or GMP certificate of manufacturer issued by regulatory authority of country of origin?</td><td>The firm has provided the copy of GMP certificate issued by DRAP vide letter No. F.8-1/2016-DDG (E&M) dated 06-02-2018.</td></tr>
<tr><td>6</td><td>Do you use API manufacturer method of Testing for testing of API?</td><td>The firm has used API Manufacturer’s method of testing</td></tr>
<tr><td>7</td><td>Do you have stability Studies Report on API?</td><td>The firm has stability studies report of API Dexlansoprazole conducted by API manufacturer.</td></tr>
<tr><td>8</td><td>If Yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified.?</td><td>The manufacturer of API has performed the stability studies of API as per SIM Method and the Related Substance/ impurities have been quantified by the API manufacturer.</td></tr>
<tr><td>9</td><td>Do you have method for quantifying the impurities in the API?</td><td>The firm has not developed methods for quantifying the impurities in API.</td></tr>
<tr><td>10</td><td>Do you have some remaining quantities of the API, Its reference standard and impurities standard?</td><td>The firm has no remaining quantity of API however Dexlansoprazole working standard is available.</td></tr>
<tr><td>11</td><td>Have you used pharmaceutical grade excipients?</td><td>Empty HGC Shell size no 3 for 30mg.<br>Empty HGC Shell size no 2 for 60mg</td></tr>
<tr><td>12</td><td>Do you have documents confirming the import of the used excipients?</td><td>Empty HGC Shell were procured locally from M/s PharmaCaps Karachi.</td></tr>
<tr><td>13</td><td>Do you have test reports and other records on the excipients?</td><td>The firm has test reports on empty shell size no 3 and 2.</td></tr>
<tr><td>14</td><td>Do you have written and authorized protocols for the development of Weldex Capsules 30mg/60mg?</td><td>The firm has protocol for the development of Weldex Capsules 30mg/60mg</td></tr>
<tr><td>15</td><td>Have you performed Drug-Excipient compatibility studies?</td><td>Not Applicable</td></tr>
<tr><td>16</td><td>Have you performed comparative studies?</td><td>Firm has not performed comparative studies.</td></tr>
<tr><td>17</td><td>Do you have Product Development / R&D Section?</td><td>The firm has no separate product development (R&D) Section. They have used the production and QC department for manufacturing and analysis. Firm was advised to develop separate R&D Facility.</td></tr>
</table>

<table>
<tr><td>18</td><td>Do you have necessary equipment's available in product development section for development of Weldex Capsules 30mg/60mg?</td><td>The firm has necessary equipment available in Production department for development of Weldex Capsules 30mg/60mg.</td></tr>
<tr><td>19</td><td>Are the equipment's in product development qualified?</td><td>The available equipment in Production Department are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD?</td><td>There is proper maintenance / calibration program for the equipment used in Production Department.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has proper qualified staff for Product Development.<br>03Pharmacists and 02Chemists 01 Microbiologist.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Weldex Capsules 30mg/60mg as required?</td><td>The firm has manufactured three stability batches 1650 Capsules of Weldex 30mg and 1650 capsules of Weldex 60mg.
<table>
<tr><th colspan="2">Weldex Capsules 30mg</th></tr>
<tr><td>Batch No</td><td>Expiry Date</td></tr>
<tr><td>T.001</td><td>FEB-2020</td></tr>
<tr><td>T.002</td><td>FEB-2020</td></tr>
<tr><td>T.003</td><td>FEB-2020</td></tr>
<tr><th colspan="2">Weldex Capsules 60mg</th></tr>
<tr><td>Batch No</td><td>Expiry Date</td></tr>
<tr><td>T.004</td><td>FEB-2020</td></tr>
<tr><td>T.005</td><td>FEB-2020</td></tr>
<tr><td>T.006</td><td>FEB-2020</td></tr>
</table></td></tr>
<tr><td>23</td><td>Do you have any criteria for fixing the batch size of stability of batches?</td><td>The criteria for fixing the batch size of stability batches is the number of samples required per testing frequencies.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has detailed record of the stability batches of Weldex Capsules 30mg/60mg.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has protocols for testing of stability batches.</td></tr>
<tr><td>26</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated method of testing of finish product Weldex Capsules 30mg/60mg, based on method of testing of API.</td></tr>
<tr><td>27</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is by any other lab?</td><td>Method transfer studies is not applicable as the firm developed their own method and validated based on method of testing of API.</td></tr>
<tr><td>28</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of the product's API and product Weldex Capsules 30mg/60mg?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the Weldex Capsules 30mg/60mg.</td></tr>
<tr><td>29</td><td>Do your method of analysis Stability indicating?</td><td>The firm has informed that as they have developed the method of analysis based on the method provided by the API/ pellets manufacturer therefore it is its stability indicating method. Force degradation studies have not been performed.</td></tr>
<tr><td>30</td><td>Do your HPLC software 21CFR compliant?</td><td>The firm has used Waters 600 Quaternary Gradient HPLC with 486 Detector for stability studies. Audit trail logs have been activated.</td></tr>
<tr><td>31</td><td>Can you show audit trail reports on Weldex Capsules testing?</td><td>The firm has audit trail Reports on their testing.</td></tr>
</table>

| | | |
|---|---|---|
| 32 | Do you have some remaining quantities of degradation products and stability batches? | The firm has some remaining quantities of stability batches. |
| 33 | Do you have batches kept on stability testing? | The firm has three stability batches kept on stability for Real time stability testing. 9 Months Real Time and 6 months Accelerated stability studies has been conducted. |
| 34 | Do you have valid calibration status for the equipment's used in Weldex Capsules 30mg/60mg production and analysis? | The firm has valid calibration status for the equipment used in Weldex Capsules 30mg/60mg production and analysis. |
| 35 | Do Proper and Continuous monitoring and control are available for stability chamber? | The firm has two stability chambers for accelerated and real time stability testing with uninterrupted power supply. Record is maintained manually on log books |
| 36 | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | Related manufacturing area, equipment, personnel and utilities can be rated as compliant. |
| 37 | **Any specific observation / recommendation by the PE&R**:<br>The panel may verify the dissolution of pellets at pH 5.5 and pH 7 for confirmation of dual delayed release profile. | The firm has performed the DDR dissolution on the pellets at pH 5.5 and 7. The necessary documents are presented by the firm. |

**Conclusions:**

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Weldex (Dexlansoprazole) 30mg & 60mg Capsules is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are compliant to GMP standards and are suited for the manufacturing of Weldex (Dexlansoprazole) 30mg & 60mg Capsules

**Recommendation:**

The panel unanimously recommends the grant of registration of Weldex (Dexlansoprazole) 30mg & 60mg Capsules in the name of the firm

**Decision: Registration Board decided to approve registration of "Weldex 30mg Capsules & Weldex 60mg Capsules (Dexlansoprazole)" by M/s Welwrd Pharmaceuticals (Pvt) Ltd., Plot # 3, Block A, phase I-II, industrial estate Hattar. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.**

**Evaluator PEC-XIV**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| **176.** | M/s Aulton Pharmaceuticals Pvt. Ltd. 84/1, Block A, Phase V, Industrial Estate Hattar. | Aultadex 30mg DDR Capsule<br>Each Capsule contains:<br>Dexlansoprazole (as dual delayed release capsule)…..30mg | Form 5-D<br>Dy No. 10236<br>27-07-2017<br>PKR 50,000/-<br>27-07-2017 | Dexilant Capsule by Takeda Pharms (**USFDA** Approved)<br><br>Inspection dated 13-02-2018 Routine GMP Inspection firm is operating at good level of GMP compliance |
| | **Remarks of Evaluator:**<br>The firm has submitted stability study data along with required documents as per checklist approved in 251st | | | |

| | |
|---|---|
| | meeting of Registration Board. Details of submitted data are as under:<br>**(Dy.# 1211 dated 10-01-2019).** |

| **STABILITY STUDY DATA** | | | |
|---|---|---|---|
| Drug | Aultadex 30mg DDR Capsule | | |
| Name of Manufacturer | M/s Aulton Pharmaceuticals Pvt. Ltd. 84/1, Block A, Phase V, Industrial Estate Hattar. | | |
| Manufacturer of API | Vision Pharmaceuticals, Islamabad | | |
| API Lot No. | DLP287 | | |
| Description of Pack (Container closure system) | 30 capsules contained in blister | | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 75% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| Time Period | Real time: 6 months<br>Accelerated: 6 months | | |
| Frequency | Accelerated: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (weeks)<br>Real Time: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (weeks) | | |
| Batch No. | Dexo T-001 | Dexo T-002 | Dexo T-003 |
| Batch Size | 2900 capsule | 2900 capsule | 2900 capsule |
| Manufacturing Date | 05-2018 | 05-2018 | 05-2018 |
| Date of Initiation | 30-05-2018 | 30-05-2018 | 30-05-2018 |
| No. of Batches | 03 | | |
| Date of Submission | **Dy.# 1211 dated 10-01-2019** | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| # | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | Vision Pharmaceuticals was issued GMP certificate based on inspection dated 26-01-2018 |
| 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. | Firm has submitted copy of invoice of purchase of 3Kg pellets of dexlansoprazole from Vision Pharmaceuticals dated 30-4-2018 |
| 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**

| 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<br><br>GMP Inspection Report Date & Remarks |
|---|---|---|---|---|
| **177.** | M/s Aulton Pharmaceuticals Pvt. Ltd. 84/1, Block A, Phase V, Industrial Estate Hattar. | Aultadex 60mg DDR Capsule<br>Each Capsule contains:<br>Dexlansoprazole (as dual delayed release capsule)…..60mg | Form 5-D<br>Dy No. 10237<br>27-07-2017<br>PKR 50,000/-<br>27-07-2017 | Dexilant Capsule by Takeda Pharms (**USFDA** Approved)<br><br>Inspection dated 13-02-2018 Routine GMP Inspection firm is operating at good level of GMP compliance |
| | **Remarks of Evaluator:**<br>The firm has submitted stability study data along with required documents as per checklist approved in 251st meeting of Registration Board. Details of submitted data are as under:<br>**(Dy.# 1212 dated 10-01-2019)** | | | |

**STABILITY STUDY DATA**

| | | | |
|---|---|---|---|
| Drug | Aultadex 60mg DDR Capsule | | |
| Name of Manufacturer | M/s Aulton Pharmaceuticals Pvt. Ltd. 84/1, Block A, Phase V, Industrial Estate Hattar. | | |
| Manufacturer of API | Vision Pharmaceuticals, Islamabad | | |
| API Lot No. | DLP287 | | |
| Description of Pack (Container closure system) | 30 capsules contained in blister | | |
| Stability Storage Condition | Real time : 30˚C ± 2˚C / 75% ± 5%RH<br>Accelerated: 40˚C ± 2˚C / 75% ± 5%RH | | |
| Time Period | Real time: 6 months<br>Accelerated: 6 months | | |
| Frequency | Accelerated: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (weeks)<br>Real Time: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (weeks) | | |
| Batch No. | Dexo T-004 | Dexo T-005 | Dexo T-006 |
| Batch Size | 2100 capsule | 2100 capsule | 2100 capsule |
| Manufacturing Date | 05-2018 | 05-2018 | 05-2018 |
| Date of Initiation | 30-05-2018 | 30-05-2018 | 30-05-2018 |
| No. of Batches | 03 | | |
| Date of Submission | **Dy.# 1212 dated 10-01-2019** | | |

**DOCUMENTS / DATA PROVIDED BY THE APPLICANT**

| # | Documents To Be Provided | Status |
|---|---|---|
| 1. | COA of API | Yes |
| 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. | Vision Pharmaceuticals was issued GMP certificate based on inspection dated 26-01-2018 |
| 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. | Firm has submitted copy of invoice of purchase of 3Kg pellets of dexlansoprazole from Vision Pharmaceuticals dated 30-4-2018 |
| 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**

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Aultadex (Dexlansoprazole) 30mg & 60mg Capsules by M/s Aulton Pharmaceuticals Pvt Limited, 84/1, Block A, Phase V, Industrial Estate Hattar**

**Reference No:** F.13-11/ 2017-PEC (Pt) dated 07-02-2019
**Investigation Date and Time:** 12th February 2019 (Afternoon)
**Investigation Site:** Premises of M/s Aulton Pharmaceuticals Pvt Limited, 84/1, Block A, Phase V, Industrial Estate Hattar.

**Background:**

Chairman Registration Board considered the applications of M/s Aulton Pharmaceuticals Pvt Limited, 84/1,Block A, Phase V, Industrial Estate Hattar for registration of Aultadex (Dexlansoprazole) 30mg & 60mg Capsules and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

**Composition of Panel:**

1. Dr. Muhammad Khalid Javed, Director Drug Testing Laboratory Peshawar.
2. *Dr. Muhammad Usman, Dean Faculty of Pharmacy, University of Lahore (Islamabad Campus).
3. Muneeb Ahmed Cheema, Assistant Director DRAP Islamabad.

* Initially Dr. Qurban Ali Member Registration Board was the panel member but due to his non-availability, Chairman Registration Board nominated Dr. Muhammad Usman.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation are summarized as under:

| S.No. | Description | Observation by panel |
|---|---|---|
| 1 | Do you have documents confirming the import of API including approval from DRAP? | The firm has locally procured3.0 Kg Dexlansoprazole pellets from M/s Vision Pharmaceuticals Pvt Limited Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad. |
| 2 | Do you have any rationale behind selecting the particular manufacturer | The firm has selected the vendor on the basis of authorization for manufacturing of Dexlansoprazole pellets and GMP certificate issued by DRAP. |

<table>
<tr><td>3</td><td>Do you have documents confirming the Import of Reference standard and Impurities standards?</td><td>Working Standard was provided by M/s Vision M/s Vision Pharmaceuticals Pvt Limited Islamabad. However the impurity standards are not available. Details of working standards are as under:<br><br><table><tr><td>Batch No.</td><td>Quantity</td></tr><tr><td>DLP/ E-013/16</td><td>1gm</td></tr><tr><td>DLP/1706013</td><td>1gm</td></tr></table></td></tr>
<tr><td>4</td><td>Do you have certificate of analysis of the API reference standard and impurities standards?</td><td>The firm has certificate of analysis for Dexlansoprazole Pellets and Dexlansoprazole working standard.-/</td></tr>
<tr><td>5</td><td>Do you have any approval of API or GMP certificate of manufacturer issued by regulatory authority of country of origin?</td><td>The firm has provided the copy of GMP certificate issued by DRAP vide letter No. F.8-1/2016-DDG (E&M) dated 06-02-2018.</td></tr>
<tr><td>6</td><td>Do you use API manufacturer method of Testing for testing of API?</td><td>The firm has used API Manufacturer’s method of testing</td></tr>
<tr><td>7</td><td>Do you have stability Studies Report on API?</td><td>The firm has stability studies report of API Dexlansoprazole conducted by API manufacturer.</td></tr>
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<tr><td>12</td><td>Do you have documents confirming the import of the used excipients?</td><td>Empty HGC Shell were procured locally from M/s PharmaCaps Karachi.</td></tr>
<tr><td>13</td><td>Do you have test reports and other records on the excipients?</td><td>The firm has test reports on empty shell size no 3 and 2.</td></tr>
<tr><td>14</td><td>Do you have written and authorized protocols for the development of Aultadex Capsules 30mg/60mg?</td><td>The firm has protocol for the development of Aultadex Capsules 30mg/60mg</td></tr>
<tr><td>15</td><td>Have you performed Drug-Excipient compatibility studies?</td><td>Not Applicable</td></tr>
<tr><td>16</td><td>Have you performed comparative studies?</td><td>Firm has not performed comparative studies.</td></tr>
<tr><td>17</td><td>Do you have Product Development / R&D Section?</td><td>The firm has no separate product development (R&D) Section. They have used the product and QC department for manufacturing and analysis. Firm is advised to develop separate R&D Facility.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment’s available in product development section for development of Aultadex Capsules 30mg/60mg?</td><td>The firm has necessary equipment available in Production department for development of Aultadex Capsules 30mg/60mg.</td></tr>
<tr><td>19</td><td>Are the equipment’s in product development qualified?</td><td>The available equipment in Production Department are qualified.</td></tr>
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<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD?</td><td>There is proper maintenance / calibration program for the equipment used in Production Department.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has proper qualified staff for Product Development. 03Pharmacists and 03Chemists 01 Microbiologist.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Aultadex Capsules 30mg/60mg as required?</td><td>The firm has manufactured three stability batches 2900 Capsules of Aultadex 30mg and 2100 capsules of Aultadex 60mg.
<table>
<tr><th colspan="2">Aultadex Capsules 30mg</th></tr>
<tr><td>Batch No</td><td>Expiry Date</td></tr>
<tr><td>Dexo.T001</td><td>APR-2020</td></tr>
<tr><td>Dexo.T002</td><td>APR-2020</td></tr>
<tr><td>Dexo.T003</td><td>APR-2020</td></tr>
</table>
<table>
<tr><th colspan="2">Aultadex Capsules 60mg</th></tr>
<tr><td>Batch No</td><td>Expiry Date</td></tr>
<tr><td>Dexo.T004</td><td>APR-2020</td></tr>
<tr><td>Dexo.T005</td><td>APR-2020</td></tr>
<tr><td>Dexo.T006</td><td>APR-2020</td></tr>
</table></td></tr>
<tr><td>23</td><td>Do you have any criteria for fixing the batch size of stability of batches?</td><td>The criteria for fixing the batch size of stability batches is the number of samples required per testing frequencies.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has detailed record of the stability batches of Aultadex Capsules 30mg/60mg.</td></tr>
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<tr><td>26</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated method of testing of finish product Aultadex Capsules 30mg/60mg, based on method of testing of API.</td></tr>
<tr><td>27</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is by any other lab?</td><td>Method transfer studies is not applicable as the firm developed their own method and validated based on method of testing of API.</td></tr>
<tr><td>28</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of the product’s API and product Aultadex Capsules 30mg/60mg?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the Aultadex Capsules 30mg/60mg.</td></tr>
<tr><td>29</td><td>Do your method of analysis Stability indicating?</td><td>The firm has informed that as they have developed the method of analysis based on the method provided by the API/ pellets manufacturer therefore it is its stability indicating method. Force degradation studies have not been performed.</td></tr>
<tr><td>30</td><td>Do your HPLC software 21CFR compliant?</td><td>The firm has used Waters 600 Quaternary Gradient HPLC with 486 Detector for stability studies. Audit trail logs have been activated.</td></tr>
<tr><td>31</td><td>Can you show audit trail reports on Aultadex Capsules testing?</td><td>The firm has audit trail Reports on their testing.</td></tr>
<tr><td>32</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm has remaining quantities of stability batches.</td></tr>
<tr><td>33</td><td>Do you have batches kept on stability testing?</td><td>The firm has three stability batches kept on stability for Accelerated and Real time stability testing. The firm is conducting the stability study as per intervals decided in 251st meeting of Registration Board. 26 weeks data for real and</td></tr>
</table>

| | | |
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| | | accelerated stability studies is available. |
| 34 | Do you have valid calibration status for the equipment's used in Aultadex Capsules 30mg/60mg production and analysis? | The firm has valid calibration status for the equipment used in Aultadex Capsules 30mg/60mg production and analysis. |
| 35 | Do Proper and Continuous monitoring and control are available for stability chamber? | The firm has two stability chambers for accelerated and real time stability testing with uninterrupted power supply. Record is maintained manually on log books |
| 36 | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | Related manufacturing area, equipment, personnel and utilities can be rated as compliant. |
| 37 | **Any specific observation / recommendation by the PE&R**: | |

**Conclusions:**

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Aultadex (Dexlansoprazole) 30mg & 60mg Capsules is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are compliant to GMP standards and are suited for the manufacturing of Aultadex (Dexlansoprazole) 30mg & 60mg Capsules

**Recommendation:**

The panel unanimously recommends the grant of registration of Aultadex (Dexlansoprazole) 30mg & 60mg Capsules in the name of the firm

**Decision: Registration Board decided to approve registration of Aultadex 30mg DDR Capsule & Aultadex 60mg DDR Capsule (Dexlansoprazole)" by M/s Aulton Pharmaceuticals. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

## Case No.04: Registration applications for local manufacturing of (veterinary) drugs

### a. New Cases

**Evaluator PEC-V**

| | | |
|---|---|---|
| **178.** | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | Tyco-Maars Oral W/S Powder |
| | Composition | Each g contains:-<br>Tylosin tartrate …….……980 mg |
| | Diary No., Date of R & I & Fee | Dy.6444, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotic |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 081736<br>Tylotar-98 Oral Powder<br>"Each g Contains:-<br>Tylosin Tartrate ……...0.98 Kg<br>"M/S. Evergreen Pharmaceuticals,<br>69-70/B, Main Glaxo Town, Industrial Area, 20th Km Ferozpur Road, Lahore. |
| | GMP Status | 13-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s D-Maarson Pharma Rawat has basic facilities for |

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| | | manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm. |
| | Remarks of Evaluator | Me too is available in different strength. |
| | Decision: **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** | |
| **179.** | Name and address of Manufacturer/ Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | Doxson Oral W/S Powder |
| | Composition | **Each g contains:-**<br>**Doxycycline HCl …… 500mg** |
| | Diary No., Date of R & I & Fee | Dy.6439, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotics |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 063782; Fairo Dox 50 Powder<br>M/s Mallard Pharmaceutical (Pvt) Ltd. Multan. |
| | GMP Status | 13-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s D-Maarson Pharma Rawat has basic facilities for manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification** | |
| **180.** | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | Gumbo-Maars Oral W/S Powder |
| | Composition | Each 100g contains:-<br>Ammonium chloride……70g<br>DL Methionine ……. 10g<br>Sorbitol ……. 5g<br>Vitamin A ....…… 1,50,000IU<br>Vitamin C …… 10g |
| | Diary No., Date of R & I & Fee | Dy.6448, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Vitamins |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 026513; Perphron-N Powder<br>M/S Farm Aid Group Haripur |
| | GMP Status | 13-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s D-Maarson Pharma Rawat has basic facilities for manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification** | |

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| **181.** | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | Multi-Maars Oral Liquid |
| | Composition | Each ml contains:-<br>Sulfadiazine …… 35.50mg<br>Sulfadimidine ……..... 28.40mg<br>Neomycin sulphate …… 1.80mg<br>Hyoscine methylbromide …. 0.04mg<br>Pectin …….. 7.10mg<br>Kaolin ……. 103.30mg<br>Vitamin B1 …… 0.15mg<br>Vitamin B2 …… 0.22mg |
| | Diary No., Date of R & I & Fee | Dy.6445, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotic, Vitamins |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100ml, 150ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 072691; Ever-X Suspension<br>By "Evergreen Pharmaceuticals,<br>69-70/B, Main Glaxo Town, Industrial Area,<br>20th KM Ferozpur Road, Lahore. |
| | GMP Status | 13-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s D-Maarson Pharma Rawat has basic facilities for manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm. |
| | Remarks of Evaluator | |
| | **Decision Approved with innovator's specification. Only the pack sizes, already approved by RB for generic / me-too product will be given.** | |
| **182.** | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | Tico-Maars Oral Liquid |
| | Composition | **Each ml contains:-**<br>**Tilmicosin phosphate …… 250mg** |
| | Diary No., Date of R & I & Fee | Dy6446, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotic |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100ml, 150ml,250ml,500ml,1Litre,2.5Litre / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 075671; Motil Liquid of "M/S. Breeze Pharma (Pvt.) Ltd.,Industrial Triangle,Kahuta Road, Islamabad." |
| | GMP Status | 13-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s D-Maarson Pharma Rawat has basic facilities for manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.** | |

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| **183.** | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | Floson Oral Liquid |
| | Composition | Each 100ml contains:-<br>Florfenicol …… 25g |
| | Diary No., Date of R & I & Fee | Dy.6437, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotic |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100ml,150ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 063639; Nobiflor 25% Liquid<br>M/s Noble Pharma, Industrial Area, Mirpur Azad Kashmir. |
| | GMP Status | 13-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s D-Maarson Pharma Rawat has basic facilities for manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by RB for generic / me-too product will be given.** | |
| **184.** | Name and address of Manufacturer / Applicant | D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat |
| | Brand Name, Dosage Form, Strength | Cina-Maars Oral Liquid |
| | Composition | Each ml contains:-<br>Enrofloxacin …… 75mg<br>Sulfamethoxypyridazine ……. 75mg<br>Sulfamethazine ……. 50mg<br>Trimethoprim …… 25mg |
| | Diary No., Date of R & I & Fee | Dy.6436, 21/02/2018, Rs.20,000 |
| | Pharmacological Group | Antibiotic |
| | Type Of Form | Form 5 |
| | Finished product Specification | Manufacturers Specification |
| | Pack Size and Demanded Price | 100ml,150ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled |
| | Approval Status of Product In Reference Regulatory Authorities | N/A |
| | Me-Too Status | 078379<br>Cenatin Oral Liquid<br>"M/S. Hawk Bio Pharma (Pvt) Ltd., Plot No.10, Street No.S-6, National Industrial Estate Rcci,Rawat, Islamabad. |
| | GMP Status | 13-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s D-Maarson Pharma Rawat has basic facilities for manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification. Only the pack sizes, already approved by RB for generic / me-too product will be given.** | |

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| **185.** | Name and address of manufacturer / Applicant | M/s Prix Pharmaceuticals (Pvt.) Limited Plot # 5, Pharmacity 30 km Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Ectomec-10 Injection (10mg/ml) |
| | Composition | Each ml of vial contains:<br>Doramectin ……..10mg |
| | Diary No. Date of R& I & fee | Dy.No.7192;26-02-2018; Rs.20,000/- (26-02-2018) |
| | Pharmacological Group | Avermectin |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 10ml glass vial & Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status | Doramec 10mg/ ml Injection of M/s Selmore Pharma (Reg. # 035149) |
| | GMP status | Last GMP inspection was conducted on 09-05-2016 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Injectable Liquid (Veterinary) section.<br>• **Vial** section needs to be confirmed.<br>• GMP report has some **observations**. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division and confirmation of injectable vial section.** | |
| **186.** | Name and address of manufacturer / Applicant | M/s Prix Pharmaceuticals (Pvt.) Limited Plot # 5, Pharmacity 30 km Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Ectomec-10 Injection (10mg/ ml) |
| | Composition | Each ml of vial contains:<br>Doramectin ……..10mg |
| | Diary No. Date of R& I & fee | Dy.No.7193;26-02-2018; Rs.20,000/- (26-02-2018) |
| | Pharmacological Group | Avermectin |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 100ml glass vial & Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |
| | Me-too status | Doramec-DMG Injection 100ml of M/s Leads Pharma (Reg. # 043544) |
| | GMP status | Last GMP inspection was conducted on 09-05-2016 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Injectable Liquid (Veterinary) section.<br>• **Vial** section needs to be confirmed.<br>• GMP report has some **observations**. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP status.** | |
| **187.** | Name and address of manufacturer / Applicant | M/s Prix Pharmaceuticals (Pvt.) Limited Plot # 5, Pharmacity 30 km Multan Road, Lahore |
| | Brand Name +Dosage Form + Strength | Pri- Florcid Injection 300mg/ ml |
| | Composition | Each ml of vial contains:<br>Florfenicol ……300mg |
| | Diary No. Date of R& I & fee | Dy.No.7191;26-02-2018; Rs.20,000/- (26-02-2018) |
| | Pharmacological Group | Fluorinated analogue of Chloramphenicol |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturers |
| | Pack size & Demanded Price | 100ml & Decontrolled |
| | Approval status of product in Reference Regulatory Authorities | N/A |

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| | Me-too status | Florofen Injection 300mg/ ml of M/s Leads Pharma (Reg. # 043160) |
| | GMP status | Last GMP inspection was conducted on 09-05-2016 and the report concludes satisfactory GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has General Injectable Liquid (Veterinary) section.<br>• **Vial** section needs to be confirmed.<br>• GMP report has some **observations**. |
| | **Decision: Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP status.** | |
| **188.** | Name and address of manufacturer / Applicant | M/s Avicenna Laboratories (Pvt.) Limited, 14-km Sheikhupura Faisalabad Road Bhikki Dist. Sheikhupura |
| | Brand Name +Dosage Form +Strength | Avicip-20 Oral Liquid (2.5 % w/v) |
| | Composition | Each 100ml contains:<br>Toltrazuril …….....2.5g |
| | Diary No. Date of R& I & fee | Dy.No.108,14-07-2012 (**Rs.20,000/-**) (12-02-2019) |
| | Pharmacological Group | Anti- Coccidial |
| | Type of Form | Form -5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 100ml, 250ml, 500ml, 1000ml & Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Kepcox 2.5% Oral Solution of M/s Better Traders International, Faisalabad (Reg. # 043587) |
| | GMP status | Last GMP inspection was conducted on 22-10-2018 and the report concludes grant of renewal of DML. |
| | Remarks of the Evaluator [XIII] | • Firm has oral liquid section as mentioned in the GMP inspection report. |
| | **Decision: Approved with innovator's specification.** | |
| **189.** | Name and address of manufacturer / Applicant | M/s Avicenna Laboratories (Pvt.) Limited, 14-km Sheikhupura Faisalabad Road Bhikki Dist. Sheikhupura |
| | Brand Name +Dosage Form+ Strength | Tycophen Powder 98% w/w |
| | Composition | Each g of powder contains:<br>Trichlorphon …….980mg (98% w/w) |
| | Diary No. Date of R& I & fee | Dy. No. 199; 02-01-2019; Rs.20,000 (12-02-2019) |
| | Pharmacological Group | Anti-bacterial |
| | Type of Form | Form -5 |
| | Finished product Specification | In-house |
| | Pack size & Demanded Price | 10g, 100g, 500g, 1000g & Decontrolled |
| | Approval status of product in Reference Regulatory Authorities. | N/A |
| | Me-too status | Seguvan powder 98% w/w of M/s Symans Pharma (Reg. # 023442) |
| | GMP status | Last inspection was conducted on 04-11-2008 and the report concludes grant of renewal of DML. |
| | Remarks of the Evaluator [XIII] | • Firm has oral powder section as mentioned in the GMP inspection report. |
| | **Decision: Approved with innovator's specification.** | |

**Case No.: 05 Registration Applications of Newly Granted DML or New Section (Veterinary)**

**a. New DML /section**

**Evaluator PEC-IX**

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| The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. The firm has applied for 07 molecules (08 products). | | |
| **190.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Dyro-X Oral Powder |
| | Composition | Each 12grams contain:<br>Neomycin sulphate…… 400mg<br>Streptomycin sulphate….400mg<br>Sulfaguanidine……4g<br>Kaolin……..4g<br>Pectin……..400mg<br>Bismuth subnitrate……2g<br>Vitamin A acetate……..80,000IU |
| | Diary No. Date of R& I & fee | Dy No. 40581: 06.12.2018 PKR 20,000/-: 06.12.2018 |
| | Pharmacological Group | Combination of antibiotics with antidiarrheals and vitamin A (not available in ATC) |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacture's specifications |
| | Pack size & Demanded Price | Carton box of 6 sachet; The firm has submitted that the price is decontrolled. |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | Diarroban Powder. Reg. No. 026438 |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm has not reply.<br>• The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.<br>• The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.<br>• The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section. |
| | **Decision: Deferred for following:**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **For submission of complete Form-5**<br>• **The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section** | |
| **191.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Diarin Oral Powder |
| | Composition | Each 28grams contain:<br>Neomycin sulphate…… 0.538g<br>Streptomycin sulphate….0.676g<br>Sulfaguanidine……5g<br>Phthalyl sulphathiazole…….1.5g<br>Riboflavin……..0.1g<br>Nicotinamide……0.5g |
| | Diary No. Date of R& I & fee | Dy No. 40582: 06.12.2018 PKR 20,000/-: 06.12.2018 |

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| | Pharmacological Group | Combination of antibiotics with antidiarrheals and vitamin (not available in ATC) |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed Innovator's specifications |
| | Pack size & Demanded Price | 28g, 100g, 500g, 1000g, 25kg; The firm has submitted that the price is decontrolled. |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | Could not be confirmed |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm did not replied.<br>• The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.<br>• The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.<br>• The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section. |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **For submission of complete Form-5**<br>• **The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section** | |
| **192.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Listin-Hi WSP |
| | Composition | Each gram contains:<br>Amoxicillin trihydrate…… 200mg<br>Lincomycin base….88mg<br>Spectinomycin base……88mg<br>Vitamin E……30mg |
| | Diary No. Date of R& I & fee | Dy No. 13006: 06.04.2018 PKR 20,000/-: 27.02.2018 |
| | Pharmacological Group | Combination of antibiotics with vitamin E (not available in ATC) |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed innovator's specifications |
| | Pack size & Demanded Price | 1kg, 2.5kg, 5kg, 10kg, 20kg, 25kg; The firm has submitted that the price is decontrolled. |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | Lincamox-S Water Soluble Powder. Reg. No. 63788 |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm did not reply.<br>• The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.<br>• The firm was asked to submit complete finished product |

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| | | specifications and testing method. However, the firm did not submit the same.<br>• The me-too product contains Lincomycin Base; however, the firm has revised Lincomycin Base to Lincomycin as HCl without submission of any fee.<br>• The me-too product contains Vitamin E acetate. The firm was asked for correction in Form 5 and Master Formula along with submission of applicable fee. However, the firm did not revise Form 5 with submission of fee. |
| | **Decision: Deferred for following:**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **For submission of complete Form-5**<br>• **Revision of formulation in line with reference product along approved by DRAP with submission of fee** | |
| **193.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Phenox Plus WSP |
| | Composition | Each gram contains:<br>Phenoxymethylpenicillin…….800mg |
| | Diary No. Date of R& I & fee | Dy No. 2022: 16.01.2018 PKR 20,000/-: 15.01.2018 |
| | Pharmacological Group | Beta-lactamase sensitive penicillins |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacture's specifications |
| | Pack size & Demanded Price | 100g, 500g, plastic bottles; 1 kg, 10kg, 25kg, plastic bag; As per SRO (10% less than the brand leader) |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | Could not be confirmed |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • Undertakings have not been signed.<br>• Reference (Pharmacopeia / innovator / manufacturer) for finished product specifications is required.<br>• Submit clear stepwise manufacturing outlines.<br>• Complete finished product specifications and testing method are needed.<br>• Details of environmental control processing including waste disposal management.<br>• Proof of me-too product (name and registration number) with same dosage form, same salt form and same strength is required<br>• Justification for overage is required.<br>• Signature at the beginning of Form 5 is missing.<br>• The firm has mentioned the word flavor. The name of flavor that will be used in the product is required. |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **For submission of complete Form-5**<br>• **Submision of clear stepwise manufacturing outlines and testing methods.** | |
| **194.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Klavimox WSP |
| | Composition | Each 100 grams contain:<br>Amoxicillin as trihydrate…….16g<br>clavulanic acid as potassium salt ……..4g |
| | Diary No. Date of R& I & fee | Dy No. 2021: 16.01.2018 PKR 20,000/-: 15.01.2018 |

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|---|---|---|
| | Pharmacological Group | Amoxicillin and beta-lactamase inhibitor |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed innovator's specifications |
| | Pack size & Demanded Price | 100g, 500g, 1 kg, 10kg, 25kg,; As per SRO (10% less than the brand leader) |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | PRIMOX-PLUS WATER SOLUBLE POWDER. Reg.#074026 |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm did not reply.<br>• The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.<br>• The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.<br>• Correction of amoxicillin as trihydrate to amoxicillin trihydrate in Master Formula is required.<br>• Details of environmental control processing including waste disposal management.<br>• The product is intended for oral use. In the proposed dosage, the firm has mentioned 1ml/20kg body weight, which is submitted for Clavimox Injection. Clarification is was asked from the firm. The firm did not reply.<br>• Correction of 'clavulanic acid as potassium' to 'potassium clavulanate' is required in Master Formula.<br>• The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee.<br>• Available in USP, wherein the monograph is for "for oral suspension'. |
| | **Decision: Deferred for following:**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.**<br>• **The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.**<br>• **Correction of amoxicillin as trihydrate to amoxicillin trihydrate in Master Formula is required.**<br>• **Details of environmental control processing including waste disposal management is needed.**<br>• **The product is intended for oral use. In the proposed dosage, the firm has mentioned 1ml/20kg body weight, which is submitted for Clavimox Injection. Clarification is required from the firm.**<br>• **Correction of 'clavulanic acid as potassium' to 'potassium clavulanate' is required in Master Formula.**<br>• **The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee.** | |
| **195.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Avipen 325 WSP |
| | Composition | Each gram contains:<br>Phenoxymethylpenicillin…….325mg |
| | Diary No. Date of R& I & fee | Dy No. 2020: 16.01.2018 PKR 20,000/-: 16.01.2018 |
| | Pharmacological Group | Beta-lactamase sensitive penicillins |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacture's specifications |
| | Pack size & Demanded Price | 100g, 500g; 1 kg, 10kg, 25kg; As per SRO (10% less than the brand leader) |
| | Approval status of product in | NA |

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| | Reference Regulatory Authorities. | |
| | Me-too status | PHENOXYPEN WATER SOLUBLE POWDER. Reg. No. 081303 |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm did not reply.<br>• The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.<br>• The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.<br>• Details of environmental control processing including waste disposal management are missing.<br>• The me-too product contains phenoxymethylpenicillin (293mg/g) eq. to potassium phenoxymethylpenicillin (325mg/g). The firm was asked for correction is required in label claim (Form 5 only) along with submission of applicable fee. The firm neither changed the label claim in Form 5 nor submitted the applicable fee. |
| | **Decision: Deferred for following:**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.**<br>• **The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.**<br>• **Details of environmental control processing including waste disposal management are missing.**<br>• **The me-too product contains phenoxymethylpenicillin (293mg/g) eq. to potassium phenoxymethylpenicillin (325mg/g). The firm was asked for correction is required in label claim (Form 5 only) along with submission of applicable fee. The firm neither changed the label claim in Form 5 nor submitted the applicable fee.** | |
| **196.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Avigrow 100 WSP |
| | Composition | Each kg contains:<br>Procaine penicillin…….12g<br>Streptomycin ……36g<br>Zinc bacitracin……52g |
| | Diary No. Date of R& I & fee | Dy No. 2020: 16.01.2018 PKR 20,000/-: 16.01.2018 |
| | Pharmacological Group | Beta-lactamase sensitive penicillins |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed innovator's specifications |
| | Pack size & Demanded Price | 100g, 500g; 1 kg, 10kg, 25kg; As per SRO (10% less than the brand leader) |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | PENSTREP POWDER. Reg. No. 017923 |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm did not reply.<br>• The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. |

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| | | • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.<br>• Details of environmental control processing including waste disposal management.<br>• The me-too product contains streptomycin sulphate. The firm revised 'streptomycin' to 'streptomycin sulphate'. The firm was asked to submit applicable fee. Then firm again changed streptomycin sulphate to streptomycin. |
| | **Decision: Deferred for following:**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5.**<br>• **The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same.**<br>• **Details of environmental control processing including waste disposal management are missing.**<br>• **The me-too product contains streptomycin sulphate. The firm revised 'streptomycin' to 'streptomycin sulphate'. The firm was asked to submit applicable fee. Then firm again changed streptomycin sulphate to streptomycin.** | |
| **197.** | Name and address of manufacturer / Applicant | Mylab Pvt. Ltd Khankah Shareef Bahawalpur |
| | Brand Name +Dosage Form + Strength | Spectamox Plus WSP |
| | Composition | Each 100 grams contain:<br>Amoxicillin trihydrate…….20g<br>Lincomycin…….8.8g<br>Spectinomycin…….8.8g |
| | Diary No. Date of R& I & fee | Dy No. 2023: 16.01.2018 PKR 20,000/-: 15.01.2018 |
| | Pharmacological Group | Amoxicillin and beta-lactamase inhibitor |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed innovator's specifications |
| | Pack size & Demanded Price | 100g, 500g, plastic bottles; 1 kg, 10kg, 25kg, plastic bag; As per SRO (10% less than the brand leader) |
| | Approval status of product in Reference Regulatory Authorities. | NA |
| | Me-too status | SPECLIMOX ORAL POWDER. Reg. No. 033235 |
| | GMP status | The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018. |
| | Remarks of the Evaluator. | • Undertaking at the end of form 5 is missing.<br>• The me-too product contains amoxicillin trihydrate. The firm has mentioned amoxicillin as trihydrate.<br>• Details of environmental control processing including waste disposal management.<br>• Justification for overage is required.<br>• The firm has mentioned the word flavor. The name of flavor that will be used in the product is required. |
| | **Decision: Deferred for following:**<br>• **Justification on scientific basis for addition of overage in master formulation.**<br>• **Undertaking at the end of form 5 is missing.**<br>• **The me-too product contains amoxicillin trihydrate. The firm has mentioned amoxicillin as trihydrate.**<br>• **Details of environmental control processing including waste disposal management.**<br>• **The firm has mentioned the word flavor. The name of flavor that will be used in the product is required**. | |

**Case No.: 06 Registration applications of categories to be considered on priority**

**a. Export Facilitation**

**Evaluator PEC-V**

| | | |
|---|---|---|
| Applications was received through letter No.F.7-7/2017-Reg-II (Vol-II)<br>"Efroze Chemical Industries Pvt. Ltd. Karachi have achieved benchmark of USD 301,199,13/- during fiscal year 2017-2018. In this regard, please find the (2 molecule) applications: | | |
| **198.** | Name and Address of Manufacturer / Applicant | Efroze Chemical Industries Pvt. Ltd. Karachi. |
| | Brand Name + Dosage Form + Strength | Ivacard 5mg Tablet |
| | Composition | Each Film coated tablet contains:<br>Ivabradine as Hydrochloride ……. 5mg |
| | Diary No. Date of R & I & fee | 38931, 22-11-18 Rs. 20,000/- (22-11-2018) |
| | Pharmacological Group | Cardiac therapy, other cardiac preparations, ATC code: C01EB17. |
| | Type of Form | Form-5 |
| | Finish Product Specification | Manufacturer's Specification |
| | Pack Size and Demanded Price | 14's , 28's ; AS PER DPC |
| | Approval Status of Product in Reference Regulatory Authority | MHRA Approved. |
| | Me Too Status with Strength and Dosage Form | 076442<br>Sivab 5mg Tablet<br>By M/s Getz Pharma Karachi . . |
| | GMP Inspection | Copy of GMP Inspection Dated 19-03-2018, Rated as Good. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |
| **199.** | Name and Address of Manufacturer / Applicant | Efroze Chemical Industries Pvt. Ltd. Karachi. |
| | Brand Name + Dosage Form + Strength | Ivacard 7.5mg Tablet |
| | Composition | Each Film coated tablet contains:<br>Ivabradine as Hydrochloride ……. 7.5mg |
| | Diary No. Date of R & I & fee | 38932, 22-11-18 Rs. 20,000/- (22-11-2018) |
| | Pharmacological Group | Cardiac therapy, other cardiac preparations, ATC code: C01EB17. |
| | Type of Form | Form-5 |
| | Finish Product Specification | Manufacturer's Specification |
| | Pack Size and Demanded Price | 14's , 28's ; AS PER DPC |
| | Approval Status of Product in Reference Regulatory Authority | MHRA Approved. |
| | Me Too Status with Strength and Dosage Form | 076443<br>Sivab 7.5mg Tablet<br>By M/s Getz Pharma Karachi . . |
| | GMP Inspection | Copy of GMP Inspection Dated 19-03-2018, Rated as Good. |
| | Remarks of Evaluator | |
| | Decision: **Approved with innovator's specification.** | |
| **200.** | Name and Address of Manufacturer / Applicant | Efroze Chemical Industries Pvt. Ltd. Karachi. |
| | Brand Name + Dosage Form + Strength | Sacutan Tablet 50mg(42mg+26mg) |
| | Composition | Each Film Coated Tablet Contains:<br>Sacubitril 24.3mg ,<br>Valsartan 25.7mg as Sacubitril Valsartan Sodium Complex |
| | Diary No. Date of R & I & fee | 42042, 07-12-18 Rs. 20,000/- (07-12-2018) |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), other combinations<br>Neprilysin inhibitor and an angiotensin II receptor blocker |
| | Type of Form | Form-5 |
| | Finish Product Specification | Manufacturer's Specification |
| | Pack Size and Demanded Price | 28's ; AS PER DPC |
| | Approval Status of Product in Reference Regulatory Authority | FDA Approved |

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|---|---|---|
| | Me Too Status with Strength and Dosage Form | - |
| | GMP Inspection | C Copy of GMP Inspection Dated 19-03-2018, Rated as Good.opy of GMP Inspection Dated 19-03-2018 |
| | Remarks of Evaluator | Submission of stability studies as the applied formulation is subsequent new drug generic version.as it is a subsequent generic. |
| | **Decision: Deferred submission on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.** | |
| **201.** | Name and Address of Manufacturer / Applicant | Efroze Chemical Industries Pvt. Ltd. Karachi. |
| | Brand Name + Dosage Form + Strength | Sacutan Tablet 100mg (49mg/51mg) |
| | Composition | Each Film Coated Tablet Contains:<br>Sacubitril 48.6mg ,<br>Valsartan 51.4mg as Sacubitril Valsartan Sodium Complex |
| | Diary No. Date of R & I & fee | 42040, 07-12-18 Rs. 20,000/- (07-12-2018) |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), other combinations Neprilysin inhibitor and an angiotensin II receptor blocker |
| | Type of Form | Form-5 |
| | Finish Product Specification | Manufacturer's Specification |
| | Pack Size and Demanded Price | 28's ; AS PER DPC |
| | Approval Status of Product in Reference Regulatory Authority | FDA Approved |
| | Me Too Status with Strength and Dosage Form | - |
| | GMP Inspection | Copy of GMP Inspection Dated 19-03-2018, Rated as Good. |
| | Remarks of Evaluator | Submission of stability studies as the applied formulation is subsequent new drug generic version.as it is a subsequent generic. |
| | **Decision: Deferred submission on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.** | |
| **202.** | Name and Address of Manufacturer / Applicant | Efroze Chemical Industries Pvt. Ltd. Karachi. |
| | Brand Name + Dosage Form + Strength | Sacutan Tablet 200mg (97mg/103mg) |
| | Composition | Each Film Coated Tablet Contains:<br>Sacubitril 91.2mg ,<br>Valsartan 102.8mg as Sacubitril Valsartan Sodium Complex |
| | Diary No. Date of R & I & fee | 42039, 07-12-18 Rs. 20,000/- (07-12-2018) |
| | Pharmacological Group | Angiotensin II receptor blockers (ARBs), other combinations Neprilysin inhibitor and an angiotensin II receptor blocker |
| | Type of Form | Form-5 |
| | Finish Product Specification | Manufacturer's Specification |
| | Pack Size and Demanded Price | 28's ; AS PER DPC |
| | Approval Status of Product in Reference Regulatory Authority | FDA Approved |
| | Me Too Status with Strength and Dosage Form | - |
| | GMP Inspection | Copy of GMP Inspection Dated 19-03-2018, Rated as Good. |
| | Remarks of Evaluator | Submission of stability studies as the applied formulation is subsequent new drug generic version.as it is a subsequent generic. |
| | **Decision: Deferred submission on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.** | |
| Applications was received through letter No.F.7-7/2017-Reg-II (Vol-II)<br>"Efroze Chemical Industries Pvt. Ltd. Karachi have achieved benchmark of USD 109,115,86/- during fiscal year 2015-2016. In this regard, please find the (1 molecule) applications: | | |
| **203.** | Name and Address of Manufacturer / Applicant | Efroze Chemical Industries Pvt. Ltd. Karachi. |
| | Brand Name + Dosage Form + Strength | Algaphan Tablet |

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|---|---|---|
| | Composition | Each Tablet Contains:<br>Orphenadrine Citrate ……35mg,<br>Paracetamol….. 450mg |
| | Diary No. Date of R & I & fee | 38930, 22-11-18 Rs. 20,000/- (22-11-2018) |
| | Pharmacological Group | NSAID's (Analgesic + Antipyretic) |
| | Type of Form | Form-5 |
| | Finish Product Specification | Manufacturer's Specification |
| | Pack Size and Demanded Price | 10's, 100's; As Per DPC. |
| | Approval Status of Product in Reference Regulatory Authority | TGA Approved |
| | Me Too Status with Strength and Dosage Form | 070661; P-Orph Tablet<br>M/s Swiss, Karachi . |
| | GMP Inspection | Copy of GMP Inspection Dated 19-03-2018, Rated as Good. |
| | Remarks of Evaluator | |
| | **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-VII**

Following cases were received from section R-I vide letter No. F.7-7-2017 Reg-II (Vol II) dated 4th February 2019. According to the contents of the letter the firm has claimed 3 molecule to be considered on priority against export worth USD 391,703/- which is duly verified from submitted documents (Form E GD and shipment invoices) as per the decision of Registration Board.

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| **204.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Glucophage XR 500mg Tablet |
| | Composition | Each Tablet Contains:<br>Metformin HCL…500mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 24450 dated 13-07-2018 Rs.20,000/- Dated 13-07-2018 |
| | Pharmacological Group | Blood glucose lowering agent (Biguanides) |
| | Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 30's, Rs. 136.00/Pack & 50's, Rs. 226.50/Pack |
| | Approval status of product in Reference Regulatory Authorities | Metuxtan SR 500 mg prolonged release tablets (MHRA) |
| | Me-too status | Metwil-XR Tablets of M/s Wilson's Pharmaceuticals |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator **VII** | |
| | **Decision: Approved** | |
| **205.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Glucophage XR 1000mg Tablet |
| | Composition | Each Tablet Contains:<br>Metformin HCL…1000mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 24451 dated 13-07-2018 Rs.20,000/- Dated 13-07-2018 |
| | Pharmacological Group | Blood glucose lowering agent(Biguanides) |
| | Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 30's, Rs. 272.00/Pack & 50's, Rs. 453.00/Pack |
| | Approval status of product in Reference Regulatory Authorities | Glumetza of USFDA approved |
| | Me-too status | Diabescot-XR 1000mg Tablets of M/s Scotmann Pharmaceuticals |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator **VII** | |
| | **Decision: Approved** | |

| | | |
|---|---|---|
| **206.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Lodopin-V Tablet 5mg/320mg |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine Besilate…5mg<br>Valsartan…320mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 29622 dated 04-09-2018 Rs.20,000/- Dated 04-09-2018 |
| | Pharmacological Group | Angiotensin II Antagonist + Calcium Channel Blocker |
| | Form | Form-5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 10's, Rs. 1675.00/Pack, 14's, Rs. 2345.00/Pack, 20's, Rs. 3350.00/Pack, 28's, Rs. 4690.00/Pack & 30's, Rs. 5025.00/Pack |
| | Approval status of product in Reference Regulatory Authorities | Exforge of USFDA approved |
| | Me-too status | VALSAN-AM Tablets of M/s Hilton Pharmaceuticals |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator [VII] | Present in USP<br>In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned.<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Approved with USP specification** | |
| **207.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Lodopin V 10/160 mg Tablet |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine Besilate…10mg<br>Valsartan…160mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 29621 dated 04-09-2018 Rs.20,000/- Dated 04-09-2018 |
| | Pharmacological Group | Angiotensin II Antagonist + Calcium Channel Blocker |
| | Form | Form-5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 10's, Rs. 900.00/Pack, 14's, Rs. 1260.00/Pack, 20's, Rs. 1800.00/Pack, 28's, Rs. 2520.00/Pack & 30's, Rs. 2700.00/Pack |
| | Approval status of product in Reference Regulatory Authorities | Exforge of USFDA approved |
| | Me-too status | NEWDAY of M/s Warric Pharmaceuticals |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator [VII] | Present in USP<br>In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Approved with USP specification** | |
| **208.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Lodopin-V Tablet 5mg/160mg |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine Besilate…5mg<br>Valsartan……..160mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.#29620 dated 04-09-2018 Rs.20,000/- 04-09-2018 |

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|---|---|---|
| | Pharmacological Group | Angiotensin II Antagonist + Calcium Channel Blocker |
| | Form | Form-5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 10's, Rs. 837.50/Pack, 14's, Rs. 1172.50/Pack, 20's, Rs. 1675.50/Pack, 28's, Rs. 2345.50/Pack & 30's, Rs. 2512.50/Pack |
| | Approval status of product in Reference Regulatory Authorities | Exforge of USFDA approved |
| | Me-too status | NEWDAY of M/s Warric Pharmaceuticals |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator [VII] | Present in USP<br>In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Approved with USP specification** | |
| **209.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Lodopin-V Tablet 10mg/80mg |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine Besilate…10mg<br>Valsartan…80mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 29619 dated 04-09-2018 Rs.20,000/- Dated 04-09-2018 |
| | Pharmacological Group | Angiotensin II Antagonist + Calcium Channel Blocker |
| | Form | Form-5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 10's, Rs. 870.54/Pack, 14's, Rs. 1218.75/Pack, 20's, Rs. 1741.07/Pack, 28's, Rs. 2437.50/Pack & 30's, Rs. 2611.61/Pack |
| | Approval status of product in Reference Regulatory Authorities | NA |
| | Me-too status | AMTAS by Getz Pharma |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator [VII] | Present in USP<br>In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned<br>Evidence in RRA<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** | |
| **210.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Lodopin-V Tablet 10mg/320mg |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine Besilate…10mg<br>Valsartan……..320mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 29623 dated 04-09-2018 Rs.20,000/- Dated 04-09-2018 |
| | Pharmacological Group | Angiotensin II Antagonist + Calcium Channel Blocker |
| | Form | Form-5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 10's, Rs. 1800.00/Pack, 14's, Rs. 2520.00/Pack, 20's, Rs. |

| | | |
|---|---|---|
| | | 3600.00/Pack, 28's, Rs. 5040.00/Pack & 30's, Rs. 5400.00/Pack |
| | Approval status of product in Reference Regulatory Authorities | Exforge FDA Approved |
| | Me-too status | Amstan by Getz Pharma |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator [VII] | Present in USP<br>In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Approved with USP specification** | |
| **211.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Lodopin-V Tablet 5mg/80mg |
| | Composition | Each Film coated Tablet Contains:<br>Amlodipine Besilate…5mg<br>Valsartan…80mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 29618 dated 04-09-2018 Rs.20,000/- Dated 04-09-2018 |
| | Pharmacological Group | Angiotensin II Antagonist + Calcium Channel Blocker |
| | Form | Form-5 |
| | Finished product Specifications | Manufacturer |
| | Pack size & Demanded Price | 10's, Rs. 500.00/Pack, 14's, Rs. 700.00/Pack, 20's, Rs. 1000.00/Pack, 28's, Rs. 1400.00/Pack & 30's, Rs. 1500.00/Pack |
| | Approval status of product in Reference Regulatory Authorities | Exforge (MHRA) |
| | Me-too status | Amstan by Getz Pharma |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator [VII] | Present in USP<br>In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Approved with USP specification** | |
| **212.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Cosome Fort 200/30 mg Tablets |
| | Composition | Each Film coated Tablet Contains:<br>Ibuprofen…200mg<br>Pseudoephedrine HCL…30mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 24452 dated 13-07-2018 Rs.20,000/- Dated 13-07-2018 |
| | Pharmacological Group | NSAID + Sympathomimetic Agent |
| | Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 10's, 50's, 100's, & 250's, Rs. As per PRC |
| | Approval status of product in Reference Regulatory Authorities | LASYNAC 200MG/30MG FILM COATED TABLETS (MHRA) |
| | Me-too status | Arinac by Abbott |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |

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|---|---|---|
| | Remarks of evaluator [VII] | In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Approved with change of brand name** | |
| **213.** | Name and address of manufacturer / Applicant | M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan |
| | Brand Name +Dosage Form + Strength | Cosome 400/60 mg Forte Tablets |
| | Composition | Each Film coated Tablet Contains:<br>Ibuprofen…400mg<br>Pseudoephedrine HCL…60mg |
| | Diary No. Date of R& I & fee | Form-5 Dy.No 24453 dated 13-07-2018 Rs.20,000/- Dated 13-07-2018 |
| | Pharmacological Group | NSAID + Sympathomimetic Agent |
| | Form | Form-5 |
| | Finished product Specifications | USP |
| | Pack size & Demanded Price | 10's, 50's, 100's, & 250's, Rs. As per PRC |
| | Approval status of product in Reference Regulatory Authorities | Lasynac Max Strength 400mg/60mg film coated tablets approved by MHRA of UK |
| | Me-too status | ARINAC FORTE by abbot |
| | GMP status | Last inspection report 15-16 August 2018, firm was found GMP compliant at the time of inspection. |
| | Remarks of evaluator [VII] | In master formulation, uncoated tablet is mentioned but the master formulation, excipients contains coating materials. On Form 5 just "each Tablet" is mentioned<br>Upon communication of above observation firm has submitted revised master formulation for film coated tablets. |
| | **Decision: Approved with change of brand name** | |

**Evaluator PEC-IX**

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|---|---|---|
| Following three cases were received from section R-I vide letter No. F.7-7/2017-Reg-II(Vol-II) dated 04.02.2019. According to the contents of the letter the firm has claimed one molecule (03 products/ strengths) to be considered on priority basis in lieu of export facilitation. | | |
| **214.** | Name and address of manufacturer / Applicant | M/s. ATCO Laboratories Ltd. B-18, S.I.T.E., Karachi |
| | Brand Name +Dosage Form + Strength | CO-IRBIOTAN 150mg/12.5mg TABLET |
| | Composition | Each film-coated tablet contains:<br>Irbesartan USP…..150mg<br>Hydrochlorothiazide……12.5mg |
| | Diary No. Date of R& I & fee | Dy No. 32762:.02.10.2018<br>PKR 20,000/-: 02.10.2018 |
| | Pharmacological Group | Irbesartan and diuretics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | Rs. 560/- per 7s, Rs. 800/- per 10s, Rs. 1120/- per 14s, Rs. 1600/- per 20s, Rs. 2240/- per 28s & Rs. 2400/- per 30s |
| | Approval status of product in Reference Regulatory Authorities. | Avalide tablet 150mg/12.5mg. **USFDA** approved |
| | Me-too status | Co- Irbisaff Tablet 150/12.5. Reg. No. 77191 |
| | GMP status | Panel inspection dated 04-09-2018 concluded that the firm was operating under satisfactory compliance of cGMP on the day of inspection. |
| | Remarks of the Evaluator. | • The firm was asked to submit latest updated Form 5 properly filled and duly signed by all concerned persons. Latest updated Form has been received |
| | **Decision: Approved.** | |

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| **215.** | Name and address of manufacturer / Applicant | M/s. ATCO Laboratories Ltd. B-18, S.I.T.E., Karachi |
| | Brand Name +Dosage Form + Strength | CO-IRBIOTAN 300mg/12.5mg TABLET |
| | Composition | Each film-coated tablet contains:<br>Irbesartan USP…..300mg<br>Hydrochlorothiazide……12.5mg |
| | Diary No. Date of R& I & fee | Dy No. 32763:.02.10.2018<br>PKR 20,000/-: 02.10.2018 |
| | Pharmacological Group | Irbesartan and diuretics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | Rs. 700/- per 7s, Rs. 1000/- per 10s, Rs. 1400/- per 14s, Rs. 2000/- per 20s, Rs. 2800/- per 28s & Rs. 3000/- per 30s |
| | Approval status of product in Reference Regulatory Authorities. | Avalide tablet 300mg/12.5mg. **USFDA** approved |
| | Me-too status | Co- Irbisaff Tablet 300/12.5. Reg. No. 77190 |
| | GMP status | Panel inspection dated 04-09-2018 concluded that the firm was operating under satisfactory compliance of cGMP on the day of inspection. |
| | Remarks of the Evaluator. | • The firm was asked to submit latest updated Form 5 properly filled and duly signed by all concerned persons. Latest updated Form has been received |
| | **Decision: Approved.** | |
| **216.** | Name and address of manufacturer / Applicant | M/s. ATCO Laboratories Ltd. B-18, S.I.T.E., Karachi |
| | Brand Name +Dosage Form + Strength | CO-IRBIOTAN 300mg/25mg TABLET |
| | Composition | Each film-coated tablet contains:<br>Irbesartan USP…..300mg<br>Hydrochlorothiazide……25mg |
| | Diary No. Date of R& I & fee | Dy No. 32764:.02.10.2018<br>PKR 20,000/-: 02.10.2018 |
| | Pharmacological Group | Irbesartan and diuretics |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | Rs. 1050/- per 7s, Rs. 1500/- per 10s, Rs. 2100/- per 14s, Rs. 3000/- per 20s, Rs. 4200/- per 28s & Rs. 4500/- per 30s |
| | Approval status of product in Reference Regulatory Authorities. | COAPROVEL 300mg/25mg film-coated tablets. **ANSM** approved.<br>Avalide tablet 300mg/25mg. **USFDA** discontinued. **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** |
| | Me-too status | Co-Irba 300/25mg Tablet. Reg. No. 58040 |
| | GMP status | Panel inspection dated 04-09-2018 concluded that the firm was operating under satisfactory compliance of cGMP on the day of inspection. |
| | Remarks of the Evaluator. | • The firm was asked to submit latest updated Form 5 properly filled and duly signed by all concerned persons. Latest updated Form has been received |
| | **Decision: Approved.** | |
| Following four cases were received from section R-I vide letter No. F.7-7/2017-Reg-II(Vol-II) dated 04.02.2019. According to the contents of the letter the firm has claimed 04 molecule (05 products/ strengths) to be considered on priority basis in lieu of export facilitation as the firm has achieved USD 486,821/- during the fiscal year 2017-2018. | | |
| **217.** | Name and address of manufacturer / Applicant | Macter International Ltd., F-216 SITE Karachi |
| | Brand Name +Dosage Form + Strength | Bismol Chewable Tablets |
| | Composition | Each chewable tablet contains:<br>Bismuth subsalicylate…..262.5mg |
| | Diary No. Date of R& I & fee | Dy No. 2921:.22.01.2019 PKR 20,000/-: 22.01.2019 |

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| | Pharmacological Group | Bismuth preparations |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per DPC/SRO |
| | Approval status of product in Reference Regulatory Authorities. | Pepto-Bismol Chewable Tablets, 262.5mg/tablet. **MHRA** approved. |
| | Me-too status | ??? |
| | GMP status | The firm was inspected on 23.05.2018, wherein the firm was reported at GOOD level of GMP compliance. |
| | Remarks of the Evaluator. | The firm was asked to<br>• Submit latest updated Form 5 properly filled and duly signed by all concerned persons.<br>• Provide evidence of approval of me-too product in Pakistan with same strength and same salt form (brand name, registration number and name of company).<br>• Submit Master Formula per batch size.<br>• Detail of environmental control processing.<br>Reply of the firm has been received |
| | **Decision: Deferred for following:**<br>• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**<br>• **Submision of Master Formula per batch size.** | |
| **218.** | Name and address of manufacturer / Applicant | Macter International Ltd., F-216 SITE Karachi |
| | Brand Name +Dosage Form + Strength | Tavora Tablets 200mg |
| | | Each film-coated tablet contains:<br>Voriconazole…..200mg |
| | Diary No. Date of R& I & fee | Dy No. 44142:.27.12.2018 PKR 20,000/-: 27.12.2018 |
| | Pharmacological Group | Triazole derivatives |
| | Type of Form | Form 5 |
| | Finished Product Specification | Available in JP |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per DPC/SRO |
| | Approval status of product in Reference Regulatory Authorities. | VFEND® (voriconazole) film-coated 200mg tablets, for oral use. **USFDA** approved |
| | Me-too status | Voric 200mg Tablet. Reg. No. 83272 |
| | GMP status | The firm was inspected on 23.05.2018, wherein the firm was reported at GOOD level of GMP compliance. |
| | Remarks of the Evaluator. | The firm was asked to<br>• Submit latest updated Form 5 properly filled and duly signed by all concerned persons.<br>• Clarify the claimed BP specifications as the finished product is not in BP.<br>• Detail of environmental control processing.<br>Reply of the firm has been received |
| | **Decision: Approved with JP specification** | |
| **219.** | Name and address of manufacturer / Applicant | Macter International Ltd., F-216 SITE Karachi |
| | Brand Name +Dosage Form + Strength | Tavora Tablets 50mg |
| | Composition | Each film-coated tablet contains:<br>Voriconazole…..50mg |
| | Diary No. Date of R& I & fee | Dy No. 44141:.27.12.2018 PKR 20,000/-: 27.12.2018 |
| | Pharmacological Group | Triazole derivatives |
| | Type of Form | Form 5 |
| | Finished Product Specification | Available in JP |
| | Pack size & Demanded Price | 10's, 20's, 30's; As per DPC/SRO |
| | Approval status of product in Reference Regulatory Authorities. | VFEND® (voriconazole) film-coated 50mg tablets, for oral use. **USFDA** approved |
| | Me-too status | Voric 50mg Tablet. Reg. No. 83916 |

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|---|---|---|
| | GMP status | The firm was inspected on 23.05.2018, wherein the firm was reported at GOOD level of GMP compliance. |
| | Remarks of the Evaluator. | The firm was asked to<br>• Submit latest updated Form 5 properly filled and duly signed by all concerned persons.<br>• Clarify the claimed BP specifications as the finished product is not in BP.<br>• Detail of environmental control processing.<br>Reply of the firm has been received |
| | **Decision: Approved with JP specification** | |
| **220.** | Name and address of manufacturer / Applicant | Macter International Ltd., F-216 SITE Karachi |
| | Brand Name +Dosage Form + Strength | Frilco Tablets 550mg |
| | Composition | Each film-coated tablet contains:<br>Rifaximin…..550mg |
| | Diary No. Date of R& I & fee | Dy No. 8325:.06.03.2018 PKR 20,000/-: 06.03.2018 |
| | Pharmacological Group | Antibiotics |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed innovator's specifications |
| | Pack size & Demanded Price | As per DPC |
| | Approval status of product in Reference Regulatory Authorities. | XIFAXAN® (rifaximin) tablets, for oral use. **USFDA** approved |
| | Me-too status | Xifaxa 550mg film-coated Tablet. Reg. No. 70438 |
| | GMP status | The firm was inspected on 23.05.2018, wherein the firm was reported at GOOD level of GMP compliance. |
| | Remarks of the Evaluator. | The firm was asked to submit<br>• Detail of environmental control processing. Reply of the firm is awaited.<br>• Reference of finished product specifications.<br>Reply of the firm has been received |
| | • **Decision: Approved with innovator's specification.** | |

**Evaluator PEC-XIII**

| Following pplications have been forwarded by registration-I section vide letter No. F.7-7/2017-Reg-II (Vol-II) dated 06-02-2019, for priority consideration in lieu of Export facilitation | | |
|---|---|---|
| **221.** | Name and address of manufacturer / Applicant | M/s Genix Pharma (Pvt.) Limited, 44, 45-B Korangi Creek Road, Karachi. |
| | Brand Name +Dosage Form + Strength | Vancom Dry Powder Injection 1g I/V |
| | Composition | Each vial contains:<br>Vancomycin as HCl…….....1g |
| | Diary No. Date of R& I & fee | Dy.No.2041;16-01-2019; Rs.20,000/- (16-01-2019) |
| | Pharmacological Group | Anti- infective/ Antibiotic |
| | Type of Form | Form- 5 |
| | Finished product Specification | U.S.P. |
| | Pack size & Demanded Price | 1's & As per PRC |
| | Approval status of product in Reference Regulatory Authorities | Approved as **lyophilized** powder in MHRA |
| | Me-too status | Vinjec -1000mg Injection of M/s Bosch Pharma<br>(Reg. # 027573) |
| | GMP status | Last GMP inspection was conducted on 23-07-2018 and the report concludes an acceptable level of GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Firm has Dry Powder Injection (General) section as mentioned in the submitted section approval letter. |
| | **DecisionApproved.** | |

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|---|---|---|
| Following pplication has been forwarded by registration-I section vide letter No. F.7-7/2017-Reg-II (Vol-II) for priority consideration in lieu of Export facilitation | | |
| **222.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories (Pvt.) Limited, A-115, S.I.T.E., Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Ticalor tablet 90mg |
| | Composition | Each film- coated tablet contains:<br>Ticagrelor ……..90mg |
| | Diary No. Date of R& I & fee | Dy.No.42669;13-12-2018; Rs.20,000/ (11-12-2018) |
| | Pharmacological Group | Platelet Aggregation Inhibitor |
| | Type of Form | Form- 5 |
| | Finished product Specification | **Not claimed** |
| | Pack size & Demanded Price | 20's & As per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | **Could not be confirmed** |
| | GMP status | Last GMP inspection was conducted on 28-06-2018 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • No USP or BP monograph is available for the applied formulation.<br>• Tablet General Section is available in the firm as mentioned in the submitted section approval letter.<br>• **Film- coating** is not applied in the master formulation.<br>• Me- too status could **not** be confirmed.<br>• **Stability** is required against the applied formulation. |
| | **Decision: Deferred for application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.** | |
| **223.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories (Pvt.) Limited, A-115, S.I.T.E., Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Agolax tablet 25mg |
| | Composition | Each film- coated tablet contains:<br>Agomelatine ……..…25mg |
| | Diary No. Date of R& I & fee | Dy.No.44512;31-12-2018; Rs.20,000/ (31-12-2018) |
| | Pharmacological Group | Anti-depressant |
| | Type of Form | Form- 5 |
| | Finished product Specification | **Not claimed** |
| | Pack size & Demanded Price | 1x 30's & As per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Valdoxan tablet 25mg of M/s Servier (Reg. # 078160) |
| | GMP status | Last GMP inspection was conducted on 28-06-2018 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Tablet General Section is available in the firm as mentioned in the submitted section approval letter.<br>• **Film- coating** is not applied in the master formulation.<br>• No USP or BP monograph is applied for the applied formulation. |
| | **Decision: Deferred for revision of formulation along with submission of requiste fee.** | |
| **224.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories (Pvt.) Limited, A-115, S.I.T.E., Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Medi-Lade tablet 25mg |
| | Composition | Each film- coated tablet contains:<br>Eltrombopag as Olamine …25mg |
| | Diary No. Date of R& I & fee | Dy.No.42670;13-12-2018; Rs.20,000/ (11-12-2018) |
| | Pharmacological Group | Anti- haemorrhagic |
| | Type of Form | Form- 5 |
| | Finished product Specification | **Not claimed** |

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|---|---|---|
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Revolade tablet 25mg of M/s GSK (Reg. # 069584) |
| | GMP status | Last GMP inspection was conducted on 28-06-2018 and the report concludes good GMP compliance. |
| | Remarks of the Evaluator [XIII] | • Tablet General Section is available in the firm as mentioned in the submitted section approval letter.<br>• No USP or BP monograph is applied for the applied formulation. |
| | **Decision: Approved with innovator's specification.** | |
| **225.** | Name and address of manufacturer / Applicant | M/s Medisure Laboratories (Pvt.) Limited, A-115, S.I.T.E., Super Highway, Karachi |
| | Brand Name +Dosage Form + Strength | Medi- Lade tablet 50mg |
| | Composition | Each film- coated tablet contains:<br>Eltrombopag as Olamine ……50mg |
| | Diary No. Date of R& I & fee | Dy.No.42671;13-12-2018; Rs.20,000/ (11-12-2018) |
| | Pharmacological Group | Anti- haemorrhagic |
| | Type of Form | Form- 5 |
| | Finished product Specification | Manufacturer's specifications. |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities | MHRA Approved |
| | Me-too status | Revolade tablet 50mg of M/s GSK (Reg. # 069585) |
| | GMP status | Last GMP inspection was conducted on 28-06-2018 and the report concludes good GMP compliance. |
| | R<br>emarks of the Evaluator [XIII] | • Tablet General Section is available in the firm as mentioned in the submitted section approval letter.<br>• No USP or BP monograph is applied for the applied formulation. |
| | **Decision: Approved with innovator's specification.** | |

### b. Import applications of priority categories defined by Registration Board in its 257th meeting

**Evaluator PEC-VIII**

| | | |
|---|---|---|
| **226.** | Name and address of Applicant | M/s Pfizer Pakistan limited, 12, Dockyard Road, West Wharf, Karachi |
| | Detail of Drug Sale License | **Address:** Pfizer Pakistan limited, Suite No.1, 12 Dockyard Road, West Wharf, Karachi.<br>**Validity: 06th January, 2020**<br>**Status:** Drug License by way of Wholesale |
| | Name and address of manufacturer | Pfizer Manufacturing Deutschland GmbH<br>Betriebsstatte Freiburg<br>Mooswaldallee 1<br>79090 Freiburg,<br>Germany |
| | Name and address of marketing authorization holder | Pfizer limited<br>Ramsgate Road<br>Sandwich<br>Kent CT NJ<br>United Kingdom |
| | Name of exporting country | Germany |
| | Type of Form | Form 5A |
| | Diary No. & Date of R& I | Dy. No.19083 Dated 25/05/2018 |
| | Fee including differential fee | Rs. 100,000/- Dated 21/03/2018 |
| | Brand Name +Dosage Form + Strength | Xalkori 250 capsule |

| | | |
|---|---|---|
| | Composition | Each capsule contains:<br>Crizotinib…. 250mg |
| | Finished Product Specification | In House |
| | Pharmacological Group | Antineoplastic agent |
| | Shelf life | 36 months |
| | Demanded Price | As per SRO |
| | Pack size | 60's |
| | International availability | Approved in US-FDA |
| | Me-too status | N/A |
| | Detail of certificates attached | **Original legalized CoPP**<br>**Certificate No.** 03/17/114227<br>**Certified by:** European Medicines Agency<br>**Issue date:** 31-10-2017<br>**Free sale in exporting country:** yes<br>**GMP:** facilities and equipment confirms to the GMP as recommended by WHO.<br>**Letter of Authorization:**<br>Letter of authorization between M/s. Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mooswaldallee 1, 79090 Freiburg, Germany & M/s Pfizer Pakistan limited, 12, Dockyard Road, West Wharf, Karachi dated 28-12-2017 is submitted by the firm.<br>Validity: Not mentioned |
| | Remarks of the Evaluator. | The firm has claimed for In House specifications and the product is not present in USP/BP.<br>Submit of credentials of the manufacturer of applied formulation.<br>Last GMP inspection report of manufacturing site conducted by concerned regulatory authority of US-FDA for injectable section.<br>Submit Stability study data according to Zone IVA condition<br>Submitted stability studies data is on following conditions:<br>Real Time: 25ºC ± 2ºC / 60% ± 5%RH<br>Accelerated:40ºC ±2ºC / 75% ± 5%RH |
| | **Decision: Approved as per import policy for finished drug.** | |
| **227.** | Name and address of Applicant | M/s Pfizer Pakistan limited, 12, Dockyard Road, West Wharf, Karachi |
| | Detail of Drug Sale License | **Address:** Pfizer Pakistan limited, Suite No.1, 12 Dockyard Road, West Wharf, Karachi.<br>**Validity: 06th January, 2020**<br>**Status:** Drug License by way of Wholesale |
| | Name and address of manufacturer | Pfizer Manufacturing Deutschland GmbH<br>Betriebsstatte Freiburg<br>Mooswaldallee 1<br>79090 Freiburg,<br>Germany |
| | Name and address of marketing authorization holder | Pfizer limited<br>Ramsgate Road<br>Sandwich<br>Kent CT NJ<br>United Kingdom |
| | Name of exporting country | Germany |
| | Type of Form | Form 5A |
| | Diary No. & Date of R& I | Dy. No.19082 Dated 25/05/2018 |
| | Fee including differential fee | Rs. 100,000/- Dated 21/03/2018 |
| | Brand Name +Dosage Form + Strength | Xalkori 200 capsule |
| | Composition | Each capsule contains:<br>Crizotinib…. 200mg |
| | Finished Product Specification | In House |

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|---|---|---|
| | Pharmacological Group | Antineoplastic agent |
| | Shelf life | 36 months |
| | Demanded Price | As per SRO |
| | Pack size | 60's |
| | International availability | Approved in US-FDA |
| | Me-too status | N/A |
| | Detail of certificates attached | **Original legalized CoPP**<br>**Certificate No.** 03/17/114227<br>**Certified by:** European Medicines Agency<br>**Issue date:** 31-10-2017<br>**Free sale in exporting country:** yes<br>**GMP:** facilities and equipment confirms to the GMP as recommended by WHO.<br>**Letter of Authorization:**<br>Letter of authorization between M/s. Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mooswaldallee 1, 79090 Freiburg, Germany & M/s Pfizer Pakistan limited, 12, Dockyard Road, West Wharf, Karachi dated 28-12-2017 is submitted by the firm.<br>Validity: Not mentioned |
| | Remarks of the Evaluator. | The firm has claimed for In House specifications and the product is not present in USP/BP.<br>Submit credentials of the manufacturer of applied formulation.<br>Last GMP inspection report of manufacturing site conducted by concerned regulatory authority of US-FDA for injectable section.<br>Submit Stability study data according to Zone IVA condition<br>Submitted stability studies data is on following conditions:<br>Real Time: 25°C ± 2°C / 60% ± 5%RH<br>Accelerated:40°C ±2°C / 75% ± 5%RH |
| | **Decision: Approved as per import policy for finished drug.** | |

**Case No.: 07 Registration Applications of Import Cases.**

**a. Deferred cases**

**i. Human**

**Evaluator PEC-V**

| | | |
|---|---|---|
| **228.** | Name and address of Applicant | M/s Iqbal & Company, 1st floor, Al-Falah Manzil, Opp. National Police Foundation, St. No. 26, Sector E-11/4, Islamabad. |
| | Detail of Drug Sale License | Address: 1st floor, Al-Falah Manzil, St. No. 26, Sector E-11/4, Islamabad.<br>Validity: 04/02/2018<br>Status: drug to sell drugs in a wholesale distributor |
| | Name and address of manufacturer | M/s Bieffe Medital S.P.A Via Stelvio 94, 230 35 Sondalo (SO),I-23035, Italy |
| | Name & address of marketing authorization holder | M/s Gambro Lundia AB Box ,Magistratsvagen 16, Lund, SE-22643, Sweden |
| | Name of exporting country | Italy |
| | Type of Form | Form 5-A |
| | Diary No. & Date of R& I | Dy. No. Dated 01/08/2016(Duplicate) |
| | Fee including differential fee | Rs. 50,000/- Dated 01/08/2016(Duplicate) |
| | Brand Name +Dosage Form + Strength | HEMOSOL B0 Solution for Haemodialysis/Haemofiltration |
| | Composition | Each ml of 2 compartment bag contains:<br>Medimar Electrolyte solution (Small Compartment A-250ml)<br>lactic acid ……. 5.4mg<br>Calcium chloride dehydrate ……5.145mg<br>Magnesium chloride hexahydrate……. 2.033mg<br>Buffer Solution (Large Compartment B-4750 ml)<br>Sodium Chloride…… 6.450mg<br>Sodium hydrogen carbonate…….. 3.090mg<br>After Reconstitution<br>Calcium (Ca+2)…….... 1.75 mmol/L<br>Magnesium (Mg+2)……..... 0.5 mmol/L<br>Sodium (Na+)……..…… 140 mmol/L<br>Chloride (Cl-)……..…….. 109.5 mmol/L<br>Lactate…….... 3 mmol/L<br>Hydrogen carbonate (HCO3-)…….. 32mmol/L |
| | Finished Product Specification | BP |
| | Pharmacological Group | Hemofiltrates |
| | Shelf life | 18 months (Polyolefin bag) |
| | Demanded Price | Not proposed |
| | Pack size | (2 x 5000ml) polyolefin bags, in a box |
| | International availability | Sweden Approved |
| | Me-too status | N/A |
| | Detail of certificates attached | Valid & Legalized CoPP Certificate No: 5.8.1-2018/007) Certified by: Medical Product Agency, Sweden Issued on: 23/01/2018:<br>GMP certificate issued by AIFA, Italy dated 28/10/2016 (validity 3 years) |
| | Remarks of the Evaluator. | |
| | Previous Decision (M-279) | Deferred for following:<br>• Submission of valid DSL of the applicant.<br>• Evidence of free sale of applied formulation in country of origin<br>• Submission of valid legalized agreement between Market Authorization Holder and applicant for CoPP. |
| | **Fresh Evaluation:**<br>**Firm has submitted**<br>**1. Valid DSL.** | |

| | |
|---|---|
| | **Address:** Al-Falah Manzil, St. No. 26, Sector E-11/4, Islamabad.<br>**Validity:** 04/01/2020<br>**Status:** Sell drugs in a wholesale distributor<br>**2. Original Legalized COPP**<br>**Certificate No:** PP10156320<br>**Issued by :** MHRA<br>**Issued on:** 20, July 2018<br>**Free sale:** Yes<br>**GMP as Recommended by: WHO:** N/A<br><br>**3. Scanned Letter of Authorization**<br>This shall confirm that Baxter AG ("Baxter"), a company established and existing under the laws of Switzerland, do hereby declare that we are the manufacturer of the following products We do hereby appoint Iqbal & Company at 1st Floor Alfalah Manzil, Street # 26, Opposite National Police Foundation, Sector E-11/4, Islamabad, as our distributor for Pakistan. This agreement letter will remain valid up to the 5th March 2019.<br>On September , 2013 – Baxter International Inc. ("Baxter") Announced that the company has successfully completed the acquisition of Gambro AB ("Gambro"), a privately held global medical technology company and leader in dialysis products based in Lund, Sweden.<br>**4. Relationship between MAH and Batch releaser**<br>Both companies are wholly owned by Baxter International, thus fall under the same legal entity. |
| | **Previous Decision (M-285):** Registration Board referred the case to Medical Device Division for the opinion whether the applied formulation falls under the category of Medical Device or otherwise. |
| | **Fresh Evaluation:**<br>Medical Device Division with reference to letter no. F. No. 16-4/2018-MD has submitted that:<br>Upon evaluation of the dossier, the above mentioned products shall be dealt as **DRUGS** due to following reasons.<br>I. The firm have provided CoPP (Certificate of Pharmaceutical Products) of the above mentioned product from Sweden which is issued only for the Pharmaceutical products and not for medical devices.<br>II. The above mentioned product has been registered as drug in different countries live UK, Sweden, Netherlands, Germany, Belgium, Australia etc. and their Market Authorization numbers are available.<br>III. Above mentioned product is categorized as Pharmacotherapeutic group: Hemofiltrates, ATC code: B05ZB as mentioned in SPC (Summary of Product Characteristics). The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, Pharmacological and chemical properties.<br>IV. The formulation of the above mentioned product is also available in European Pharmacopoeia.<br>V. The product is administered directly into the bloodstream (Intravenously). GMDN code is available for Haemodialysis concentrate and dialysate solution but no GMDN code is found for solution to be administered intravenously to correct chemical imbalance of the blood caused by kidney failure. |
| **Decision: Registration Board deferred the case for further deliberation** | |

**Case No.: 08 Miscellaneous Cases:**

**Report on assessment and confirmation of manufacturing capacity of M/s EG Pharmaceuticals, Industrial Triangle, Kahuta Road, Islamabad.**

**Evaluator PEC-II**

**Reference No:** No. F.13-11/2017-PEC dated 16th October, 2018.

**Inspection Date:** 3rd December, 2018

**Background:**

Registration Board in its 283rd meeting considered registration application of drugs to be manufactured on contact by M/s EG Pharmaceuticals, Islamabad. The Board deferred the applications for assessment and confirmation of manufacturing capacity of M/s EG Pharmaceutical by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission.

**Composition of Panel:**

The Chairman Registration Board approved the following panel for aforesaid purpose.

1. Mr. Abdullah, Additional Director, PE&R Division, DRAP Islamabad.
2. Mrs. Tehreem Sara, Deputy Director RRR, PE&R Division, DRAP Islamabad
3. Mr. Asif Jalil, In-charge PEC, P.E. & R Division, DRAP, Islamabad

**Scope of Inspection:**

The inspection was conducted for assessment and confirmation of manufacturing capacity of M/s Bio-labs for following sections:

1. Dry powder Injection (Cephalosporin)
2. Ampoule (General)
3. Vial (General)
4. Capsule (Cephalosporin)
5. Dry Powder Suspension (Cephalosporin)

As per section approval letter issued to the firm on 29-08-2012, in addition to aforesaid sections, firm also has Tablet and Capsule section.

Manufacturing record/data was evaluated from **October-2017 to September-2018** (1 year) for the said purpose. The details of capacity calculations are as under:

| **Registered Products** | |
|---|---|
| Total registered products of EG Pharmaceutical | 79 |
| Registered Products on Contract from EG Pharmaceutical | 23 |

## SECTION WISE CAPACITY CALCULATION

### A. CAPACITY OF DRY POWDER INJECTION (CEPHALOSPORIN) SECTION

| ***EG Pharma Registrations*** | ***EG Pharma Pending applications*** | ***Contract Products Registrations*** | ***Contract products Pending applications*** |
|---|---|---|---|
| 12 | 1 | 17 | 10 |

| STEP WISE CAPACITY OF EACH PROCESS | | | | | | | |
|---|---|---|---|---|---|---|---|
| Capacity - Washing of vials (per hour) | Capacity - Washing per month with single shift of 7 working hours (23 working Days) | Capacity – Dry heat sterilization - Single shift (Load per Day) | **Capacity - Dry heat sterilization per month Single Shift (23 working Days)** | Capacity - Filling (per hour) | Capacity - Filling per Month with single shift of 7 working hours (23 working Days) | Capacity – packing per hour | Capacity - packing per Month with Single shift of 7 working hours (23 working Days) |
| 4320 | 695,520 | 11,400 | **262,200** | 27,00 | 434,700 | 2250 | 362,250 |

***Capacity calculated with respect to the* Dry heat sterilization *being capacity limiting step***

| QUARTER WISE CAPACITY UTILIZED | | | |
|---|---|---|---|
| Quarter | Actual Production | Capacity | Capacity utilized in % |
| 4th -2017 | 164070 | 786600 | 20.85 |
| 1st -2018 | 193933 | 786600 | 24.65 |
| 2nd -2018 | 173500 | 786600 | 22.05 |
| 3rd -2018 | 177000 | 786600 | 22.50 |
| Average Capacity Utilized in % | | | 22.51 |

**Manufacturing Capacity Utilized (average) :** ***22.51%***
**Manufacturing Capacity Available (average) :** ***77.49%***

## CAPACITY OF AMPOULE (GENERAL) SECTION

| *EG Pharma Registrations* | *EG Pharma Pending applications* | *Contract products Registrations* | *Contract products Pending applications* |
|---|---|---|---|
| 9 | 3 | 0 | 3 |

| STEP WISE CAPACITY OF EACH PROCESS | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Capacity - Washing (per hour) | Capacity - Washing per month with single shift of 7 working hours (23 working Days) | Capacity – Dry heat sterilization - Single shift (Load per Day) | Capacity - Dry heat sterilization per month (23 working Days) | Capacity - Filling (per hour) | Capacity - Filling per Month with single shift of 7 working hours (23 working Days) | Capacity – Blistering/ packing per hour | Capacity - Blistering per Month with Single shift of 7 working hours (23 working Days) | **Capacity- Terminal sterilization per month having 2 loads per day (21000 per load) (23 working Days)** |
| 6120 | 985,320 | 45,400 | 10,44,200 | 6480 | 10,43,280 | 27,000 | 43,47,000 | **966,000** |

***Capacity calculated with respect to Terminal* sterilization *being capacity limiting step***

| QUARTER WISE CAPACITY UTILIZED | | | |
|---|---|---|---|
| Quarter | Actual Production | Capacity | Capacity utilized in % |
| 4th -2017 | 570,000 | 28,98,000 | 19.66 |
| 1st -2018 | 127,000 | 28,98,000 | 4.38 |
| 2nd -2018 | 240,000 | 28,98,000 | 8.28 |

| | | | |
|---|---|---|---|
| 3rd -2018 | 417,000 | 28,98,000 | 14.38 |
| Average Capacity Utilized in % | | | 11.67 |

**Manufacturing Capacity Utilized (average) :** ***11.67%***
**Manufacturing Capacity Available (average) :** ***88.33%***

**B. CAPACITY OF VIAL (GENERAL) SECTION**

| *EG Pharma Registrations* | *EG Pharma Pending applications* | *Contract products Registrations* | *Contract products Pending applications* |
|---|---|---|---|
| 9 | 0 | 0 | 1 |

| **STEP WISE CAPACITY OF EACH PROCESS** | | | | | | | |
|---|---|---|---|---|---|---|---|
| Capacity - Washing (per hour) | Capacity - Washing per month with single shift of 7 working hours (23 working Days) | Capacity – Dry heat sterilization - Single shift (Load per Day) | **Capacity - Dry heat sterilization per month Single Shift (23 working Days)** | Capacity - Filling (per hour) | Capacity - Filling per Month with single shift of 7 working hours (23 working Days) | Capacity - packing (per hour) | Capacity - packing per Month with single shift of 7 working hours (23 working Days) |
| 2400 | 386,400 | 2800 | **64,400** | 1320 | 212,520 | 2200 | 354,200 |

***Capacity calculated with respect to the* Dry heat sterilization *being capacity limiting step***

| **QUARTER WISE CAPACITY UTILIZED** | | | |
|---|---|---|---|
| Quarter | Actual Production | Capacity | Capacity utilized in % |
| 4th -2017 | 83,920 | 193,200 | 43.43 |
| 1st -2018 | 123,130 | 193,200 | 63.73 |
| 2nd -2018 | 120,750 | 193,200 | 62.50 |
| 3rd -2018 | 84,400 | 193,200 | 43.68 |
| Average Capacity Utilized in % | | | 53.33 |

**Manufacturing Capacity Utilized average) :** ***53.33%***
**Manufacturing Capacity Available (average) :** ***46.67%***

**C. CAPACITY OF CAPSULE (CEPHALOSPORIN) SECTION**

| *EG Pharma Registrations* | *EG Pharma Pending applications* | *Contract products Registrations* | *Contract products Pending applications* |
|---|---|---|---|
| 6 | 0 | 2 | 0 |

| **STEP WISE CAPACITY OF EACH PROCESS** | | | | | | | |
|---|---|---|---|---|---|---|---|
| Capacity – Mixing of powder (2 batches per day) | Capacity - mixing per month with single shift of 7 working hours (23 working Days) | Capacity - Filling (per hour) | Capacity - Filling per Month with single shift of 7 working hours (23 working Days) | Capacity - blistering (per hour) | Capacity - blistering per Month with single shift of 7 working hours (23 working Days) | Capacity - packing (per hour) | Capacity - packing per Month with single shift of 7 working hours (23 working Days) |
| 80,000 | 18,40,000 | 7200 | 11,59,200 | 16,200 | 26,08,200 | 3000 | **483,000** |

***Capacity calculated with respect to packing being capacity limiting step***

| **QUARTER WISE CAPACITY UTILIZED** | | | |
|---|---|---|---|
| Quarter | Actual Production | Capacity | Capacity utilized in % |
| 4th -2017 | 70,590 capsules | 14,49,000 | 4.87 |
| 1st -2018 | 102,900 capsules | 14,49,000 | 7.10 |
| 2nd -2018 | 97,300 capsules | 14,49,000 | 6.71 |
| 3rd -2018 | 99,900 capsules | 14,49,000 | 6.89 |

| | |
|---|---|
| Average Capacity Utilized in % | 6.39 |

**Manufacturing Capacity Utilized (average) :** ***6.39 %***
**Manufacturing Capacity Available (average) :** ***93.61 %***

## CAPACITY OF DRY POWDER SUSPENSION (CEPHALOSPORIN) SECTION

| *EG Pharma Registrations* | *EG Pharma Pending applications* | *Contract products Registrations* | *Contract products Pending applications* |
|---|---|---|---|
| 8 | 1 | 3 | 1 |

| **STEP WISE CAPACITY OF EACH PROCESS** | | | | | |
|---|---|---|---|---|---|
| Capacity – Mixing of powder (2 Batches per day) | Capacity - mixing per month with single shift of 7 working hours (23 working Days) | Capacity - Filling of bottles (per hour) | **Capacity - Filling per Month with single shift of 7 working hours (23 working Days)** | Capacity - packing (per hour) | Capacity - packing per Month with single shift of 7 working hours (23 working Days) |
| 20,000 | 460,000 | 1020 | **164,220** | 1800 | 289,800 |

***Capacity calculated with respect to filling being capacity limiting step***

| **QUARTER WISE CAPACITY UTILIZED** | | | |
|---|---|---|---|
| Quarter | Actual Production | Capacity | Capacity utilized in % |
| 4th -2017 | 11,800 | 492,660 | 2.39 |
| 1st -2018 | 15,000 | 492,660 | 3.04 |
| 2nd -2018 | 47,500 | 492,660 | 9.64 |
| 3rd -2018 | 45,00 | 492,660 | 0.91 |
| Average Capacity Utilized in % | | | 3.99 |

**Manufacturing Capacity Utilized (average) :** ***3.99 %***
**Manufacturing Capacity Available (average) :** ***96.01 %***

## D. CAPACITY OF QUALITY CONTROL DEPARTMENT

| **Quality Control Equipment Details** | | | |
|---|---|---|---|
| S.No | Equipment | Quantity | Capacity per day |
| 1 | HPLC | 1 | Max 2 |
| 2 | UV Spectrophotometer | 1 | 20 |
| 3 | pH Meter | 1 | 50 |
| 4 | Balance | 1 | 80 |
| 5 | Moisture Analyzer | 1 | 30 |
| 6 | Melting Point Apparatus | 1 | 20 |
| 7 | Incubators ( hot and cool) | 1 set | 5 |
| 8 | Filtration assembly | 3 | 6 |
| 9 | Stability chambers | 1 set | -- |
| 10 | Tablet disintegration test apparatus | 1 | 20 |
| 11 | Dissolution test apparatus | 1 | 4 |
| 12 | Rafractometer | 1 | 30 |
| 13 | Hot sterilization oven | 1 | 5 |
| 14 | Autoclave | 1 | 3 |

| **HPLC Capacity Calculation Quarter Wise (Max 2 tests/day) TOTAL 1 HPLC** | | | | |
|---|---|---|---|---|
| QUARTER | Average Capacity of 1 HPLC | Performed | Capacity Utilized % | Capacity Available % |
| 4th /2017 | 138 | 10 | 7.24 | 92.76 |

| | | | | |
|---|---|---|---|---|
| 1st /2018 | 138 | 16 | 11.59 | 88.41 |
| 2nd /2018 | 138 | 10 | 7.24 | 92.76 |
| 3rd /2018 | 138 | 11 | 7.97 | 92.03 |
| **Average capacity Available:** | | | | **91.49%** |

| **UV Spectrophotometer Capacity Calculation Quarter Wise (Average 20 tests/day)** | | | | |
|---|---|---|---|---|
| Quarter | Capacity | Performed | Capacity Utilized % | Capacity Available % |
| 4th /2017 | 1380 | 105 | 7.60 | 92.4 |
| 1st /2018 | 1380 | 163 | 11.81 | 88.19 |
| 2nd /2018 | 1380 | 144 | 10.4 | 89.6 |
| 3rd /2018 | 1380 | 77 | 5.57 | 94.43 |
| **Average capacity Available:** | | | | **91.55%** |

| **Capacity Calculation for sterility testing Quarter Wise depending on incubators (Average 5 tests/day)** | | | | |
|---|---|---|---|---|
| Quarter | Capacity | Test Performed | Capacity Utilized % | Capacity Available % |
| 4th /2017 | 345 | 33 | 9.56 | 90.44 |
| 1st /2018 | 345 | 93 | 26.95 | 73.05 |
| 2nd /2018 | 345 | 105 | 30.43 | 69.57 |
| 3rd /2018 | 345 | 95 | 27.53 | 72.47 |
| **Average capacity available:** | | | | **76.38%** |

**CONCLUSION:**

Production capacity utilized and available for following sections and QC capacity utilized and available is summarized as follow:

| *Section* | *EG Pharma Registrations* | *EG Pharma Pending applications* | *Contract Products Registrations* | *Contract products Pending applications* | Manufacturing Capacity Utilized (average) | **Manufacturing Capacity Available (average)** |
|---|---|---|---|---|---|---|
| Dry Powder Injection (Cephalosporin) Section | 12 | 1 | 17 | 10 | 22.51% | **77.49%** |
| Ampoule (General)) Section | 9 | 3 | 0 | 3 | 11.67% | **88.33%** |
| Vial (General) Section | 9 | 0 | 0 | 1 | 53.33% | **46.67%** |
| Capsule (Cephalosporin) Section | 6 | 0 | 2 | 0 | 6.39 % | **93.61 %** |
| Dry Powder Suspension (Cephalosporin) Section | 8 | 1 | 3 | 1 | 3.99 % | **96.01 %** |

**QC Department:**

| | |
|---|---|
| HPLC Average capacity Available: | 91.49 % |
| UV SPECTROPHOTOMETER Average capacity Available: | 91.55 % |
| STERILITY TESTING Average capacity Available: | 76.38 % |

**Decision of 287th meeting:** Registration Board discussed the inspection report on assessment and confirmation of manufacturing capacity of M/s EG Pharmaceuticals, Industrial Triangle, Kahuta Road, Islamabad in detail. Deliberations were made on used and available capacity keeping in view registered product, currently applied products. Further Board was apprised that firm has been using UV spectrophotometric methods for most of the products. After thorough deliberation, the Board decided to defer all applied products of contract manufacturing from M/s EG Pharmaceuticals, Islamabad. The Board further directed the M/s EG Pharmaceuticals, Islamabad to review existing methods for their already registered products in light of pharmacopoeal requirements and enhance its analytical capacity of Qualtity Control Laboratory, accordingly.

**Reply of the Firm:** Firm has submitted as under:

"The inspection by the panel was done in due course of time and a detailed report submitted, highlighting that we have ample facilities to keep on doing contract manufacturing for other companies. It was however observed that in the Quality control lab some of the products were not tested on HPLC.

We pointed out that the products which needed to be checked on HPLC as per USP recommendation are being done on HPLC and the remaining products on other recommended methods as per inventor's specifications or EG's internal specifications.

Now, as part of an upgradation process, we are switching over most products to be tested on HPLC. For us, this is no problem because our current utilization of HPLC for the registered products as per capacity inspection report is only 8.10 percent. Even if we have to put more products on this apparatus, we still have 91.49 percent capacity available with us, as observed by the inspecting panel. The current testing capacity of quality control lab is sufficient with respect to actual production.

Another point, which needs to be considered is, that our sale per year is very low and the units sold per year are extremely less for our kind of setup, consequently leading to heavy losses each month.

As our market sale production is low, so we make the products in smaller batches, which is enough to cater needs of the market. If required, these batches can be increased in size by more than three folds. So, if needed we can easily make the same number of units in lessor number of batches, consequently reducing load on our QC lab by many folds. We can also go for other measures to reduce load on QC Lab, if and when desired. In spite of all this positive picture, we still have decided for the upgradation of our Quality control lab and **purchased another HPLC**, **Ultrasonic bath, conductivity meter, filtration assembly, HPLC Column and an additional generator for backup supply**. (Copies of invoices submitted)

Keeping in view our modest production during the previous years and the addition of another HPLC, we are sure that our case would be sympathetically considered and we allowed to continue further contract manufacturing."

**Decision:** **Registration Board upon detailed deliberation and considering the measures taken by the firm for upgradation of QC lab decided to allow contract manufacturing by M/s EG Pharmaceuticals, Industrial Triangle Kahuta Road, Islamabad. The Board directed M/s EG Pharmaceuticals, Islamabad to submit revised methods for their already registered products in light of latest pharmacopoeal monographs, as applicable before issuance of registration letters.**

Following applications of contract manufacturing from M/s EG Pharmaceuticals, Industrial Triangle Kahuta road, Islamabad were deferred in 287th meeting for above cited decision:

| | | |
|---|---|---|
| **1.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: **Contract Manufacturing** by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Velzone Injection 250 mg I.M. |
| | Composition | Each vial contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….250mg |
| | Diary No. Date of R& I & fee | Dy No. 26899: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 250mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved |
| | Me-too status | Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556 |
| | GMP status | The firm was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm (M/s EG Pharmaceuticals) was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deferred for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved.** | |
| **2.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: Contract Manufacturing by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Velzone Injection 250 mg I.V. |
| | Composition | Each vial contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….250mg |
| | Diary No. Date of R& I & fee | Dy No. 26898: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 250mg (IV) by Lupin Pharmaceuticals Inc. US-FDA approved |

| | | |
|---|---|---|
| | Me-too status | Ceftirains 250mg (ceftriaxone Sodium) I.V Injection by Sunrise Pharma (Pvt) Ltd. Reg. No. 78655 |
| | GMP status | The firm (M/s EG Pharmaceuticals) was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deffered for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved** | |
| **3.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: Contract Manufacturing by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Velzone IM Injection 500mg |
| | Composition | Each vial contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….500mg |
| | Diary No. Date of R& I & fee | Dy No. 26901: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 500mg (IM) by Lupin Pharmaceuticals Inc. US-FDA approved |
| | Me-too status | Wincef 500 mg (Ceftriaxone sodium) IM injection by Wnsfeild Pharmaceuticals. Reg. No. 68371 |
| | GMP status | The firm (M/s EG Pharmaceuticals) was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated |

| | | |
|---|---|---|
| | | 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deffered for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved.** | |
| **4.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: Contract Manufacturing by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Velzone I.V. Injection 500mg |
| | Composition | Each vial contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….500mg |
| | Diary No. Date of R& I & fee | Dy No. 26900: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 500mg (IV) by Lupin Pharmaceuticals Inc. US-FDA approved |
| | Me-too status | Wincef 500 mg (Ceftriaxone sodium) IV by Wel Wink Pharmaceuticals. Reg. No. 78097 |
| | GMP status | The firm (M/s EG Pharmaceuticals) was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deffered for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved** | |
| **5.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: Contract Manufacturing by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Velzone I.V. Injection 1g |

| | | |
|---|---|---|
| | Composition | Each vial contains:<br>Ceftriaxone sodium eq. to Ceftriaxone…….1g |
| | Diary No. Date of R& I & fee | Dy No. 26902: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins |
| | Type of Form | Form 5 |
| | Finished Product Specification | USP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Ceftriaxone 1 g (IV) by Lupin Pharmaceuticals Inc. US-FDA approved |
| | Me-too status | Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection by Alkemy Pharma. Reg. No. 70663 |
| | GMP status | The firm (M/s EG Pharmaceuticals) was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deffered for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved.** | |
| **6.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: Contract Manufacturing by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Subac IV Injection 1g |
| | Composition | Each vial contains:<br>Cefoperazone sodium…….500mg<br>Sulbactam sodium…….500mg |
| | Diary No. Date of R& I & fee | Dy No. 26896: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins and beta-lactamase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Sulperazon Injection by Pfizer Inc. PMDA Approved |
| | Me-too status | Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028 |
| | GMP status | The firm (M/s EG Pharmaceuticals) was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |

| | | |
|---|---|---|
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deffered for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved** | |
| **7.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: Contract Manufacturing by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Subac IV Injection 2g |
| | Composition | Each vial contains:<br>Cefoperazone sodium…….1g<br>Sulbactam sodium…….1g |
| | Diary No. Date of R& I & fee | Dy No. 26897: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Third generation cephalosporins and beta-lactamase inhibitors |
| | Type of Form | Form 5 |
| | Finished Product Specification | JP |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia |
| | Me-too status | Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027 |
| | GMP status | The firm (M/s EG Pharmaceuticals) was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) |

| | | |
|---|---|---|
| | | 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deffered for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved** | |
| **8.** | Name and address of manufacturer / Applicant | M/s Convell Laboratories, Saidu Sharif Swat: Contract Manufacturing by M/s EG Pharmaceuticals, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad |
| | Brand Name +Dosage Form + Strength | Convell D IM/Oral |
| | Composition | Each 1 ml ampoule contains:<br>Cholecalciferol……5mg |
| | Diary No. Date of R& I & fee | Dy No. 26895: 29.12.2017 PKR 50,000/-: 29.12.2017 |
| | Pharmacological Group | Vitamin D3 analogue |
| | Type of Form | Form 5 |
| | Finished Product Specification | The firm has claimed manufacturer specifications |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Vitamin D3 Good 200,000 IU / 1 ml, oral solution in ampoule and Vitamin D3 Good 200,000 IU / 1 ml, solution for injection IM in ampoule by Bouchara-Recordati. ANSM Approved |
| | Me-too status | ORA-D3 Injection by Ameer & Adnan Pharmaceuticals (Pvt.) Ltd. Reg. No. 78639 |
| | GMP status | The firm (M/s EG Pharmaceuticals) was last inspected on 29.08.2018 & 03.09.2018, wherein the firm was considered operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under |
| | Remarks of the Evaluator. | • The firm was asked to provide list of already approved and applied products for contract manufacturing. In response the firm submitted that they have never applied for contract manufacturing.<br>• The firm was asked to provide list of all approved sections. In response, the firm submitted that they have the following approved sections: 1. Tablet section (General) 2. Capsule section (General) 3. Dry Powder section (General) 4. Liquid section (General) 5. Psychotropic section 6. Capsule section (cephalosporin) 7. Dry powder section (cephalosporin).<br>The firm has also submitted the inspection report dated 13.12.2014, wherein the panel has inspected the following sections and has recommended the grant of renewal of DML by way of formulation:<br>1. Tablet General/antibiotic 2. Capsule (General) 3. Dry Powder section General/antibiotic 4. Liquid syrup (General) 5. Tablet Psychotropic 6. Capsule (cephalosporin) 7. Dry powder (cephalosporin) 8. Penicillin dry powder 9. Penicillin capsule |
| | Decision of 286th meeting | The Registration Board deffered for capacity evaluation of M/s EG Pharmaceuticals |
| | Evaluation by PEC | |
| | **Decision: Approved with innovator's specification.** | |
| **9.** | Name and address of manufacturer / Applicant | M/s Medisynth Pharmaceuticals, Plot No. 55, Street No.S-5, National Industrial Zone, Rawat. **Contract manufacturing by** M/s EG Pharmaceuticals, Industrial Triangle Kahuta road, Islamabad. |
| | Brand Name+Dosage Form+ Strength | Fersyn 100mg/5ml |
| | Composition | Each 5ml ampoule contains:<br>Iron (III)-hydroxide sucrose complex eq. to elemental Iron….. 100mg |
| | Diary No. Date of R& I & fee | Dy. No. 3638; 23-05-2017; Rs.50,000/- (22-05-2017) |

| | | |
|---|---|---|
| | Pharmacological Group | Iron supplement |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | Venofer approved by USFDA |
| | Me-too status | Venofer I.V. Injection of M/s Gastro Care Karachi (Reg.#023654) |
| | GMP status | Last GMP inspection of EG Pharma conducted on 22-06-2017 the report concludes that overall firm is operating at reasonable level of compliance with GMP. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |
| **10.** | Name and address of manufacturer / Applicant | M/s Medisynth Pharmaceuticals, Plot No. 55, Street No.S-5, National Industrial Zone, Rawat. **Contract manufacturing by** M/s EG Pharmaceuticals, Industrial Triangle Kahuta road, Islamabad. |
| | Brand Name +Dosage Form + Strength | Calmed Injection 5mg/ml |
| | Composition | Each ml ampoule contains:<br>Cholecalciferol…..5mg |
| | Diary No. Date of R& I & fee | Dy. No. 3639; 23-05-2017; Rs.50,000/- (22-05-2017) |
| | Pharmacological Group | Vitamin D3 analogue |
| | Type of Form | Form-5 |
| | Finished product Specification | Manufacturer specification |
| | Pack size & Demanded Price | As per SRO |
| | Approval status of product in Reference Regulatory Authorities. | ANSM approved |
| | Me-too status | Oral D-3 of M/s Schazoo Pharma |
| | GMP status | Last GMP inspection of EG Pharma conducted on 22-06-2017 the report concludes that overall firm is operating at reasonable level of compliance with GMP. |
| | Remarks of the Evaluator. | |
| | **Decision: Approved with innovator's specification.** | |

**Item No. II: Division of Biological Evaluation & Research.**

**1. Imported Human Biological from reference countries.**

| | | |
|---|---|---|
| **1.** | Name and address of Importer | M/s Ali Gohar and company (Pvt.) limited state life building 1-B, I.I. Chundrigar Road, Karachi-74000, P.O. Box 5167 |
| | Detail of DSL | No. 0427 valid upto 21-09-2019 |
| | Name and address of Manufacturer | Product License Holder:<br>M/s Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173 55216 Ingelheim am Rhein, Germany<br>Manufacturer:<br>M/s Boehringer Ingelheim Pharma GmbH & Co. KG Production site: Biberach Birkendorfer Strasse 65 88397 Biberach/ RiB, Germany |
| | Brand Name +Dosage Form + Strength | Actilyse<br>Powder and solvent for solution for injection and infusion<br>1mg/1ml when constituted |
| | Diary No. Date of R& I & fee | Dy No. 14469/2017(R&I) Date: 11-09-2017.<br>Rs. 50,000/- dated 11-09-2017 |
| | Composition | Each vial contains:<br>Alteplase……50mg<br>Solvent:<br>Sterile water for injection…….50ml |
| | Pharmacological Group | Tissue plasminogen activator (tPA) |
| | Type of Form | Form-5A |
| | Finished Product Specification | Ph Eur. Spec's |
| | Shelf Life | 3 years (below $30^0$C |
| | Document Details | Valid legalized CoPP No. Z47187 |
| | Pack size & Demanded Price | 1 vial of powder + 1 vial of solvent (50ml)/ Rs. 150,370.34 |
| | International Availability | Germany |
| | Products already registered in Pakistan | Not available |
| | Remarks of evaluator | |
| **Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of Germany (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import policy for finished drugs.** | | |

**2. MMR Vaccine Case of M/s Amsons Vaccine and Pharma, Islamabad.**

The vaccine name Measles, Mumps, Rubella vaccine live, attenuated (freeze dried) was registered in the name of M/s. Amsons Vaccine and Pharma (Reg. No. 013272). As per copy of transfer of registration, the product is registered in the form of Naked vials from Serum Institute of India and local repacking at M/s. Amson Vaccine and Pharma, Islamabad. The company has now informed that the manufacturer abroad has difficulty in exporting naked vials. The firm has requested to grant permission to import labeled vials instead of naked vials.

**Decision of 249th meeting of RB:**

*"The Registration Board accepted request of firm and allowed import of labeled vials instead of naked vial of the product (Reg. No. 013272) and import in form of naked vials of Reg. No. 013272 stand cancelled. The rest of conditions of registration remain same and valid"*

Firm stated that MMR (Measle, Mumps, Rubella) vaccine is registered in their name against registration No.013272 dated 15-7-1992 in presentation of 10x1 dose.

MMR vaccine is mainly used in the private market whereas single dose presentation is accepted and preferred. In order to ensure smooth supply of vaccine and avoid any shortage, we would

request that we may be allowed to import MMR labeled vaccine in 10x1 presentation which will then be re-packed in single vial presentation along with an auto disable registered syringe which will be provided on FOC basis. It is therefore requested that we may be allowed,

Local re-packing of MMR vaccine in single vial/packs along with the registered syringe on our facility.

**Decision: Keeping in view reported shortages of MMR vaccine in market, Registration Board approved request of the firm. Firm shall submit following documents for further processing of case:**

**a. Verification of last renewal submission.**
**b. Confirmation of QC release facility of M/s Amson Vaccines & Pharma Islamabad for said product.**
**c. NOC from manufacturer/ principal abroad regarding the local repacking in single packs.**

**MRP shall be confirmed from Pricing Division of single pack as initial registration was granted for multipack of 10's. Registration Board authorized its Chairman for issuance of registration letter after completion of above deficiencies.**

### 3. Request for issuance of registration letter on new company name/title

Following products of M/s. Merck, specialties (private) limited Karachi have been approved in 240th meeting of Registration Board. Registration letters were not issued due to change in importer name which is now approved in 279th meeting of Registration Board from M/s Merck Specialties (Private) Limited to M/s Martin Dow Marker Specialties (Private) Limited.

Now firm requested to issue the registration letter with new approved importer name. The details of approved products are as under:

| Sr. # | Importer/ Manufacturer | Brand Name & Composition | Decision of RB |
|---|---|---|---|
| 1. | M/s Merck Specialities (Private) Limited<br><br>M/s. Merck Serono S.P.A. VIA Delle Magnolie (LOC. Frazione Zona Industriale), Italy. | Crinone ® 8% Vaginal Gel<br>Each applicator contains: -<br>1.45g of Gel but delivers A controlled 1.125g of Gel (90mg Progesterone/1.125 G dose)<br>(Progestin (Sex Hormones). | **M-240**<br>Approved |
| 2. | | LUVERIS 75 IU<br>Powder and solvent for solution for Injection.<br>Each vial contains:<br>Lutropin alfa (Recombinant human luteinizing hormone, lyophilized) ……..75IU | **M-257**<br>Keeping in view the approval status of product by EMA and information of legalized CoPP, Registration Board approved the product as per Import Policy for finished drugs. |

**Decision of 279th meeting of RB regarding change in importer name:**

Registration Board approved the change in name of importer of Gonal-F 75IU Injection (Reg. No. 028418) & Erbitux 5mg/ml Injection (Reg. No. 052292) from M/s Merck Specialities (Private) Limited to M/s Martin Dow Marker Specialities (Private) Limited.

The firm has submitted following documents:

a. Application with Fee Challans of Rs. 100,000/- for each product.
b. Copy of Drug Sale License with new name valid till 27th Nov. 2019.
c. Copy of Approval of new name by SECP / registrar of firm.
d. NOC with new name of importer by Manufacturer instead of Sole Agency agreement.
e. Undertaking by the firm that no case is pending at any forum / court of law regarding previous name.
f. Undertaking that the provided information/ documents are true/ correct.

**Remarks of Evaluator:**

Products already approved but CoPP/GMP+FSC not trace able firm submit commitment letter to submit CoPP before issuance of Registration letter.

**Decision:** **Registration Board approved the change in name of importer of Luveris 8% Vaginal gel and Crinone 75IU from M/s Merck Specialities (Private) Limited to M/s Martin Dow Marker Specialities (Private) Limited. The firm will submit valid legalized CoPPs of said products before issuance of registration letters. Registration Board has authorized its Chairman for issuance of registration letter after submission of valid legalized CoPPs by the firm.**

**4. Application for Registration of Eritrogen (Erythropoietin) 2000IU PFS, 4000IU PFS, 10000IU PFS and 10000IU Vial Applied by M/s BF Biosciences Ltd., Lahore Deferred in 286th Meeting of Registration Board.**

Following products of M/s BF Biosciences Ltd., Lahore were deferred in 286th meeting of Registration Board as per following details:

| Name of Manufacturer | Brand Name, Composition, Pharmacological group, Shelf life | Type of Form, Dy. No & date of application, Fee status, Packing &demanded MRP | Documentary details (CoPP etc.) Reference agencies status, Me too |
|---|---|---|---|
| M/s BF Biosciences Ltd., 5km- Sunder Raiwind Road, Raiwind, Lahore | Eritrogen 2000IU<br>Each prefilled syringe (1ml) contains:<br>Recombinant Human Erythropoietin alpha.....2000IU<br><br>Mitosis stimulating factor & differentiating hormone<br><br>Shelf Life: 24 months | Form-5<br>134/2014(R&I)<br>09-05-2014<br>Rs. 20000<br>07-05-2014<br>Pack of 6's (PFS)<br>Price:<br>As per SRO | DML No. 000655 dated 30-01-2014<br>GMP certificate No. 20132021-000 013-18 dated 019-04-2018 of M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', ParqueTecologicoLitoral , of the Province of Santa Fe, of the Argentine Republic valid for 01 year.<br><br>Eprex of Janssen-Cilag Ltd., UK<br><br>Sepo 2000IU/ml PFS by Al-Karim Distributors, Karachi. |
| | Eritrogen 4000IU<br>Each prefilled syringe (1ml) contains:<br>Recombinant Human Erythropoietin alpha.....4000IU<br><br>Mitosis stimulating factor & differentiating hormone<br><br>Shelf Life: 24 months | Form-5<br>135/2014(R&I)<br>09-05-2014<br>Rs. 20000<br>07-05-2014<br>Pack of 6's (PFS)<br>Price:<br>As per SRO | DML No. 000655 dated 30-01-2014<br>GMP certificate No. 20132021-000 013-18 dated 019-04-2018 of M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', ParqueTecologicoLitoral , of the Province of Santa Fe, of the Argentine Republic valid for 01 year.<br>Eprex of Janssen-Cilag Ltd., UK<br><br>Sepo 2000IU/ml PFS by Al-Karim Distributors, Karachi. |
| | Eritrogen 10000IU<br>Each prefilled syringe (1ml) contains:<br>Recombinant Human Erythropoietin alpha.....10000IU<br><br>Mitosis stimulating factor & differentiating hormone<br><br>Shelf Life: 24 months | Form-5<br>136/2014(R&I)<br>09-05-2014<br>Rs. 20000<br>07-05-2014<br>Pack of 6's (PFS)<br>Price:<br>As per SRO | ` DML No. 000655 dated 30-01-2014<br>GMP certificate No. 20132021-000 013-18 dated 019-04-2018 of M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', ParqueTecologicoLitoral , of the Province of Santa Fe, of the Argentine Republic valid for 01 year.<br><br>Eprex of Janssen-Cilag Ltd., UK<br><br>Sepo 2000IU/ml PFS by Al-Karim Distributors, Karachi. |

| | | | |
|---|---|---|---|
| | Eritrogen 10000IU<br>Each vial (1ml) contains:<br>Recombinant Human Erythropoietin alpha.....10000IU<br><br>Mitosis stimulating factor & differentiating hormone<br><br>Shelf Life: 24 months | Form-5<br>682/2014(R&I)<br>13-06-2014<br>Rs. 20000 11-06-2014<br>Pack of 6's (Vials)<br>Price:<br>As per SRO | DML No. 000655 dated 30-01-2014<br>GMP certificate No. 20132021-000 013-18 dated 019-04-2018 of M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', ParqueTecologicoLitoral , of the Province of Santa Fe, of the Argentine Republic valid for 01 year.<br><br>Eprex of Janssen-Cilag Ltd., UK<br>Sepo 2000IU/ml PFS by Al-Karim Distributors, Karachi. |

**Case history:**

The products were approved in 273rd meeting of Registration Board held on 28-29th August 2017. The data provided by the firm was in light of 246th meeting of Registration Board at that time. The case was again taken in 276th meeting of Registration Board wherein the board decided as under;

> *"Registration Board deferred the matter of issuance of registration letter till the recommendations of working group for local manufacturing of Biological drugs"*

Working group for local manufacturing ofBiological drugs recommended certain regulatory requirements which were adopted as guidelines for the registration of rDNA therapeutic proteins by the Registration Board in its 278th meeting.

Now the firm has submitted data in light of decision made by the Registration Board in its 278th meeting. Detail is summarized as under;

| The firm has submitted the documents/data in the light of regulatory guideline for biological products approved in 278th meeting of Registration Board as per following details: | |
|---|---|
| Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form) | Documents submitted by firm |
| The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide concentrate / ready to fill bulk of biological drug to Pakistani manufacturers for further processing) as an evidence that the manufacturer is an authorized manufacturer of biological drug in the country of origin. | Copy of GMP certificate No. 20132021-000 013-18 dated 19-04-2018 of M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', Parque Tecologico Litoral , of the Province of Santa Fe, of the Argentine Republic valid for 01 year. |
| The firms shall provide legalized free sale certificate/CoPP either from country of origin or by any reference regulatory authority as adopted by Registration Board of finished product as evidence that the final product has been manufactured by same concentrate/ready to fill bulk after submission of data to the concerned regulatory authority. | Details are included below |
| The firm shall provide the complete Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board to demonstrate the bio-similarity. | Details are included below |
| The firm shall provide the lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (If applicable). | Lot release certificate of the finished product manufactured by same bulk concentrate/ ready to fill from country of export (Not applicable). |
| The firm shall provide the 6 months accelerated and real time stability studies for drug substance. | Details are included below. |
| The local manufacturer shall manufacture three trial batches of the finished biological product to finalize | The firm has submitted stability study data and CoA wherein the tests conducted are as under; |

| | |
|---|---|
| the formulation and then perform analytical studies(Physicochemical and biological) including protein content, appearance, pH, Osmolarity, composition of key excipients including stabilizers (if formulation is same), visible/subvisible particles, identity testing to parent molecule, purity testing, in vitro biological activity, sterility, Pyrogen content, safety, potency and toxicity with support of iso-electro focusing data, gel electrophoresis, Western-Blot and other analytical techniques). The firm shall submit the results for processing of registration application. | • Appearance<br>• Leak test<br>• pH<br>• Extractable volume<br>• Immuno characterization<br>• Potency<br>• Sterility<br>• Bacterial endotoxins<br>• Particulate matter.<br>• Sialic acid content<br>• Protein concentration<br>• Peptide mapping<br>• Identification (by SDS page)<br>• Isoforms content<br>• Dimers and related proteins of higher molecular mass |
| The manufacturer shall perform all tests locally as detailed on Certificate of analysis. | Certificate of analysis of finished product is not provided from country of origin. The firm has provided its own certificate of analysis. |
| The firm shall also provide the list of finished products being manufactured from same bulk concentrate or ready to fill form in any country of the world (if available). | The firm has submitted the list indicating following products from bulk of same source;<br>Hemastim: Mauritani, Ivory Cost, Ecuador, Gabon, Mali, Congo republic.<br>Alvoetin: Myanmar<br>Acromax: Ecuador |
| The firm shall provide the agreement with the source (of bulk concentrate/ready to fill) that if there shall be any critical change in manufacturing process, biological systems used to manufacture, etc. the firm shall inform DRAP immediately along with relevant documents. | Provided |
| Regular monitoring through pharmacovigilance reporting system shall be observed through proper pharmacovigilance cell of the manufacturer and report will be forwarded to the National Pharmacovigilance Centre, Division of Pharmacy Services and Biological Division of DRAP. In case of any severe adverse event, immediate mandatory reporting procedure shall be followed. | Post marketing surveillance system.<br>Recall system |
| The firm shall inform DRAP if there shall be any adverse event or ADR reporting from the country of manufacture of concentrate/ready to fill bulk and finished product as required vide Rules 30 of Drug (LR&A) Rule. | Provided the undertaking and agreement with manufacturer of concentrate/ready to fill bulk. |
| Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin. | |
| WHO Bio-similarity guidelines | Data submitted by the firm |

| | |
|---|---|
| **Quality Comparison** Physicochemical characterization | Under Eludication of structure of API, comparative analysis with 2 batches of Procrit 4000IU of Janssen Products, LP is provided by M/s ZELLTEK S.A, Argentine Republic.<br>i. Mass of C-terminal peptide<br>ii. Mass of N-terminal peptide<br>iii. Molecular mass of native protein<br>iv. Identification by RP-HPLC<br>v. Content of EPO<br>vi. Determination of Impurities by Western Blot<br>vii. Bacterial Endotoxins<br>viii. Stability under stress conditions- Temperature<br>ix. Stability under stress conditions- pH<br>x. Determination of sequence of aminoacids<br>xi. Integrity of Disulfide Bond<br>xii. Percentual content of isoforms<br>xiii. Profile of native N-glycans<br>xiv. Occupation of the site of O-glycosylation |
| Biological Activity | Biological activity in vivo |
| Immunochemical properties | Immunoidentification (Western Blot) |
| Impurities | Determination of Impurities by Western Blot |
| Stability Studies | Stability studies are provided. |
| Non-clinical Studies | i. In Vivo primary Pharmacodynamic Study:<br>ii. In Vitro primary Pharmacodynamic Study:<br>iii. Pharmacokinetics in Wister rats<br>iv. Toxicity & immunogenicity and local tolerance after repeated dose in Wister rats |
| Clinical Studies | i. Reports of human pharmacokinetics and initial tolerability study.<br>ii. Reports of human pharmadynamics.<br>iii. Report of comparative pilot study between two recombinant human erythropoitins, in the treatment of anemia associated to chronic kidney disease in patients in chronic haemodylasis. |
| **Decision of RB in 286th meeting** | *Registration Board deferred the product for submission of following by the firm:*<br>*a. Valid legalized CoPP/ FSC.*<br>*b. Accelerated stability data of drug substance.*<br>c. *Certificate of Analysis (CoA) of Eritrogen 10000IU vial from country of origin.* |

The firm has now submitted the following documents:

a. Valid legalized CoPPs No. 20132019-001912-18 date 28-12-2018, 20132019-001911-18 dated 28-12-2018 and 20132019- 001913-18 dated 17-12-2018 for Eritrogen 2000IU vial, 4000IU vial, 10000IU vial indicating product license holder and manufacturer as per following details:
   **Product License Holder:** M/s Bioprofarma Bago S.A., Terrada 1270, Ciudad Autonoma de Buenos Aires, Republica Argentina (Also invoved in packaging and/ or labeling).
   **Manufacturer:** M/s Pharma S.A., Estados Unidos 5105, Partido de Malvinas Argentinas, Provincia de Buenos Aires, Republica Argentina.
   The firm submitted the copy of bill invoice of M/s Zelltak S.A. (Bulk Manufacturer) in name of above product license holder for 9858.27mg of Recombinant Human Erythropoeitin.
b. The firm has submitted accelerated stability data of drug substance for 90 days on $5\pm3^0$C and submitted the reference of ICH guidelines which states as follows:
   *"For drug substances intended for storage in a freezer, the re-test period should be based on the real time data obtained at the long term storage condition. In the absence of an accelerated storage condition for drug substances intended to be stored in a freezer, testing on a single batch at an elevated temperature (e.g., 5°C ± 3°C or 25°C ± 2°C) for an appropriate time period should be conducted to address the effect of short term excursions outside the proposed label storage condition, e.g., during shipping or handling."*
c. Certificate of analysis of Eritrogen 10000IU Vial of M/s Bioprofarma Bago.

**Discussion:**

The bulk of Recombinant Human Erythropoeitin for above products will be imported from M/s ZELLTEK S.A, Ruta Nacional No 168 S/N, Pasaje "EI Pozo', Parque Tecologico Litoral , of the Province of Santa Fe, of the Argentine Republic and local formulation, filling and QC release will be done at M/s BF Biosciences Ltd., 5km- Sunder Raiwind Road, Raiwind, Lahore. M/s ZELLTEK S.A., Argentina only

manufactures bulk of Erythropoietin while the finished product is not manufactured by them. The firm has submitted valid legalized CoPPs for Eritrogen 2000IU vial, 4000IU vial and 10000IU vial indicating product license holder as M/s Bioprofarma Bago S.A., Terrada 1270, Ciudad Autonoma de Buenos Aires, Republica Argentina and copy of bill invoice along with its notarized translation of M/s Zelltak S.A. (Bulk Manufacturer) in name of M/s Bioprofarma Bago S.A., Terrada 1270, Ciudad Autonoma de Buenos Aires, Republica Argentina for 9858.27mg of Recombinant Human Erythropoeitin to confirm that the product being manufactured by the same bulk is available in country of origin as required by Registration Board in its 278th meeting.

**Decision: Keeping in view the position explained above, GMP certificate of M/s BF Biosciences, Lahore and data submitted in light of decision of 278th meeting; Registration Board approved the products.**

**5. Regulatory requirements for registration of locally manufactured Enoxaparins.**

Registration Board in its 281st meeting held 11th to 13th April 2018 decided following regulatory requirement regarding import applications of enoxaparin;

*"Registration Board deliberated the matter in detail and decided that for registration of Enoxaparins the applicants will provide following documents along with Form-5A:*

*i. The physical and chemical characteristics of enoxaparin.*
*ii. The nature of the heparin material and the chemical process used to break up heparin chains into smaller pieces.*
*iii. The nature and arrangement of components that constitute enoxaparin.*
*iv. Certain laboratory measurements of the product's anticoagulant activity."*

It is submitted that Registration Board in its 278th meeting has decided to adopt certain guidelines as regulatory requirements for the registration of rDNA therapeutic proteins for finished form importers as well as local manufacturer. While for enoxaparin, guidelines only for finished importers were adopted. As biological drug division is receiving applications from local manufacturer as well, so, in this regard the Registration Board is requested to set guidelines as regulatory requirements for the registration for local manufacturer.

The case was considered in 282nd meeting of Registration Board wherein the Board decided as follows:

*"Registration Board referred the case to Expert working group on Biological Drugs constituted in 273rd meeting of Registration Board."*

Registration Board in its 273rd meeting constituted following Expert working on Biological Drugs:

*"Registration Board deliberated the matter and constituted following committee to make guidelines for the evaluation of different classes/categories of Biological Drugs (Human & Veterinary) keeping in view the statutory requirements as well as the current scenario of Pakistan.*

*a. Maj. Gen. Tahir Mukhtar Commandant AFIRM. (Chairman)*
*b. Dr. Noor Us Sabah, Director Biological Drugs (Member)*
*c. Dr. Qurban Ali, DG NVL (Member)*
*d. M. Akhtar Abbas Khan, Dy. Director Biological (Secretary)*
*e. Representative of Pharma Bureau, PPMA and PCDA (Observer)*
*f. The committee can co-opt any expert as a member for its technical assistance.*

In this context, it is submitted that Mr. Akhter Abbas Khan, Dy. Director Biological Drugs is Secretary of this working group but he has been transferred from Division of BE&R therefore Registration Board may nominate another Secretary please.

**Decision: Keeping in view the position explained above; Registration Board nominated Mr. Muhammad Zubair Masood, Assistant Director Biological Drugs as Secretary of committee to make guidelines for the evaluation of different classes/categories of Biological Drugs (Human & Veterinary) keeping in view the statutory requirements as well as the current scenario of Pakistan.**

**6. Change of specifications of already approved products applied by M/s Shamco Traders (Pvt) Ltd., Lahore deferred in 287th meeting of Registration Board.**

M/s Shamco Traders (Pvt) Ltd., Lahore applied for the change in specifications of their products approved in different meetings of Registration Board as per following details:

| Sr. No. | Name of Manufacturer | Brand Name & Composition | Decision of RB |
|---|---|---|---|
| 1. | M/s Dong-A ST Co., Ltd. (Dong-A Pharmaceutical Co., Ltd. Before Split-Off on March 5th, 2013) (N-dong, B-dong Section 2) 493 Nongong-ro, Nongong-eup, Dalseong-gun, Daegu, Republic of Korea | Eporon PFS 2000IU/0.5ml<br>Each 0.5ml contains:<br>Recombinant human erythropoietin…….2000IU | *Keeping in view the biosimilarity data and valid legalized CoPP provided by the firm; Registration Board approved the product subject to price fixation by the Federal Government and compliance of current Import Policy for Finished Drugs.* **(M-275)** |
| 2. | | Eporon PFS 4000IU/0.4ml<br>Each 0.4ml contains:<br>(Recombinant human erythropoietin…….4000IU | |
| 3. | | Eporon® Injection PFS 10,000IU/1.0ml<br>Each PFS of 1ml contains:<br>Recombinant Human Erythropoietin……10000IU | *Keeping in view the biosimilarity data and valid legalized GMP and FSC provided by the firm indicating the product is available in country of origin; Registration Board cancelled the registration of Eporon Injection10000IU (Reg. No. 047638) from M/s Century Pharmaceuticals (Pvt) Ltd, Karachi and granted in name of M/s Shamco Traders (Pvt) Ltd., Lahore with British Pharmacopoeia Specifications subject to the compliance of current Import Policy for Finished Drugs, verification of cold storage facility and comments on the price of the product from Pricing division.* **(M-285)** |

The firm then applied for inspection exemption of manufacturer abroad for products at sr. no. 1 & 2 and the exemption was granted in 283rd meeting of Registration Board. Then the firm vide letter dated **05-10-2018** demanded **British Pharmacopoeia specifications** for their products at sr. no. 1&2. Accordingly, registration letters were prepared with BP specifications. The Chairman Registration Board then pointed out that the Free Sale Certificate submitted by the firm indicates that the products are permitted to be freely sold in over seas markets. Accordingly, the firm was asked to submit valid legalized CoPPs for above products. The firm on 13-12-2018 submitted the valid legalized CoPPs vide no. 2018-A1-1727, 2018-A1-1730 and 2018-A1-1734 dated 14-11-2018 for above products respectively.

Moreover, on **20-12-2018** the firm submitted that their manufacturer M/s Dong-A ST, Korea is following In-house specs for their finished drug. The firm requested to issue registration letters with **In-house specs** and submitted a comparison of Dong-A in house specs with BP Specs.

The case was considered in 287th meeting of Registration Board wherein the Board decided as follows:

*"Registration Board deferred the case for complete and conclusive evaluation by DBER of finished product specification submitted by the firm in comparison with British Pharmacopoeia"*

Now the firm has submitted that they withdraw their earlier request and ready to accept the BP specifications for their above products.

**Decision: Registration Board acceded to the request of the firm and advised to issue registration letters with British Pharmacopoeia specifications.**

## 7. Human Vaccines applied by M/s. Amson Vaccine & Pharma Pvt Ltd., Islamabad deferred in 287th meeting of Registration Board.

Following product of M/s Amson vaccine & Pharma Pvt. Ltd. deferred in 287th meeting of Registration Board as per following details:

| | |
|---|---|
| **Name of Importer** | M/s. Amson Vaccine & Pharma Pvt Ltd<br>Industrial Triangle Kahuta Road, Islamabad |
| Name of Manufacturer | M/s Haffkine Bio Pharmaceutical Corpn. Ltd Acharya Donde Marg, Parel Mumbai 400012 (India) (A Govt. of Maharashtra Undertaking) |
| Brand Name +Dosage Form + Strength | Monovalent Type 1 Oral Poliomyelitis Vaccine IP (mOPV1)<br>20 doses (2mL) Vial |
| Composition | Each Dose of 2 drops (0.1ml) contains:<br>Poliovirus (Sabin) P.M.K.C.C…… Type 1 – $10^{6.0}CCID_{50}$ |
| Finished product specifications | IP |
| Approval status of this product in Reference countries | NA |
| Pharmacological Group | Oral Vaccine |
| Shelf life | 24 Months at-$20^0$C |
| International Availability of this product | INDIA |
| Similar Product already registered in Pakistan | Polio monovalent type 1 vaccine by M/s SMS |
| Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A dated 16-10-2018<br>R&I Dy.No.39365dated 29-11-2018.<br>Rs.100,000/- dated26-11-2018. |
| Demanded Price/ Pack size | Price not demanded/ 20 doses (2mL) vial |
| General documentation | 1. Original Sole Agency Certificate dated 31-10-2018.<br>2. Legalized valid GMP Certificate No.NEW-WHO-GMP/CERT/MD/51564/2017/11/20148 dated 21-7-2017.<br>3. Legalized FSC Certificate No.6084738 dated 30-10-2018.<br>4. WHO prequalified vaccine available at https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=186 accessed on 15-02-2019. |

Decision of 287th meeting of RB:

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

a. Accelerated stability data.
b. Complete clinical trial data.
c. Clarification regarding IP specifications mentioned in CoPP while product is available in BP.

Now the firm has submitted:

a. accelerated stability data at $37^0$C for 7 days which shows that mOPV1 at $37^0$C is stable upto 2 days.
b. We are also attaching the relevant emails which are self-explanatory. The email sent by Dr.Jacqueline Fournier Caruana (Dr. Jacky for short) the then Head of the OPV Pre-qualification from WHO clearly states & we quote verbatim "No clinical studies will be conducted by WHO on the mOPV1 filled by Haffkine as the ongoing trial with the Panacea product filled from the same bulks supplied by Bio Farma will provide appropriate information on efficacy and safety of the mOPVI1 that would serve the PQ purposes of both products"
c. Firm clarify that both IP and BP specifications are same.

**Decision:** **Keeping in view WHO Prequalification, valid legalized GMP and FSC; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**

## 8. Imported Veterinary Biologicals from Non-reference countries.

| | | |
|---|---|---|
| 1. | **Name of Importer** | M/s Orion Group,P-97 Usama Block, Near Wood Burry Homes, Muslim Town No. 1, Lasani Pulli Sargodha Road, Faisalabad. |
| | DSL details | No. EDO(H) 2657-FTC/DL dated 12-11-2016 valid till 11-11-2018 |
| | Name of Manufacturer | M/s Federal State Enterprise "Shchelkovo biokombinant",<br>Biokombinant Township, Shelkovskii district, Moscow region, 141142, Russian Federation. |
| | Brand Name +Dosage Form + Strength | The cultural monovalent and polyvalent emulsified inactivated vaccine against foot-and-mouth disease |
| | Composition | Each 2ml of vaccine contains:<br>Inactivated FM D virus antigen of strains of one or more types A, O, Asia-1……1ml<br>Adjuvant Montanide ISA 206……..1ml |
| | Finished product specifications | Ph. Eur. Specs. |
| | Pharmacological Group | Veterinary Vaccine |
| | Shelf life | 18 months ($2^0$C-$8^0$C) |
| | International availability | Tajikistan, Uzbekistan, Armenia etc. |
| | Products already registered in Pakistan | Arriah Vac of M/s Mustafa Brothers, Faisalabad |
| | Type of Form<br>Dy No & Date of application,<br>Fee submitted | Form-5A<br>Dy. No. 37785 Dated 15-11-2018<br>Rs. 100000/- Dated 15-11-2018 |
| | Demanded Price / Pack size | 50ml (25 doses) Bottle |
| | General documentation | Legalized CoPP No. 01026 dated 29-01-2016 valid till 29-01-2019 issued by All-Russian Scientific and Research Institute for Certification (JSC"VNIIS").<br>Valid legalized FSC No. 1442 dated 07-09-2018 issued by Head Administrative Authority For Veterinary of the Moscow Region. |
| | Remarks of Evaluator | • The GMP certificate submitted by the firm was valid at the time of submission but has expired now. Moreover, the GMP certificate provided by the firm is not issued by authorized body. The firm submitted a link for verification of authorization which was not accessible. Furthermore, All-Russian Scientific and Research Institute for Certification (JSC"VNIIS") is accredited by Federal Accreditation Agency of Russia but the authorized body for issuance of GMP certificate is Federal Service for Veterinary and Phytosanitary Surveillance as per Russian Government Resolution no. 1314 of December 3, 2015.<br>• The Free Sale Certificate submitted by the firm indicates Brand name as monovalent and polyvalent while the vaccine should be either monovalent or polyvalent. Moreover, the composition mentioned on FSC is not specifiying the no. of strains of FMD virus used. It indicates one or more while it should be specific. The firm informed that the brand name is registered in Russia as such but they will submit revised FSC with correct brand name before issuance of registration letter. |
| **Decision:** | | **Keeping in view the valid legalized GMP certificate and valid legalized FSC indicating product availability in country of origin; Registration Board approved the above product subject to compliance of current Import policy for finished drugs. Registration Board advised DBER to send an email to Federal Service for Veterinary and Phytosanitary Surveillance, Russia regarding verification of authorization of All-Russian Scientific and Research Institute for Certification (JSC"VNIIS") for issuance of GMP certificate. The firm will submit revised valid legalized FSC with correct brand name and composition before issuance of registration letter. The same will also be verified during inspection of manufacturer abroad. Registration Board has authorized its Chairman for issuance of registration letter after said verification.** |

**Item No.III: Registration-I Section**

**Case No.1. Request for Change In Registration Status from M/s Macter International Ltd, Karachi To M/s Cibex (Pvt.) Ltd, Karachi.**

Registration Board, in its 248th meeting considered the request of M/s Cibex (Pvt.) Ltd Plot No. F-405, S.I.T.E, Karachi wherein it was informed by the firm that have developed their facility for manufacturing of Tablet (General), Capsule (General), Sachet (General), Tablet (General Antibiotics), Liquid Manufacturing, Capsule (General Antibiotics), Dry Syrup (General Antibiotics), Ointment-I (Steriods) and Ointment-II (Non Steriods) located at Plot No. F-405, S.I.T.E, Karachi vide Drug Manufacturing License No.000784.

The firm has requested for transfer of their following registered drugs from M/s Macter International Ltd, Karachi to their name as per following details: -

| Sr. No. | Reg. No. | Brand Name(s) | Formulation / Generic Name | Date of Registration | Remarks |
|---|---|---|---|---|---|
| 1. | 027108 | Famobex Suspension | Each 5ml contains:- Famotidine….10mg | 13-06-2001 | The applied formulation is not approved in SRA's |
| 2. | 039198 | Catafen Tablets 100mg | Each sugar coated tablet contains:- Diclofenac Potassium…….100mg | 26-05-2005 | Formalities required as per Form -5 are complete |

Registration Board in its 248th meeting approved the product at Sr.No.2 and deferred the product at Sr.No.1 for review of formulation.

For product at Sr.No.1 the firm has submitted that the same formulation is freely available, manufactured and marketed by multiple firms in Pakistan. These products are old registered products and were registered prior from the implementation of SRA regime. DRAP has not taken any action to withdraw this product from the market or stop its manufacturing. DRAP has also awarded price increase for same product (Al-Famot) to Ali Industries vide SRO 908(I)/2017 dated 07-09-2017, which demonstrate DRAP's intention to patronize selected companies which unfortunately is discriminating. W.r.t. product at Sr.No.2, the firm has stated that multiple companies are still manufacturing the 75mg and 100mg strength of this molecule without any hindrance from DRAP. Therefore, non issuance of registration is unconstitutional and illegal. . They have requested to grant them registration of above products.

Furthermore, the firm has submitted that "if DRAP issues registration letters of above mentioned two products, we are ready to withdraw the suit (CP Suit No.1545/2017, Cibex vs DRAP & others) filed by us against DRAP and also undertake to stop manufacturing and marketing these two products if other companies are compelled by DRAP to withdraw these products from market."

The case was deferred in 14th meeting of PRVC for deliberation in next meeting. Later on the case was reconsidered in 19th PRVC with following decision taken:

*Decision of 19th PRVC:*

*The Committee deferred the case for presentation before registration board in next meeting with complete background, record and updated status of WP No 1695/2017 filed in Islamabad High Court Islamabad by M/s. Quaper Pharma V/S Federation of Pakistan, in the case of Diclofenec Potassium 100 mg Tablets.*

**Background**

W.r.t above mentioned two formulations, the Registration Board has already taken following decisions:

| Sr. No. | Formulation | Ref. Meeting No. of Reg. Board | Decision/Remarks |
|---|---|---|---|
| 1. | Famotidine 10mg/5ml Suspension | M-250 | ***Remarks:*** ***Not approved by reference drug regulatory agencies. Internationally available formulation is dry powder for suspension in the strength of 40 mg/ 5 ml.*** ***(Ref: US FDA)*** **Decision:** i. Applicants shall revise their formulation as per innovator (new registration application with complete fee) within six months if manufacturing facility is approved by CLB. ii. For already registered drugs, same procedure as mentioned above (at Sr. No. i) shall be adopted. Otherwise show cause notice shall be issued for de-registration of registered drugs in this formulation. iii. All such application shall be processed on priority basis. |
| 2. | Diclofenac Potassium 75mg & 100mg | M-258 | **Decision:** Diclofenac Potassium is not registered in any reference country in dose more than 50mg, thus Registration Board decided to issue show cause notices to manufacturers of Diclofenac Potassium (75 and 100mg) for de-registration of these products. |

In this regard, manufactures of Diclofenac Potassium 75mg & 100mg Tablets have already been issued show cause notice including following firms:

| S. No | Reg. No. | Firm Name | Name of drug(s) & Composition |
|---|---|---|---|
| 1. | 021634 | M/s Global Pharmaceuticals, Plot no.204-205, Industrial Triangle, Kahuta Road, Islamabad. | Artinil-K Tablets 75mg<br>Each tablet contains:<br>Diclofenac Potassium……..75mg |
| 2. | 066670 | M/s. Medizan Labs. (Pvt) Ltd. P.No. 313, Industrial Triangle Kahuta Road, Islamabad | Qrelif-75 Tablets<br>Each tablet contains:<br>Diclofenac Potassium…….75mg |
| 3. | 027876 | M/s. Valor Pharmaceuticals,<br>124/A Kahuta Road, Industrial Triangle Zone, Islamabad. | Vaclo-Pot Tablets<br>Each tablet contains:<br>Diclofenac Potassium…….75mg |
| 4. | 028340 | M/s. Robins Pharmaceuticals Industries, 43, Industrial Triangle, Kahutta Road, Islamabad | Dinak Tablets<br>Each tablet contains:<br>Diclofenac Potassium…….75mg |
| 5. | 031800 | Technovision Pharmaceuticals<br>295-Industrial Triangle, Kahuta Road. | Ketagesic-75 Tablets<br>Each tablet contains:<br>Diclofenac Potassium…….75mg |
| 6. | 037415 | Makson Pharmaceuticals<br>Plot No.80-B, Street No.6I-10/3, Industrial Area Islamabad | Makaid-K 75Mg Tablets<br>Each tablet contains:<br>Diclofenac Potassium…….75mg |
| 7. | 056845 | Webros Pharmaceuticals, Plot# 1, Street# 10, RCCI Industrial Estate, Rawat, Islamabad | Deltaflam Tablets 75mg.<br>Each Tablet Contains :-<br>Diclofenac Potassium.....75mg. |
| 8. | 038437 | Pearl Pharmaceuticals, Plot No.204, Street No.1, I-10/3, Islamabad | Phlodic-K<br>Each Tablet Contains :-<br>Diclofenac Potassium.....75mg. |
| 9. | 024333 | Candid Pharmaceutical, Opposite Pasrur Suagr Mills Sialkot Road, Pasru | Kalfen Tablets<br>Each tablet contains:-<br>Diclofenac Potassium.....75mg |
| 10. | 047860 | M/s. Wise Pharmaceuticals, Plot no.3-A, S-1, RCCI Industrial Estate, Rawat, Islamabad. | Achex-75mg Tablets<br>Each film coated tablet contains:<br>Diclofenac Potassium.....75mg |

| | | | |
|---|---|---|---|
| 11. | 049385 | M/s shawan Pharmaceuticals, Plot no.37, road NS-1, National Industrial Zone Rawat Islamabad | Lofen Tablets<br>Each tablet contains:<br>Diclofenac Potassium.....75mg |
| 12. | 043655 | Miracle Pharmaceuticals (Pvt.) Ltd. Pharmaceuticals (Pvt) Ltd | Marinac-P 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 13. | 043987 | M/s Neomedix Pharmaceuticals, Islamabad | Neofenik- 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 14. | 037574 | M/s Vision Pharmaceuticals, Islamabad | Deflam 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 15. | 038553 | M/s Glitz Pharmaceuticals, Islamabad | Glif-K 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 16. | 050019 | M/s Caraway Pharmaceuticals, Islamabad | Carafenac-P 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 17. | 050107 | M/s Harrison Pharmaceuticals, Islamabad | Diclokam-K 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 18. | 050953 | M/s Leads Pharma, Islamabad | Diclosoft-K 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 19. | 052552 | M/s Panacea Pharmaceuticals, Islamabad | Tasilex 75 Tablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |
| 20. | 052727 | M/s Paramount Pharmaceuticals, Islamabad | Ronset SRTablets<br>Each tablet contains:-<br>Diclofenac Potassium ..... 75mg |

**Status of WP No 1695/2017**

*M/s. Quaper Pharmaceuticals (Pvt) Limited, Sargodha has filed a Writ Petition in Islamabad High Court Islamabad v/s Federation of Pakistan, Drugs Registration Board etc against issuance of show cause notice in the case of Diclofenec Potassium 75mg Tablets. The case was heard on 30-05-2017and adjourned.*

**Decision: Registration Board decided that all registration holders of "Diclofenac Potassium 75mg & 100mg" shall be called for personal hearing.**

**Case No.2: Request of M/s Pfizer Pakistan Limited, Karachi for Change in Registration Status of Products Registered in The Name of M/s. ICI Pakistan Limited, Karachi.**

M/s Pfizer Pakistan ltd. has applied for cancellation of registration of below mentioned products from M/s ICI Pakistan Ltd, Karachi and grant of registration to M/s Pfizer Pakistan Limited, Karachi with following changes:

1. Change of registration status from finished import to bulk import & inclusion of secondary Packaging site.
2. Change of primary packaging (vial filling) & release site.
3. Extension in shelf life from 36 months to 48 months.

Details are as under:

| S. No | Name of Drug and Composition | Initial Date of Reg./Renewal Status | i. Existing Registration Holder<br>ii. Manufacturing & Packaging sites<br>iii. Shelf life | i. Proposed Registration Holder<br>ii. Manufacturing & Packaging sites<br>iii. Shelf life. |
|---|---|---|---|---|
| 1. | Meronem IM/IV 500mg Injection<br>Each vial contains:<br>Meropenem Trihydrate (Anhydrous) eq. to…500mg<br><br>(Fee deposited Rs.100,000/-)<br>**(Reg.No. 018543)** | 04-01-1996<br>Last renewal applied on 07-08-2015 | i. ICI Pakistan Limited<br>ii. ACS Dobfar SpA Viale Addetta, 4/12, I-20067 TRIBIANO, Milan, Italy<br>iii. 36 months | i. Pfizer Pakistan Limited<br>ii. Manufactured by:<br>**ACS Dobfar S.P.A**<br>Viale Addetta, 4/12, I-20067 TRIBIANO, Milan, Italy<br>Primary Packaging (Via Filling) by:<br>**Zambon Switzerland Limited** Via Industria, N.13, Cadempino, 6814, Switzerland.<br>Import & Secondary Packaging By:<br>**Pfizer Pakistan Limited** B-2,S.I.T.E., Karachi, Pakistan (DML No.000025).<br>iii. 48 months |
| 2. | Meronem IV 1g Injection<br>Each vial contains:<br>Meropenem Trihydrate (Anhydrous) eq. to …1g<br>(Fee deposited Rs.100,000/-)<br>**(Reg.No. 018548)** | 04-01-1996<br>Last renewal applied on 07-08-2015 | i. ICI Pakistan Limited<br>ii. ACS Dobfar SpA Viale Addetta, 4/12, I-20067 TRIBIANO, Milan, Italy<br>iii. 36 months | i. Pfizer Pakistan Limited<br>ii. Manufactured by:<br>**ACS Dobfar S.P.A**<br>Viale Addetta, 4/12, I-20067 TRIBIANO, Milan, Italy<br>Primary Packaging (Via Filling) by:<br>**Zambon Switzerland Limited** Via Industria, N.13, Cadempino, 6814, Switzerland.<br>Import & Secondary Packaging By:<br>**Pfizer Pakistan Limited** B-2,S.I.T.E., Karachi, Pakistan (DML No.000025).<br>iii. 48 months |
| Information as per legalized CoPP (No.PP10151938, Certified by MHRA) | | | | |
| Product License Holder:<br>M/s. Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom | | Manufacturer:<br>ACS Dobfar S.P.A, Viale Addetta, 4/12, TRIBIANO, Milan, I-20067, Italy | | Packaging Site:<br>Zambon Switzerland Limited Via Industria, N.13, Cadempino, 6814, Switzerland. |

Detail of documents submitted by the firm:

1. Application on Form 5-A with fee of Rs.200,000/-.
2. Copies of initial letter of registration & last renewal status.
3. Authority letter from Pfizer UK to Pfizer Pakistan.
4. NOC from ICI Pakistan Limited (existing registration holder) dated 01-01-2019.
5. Original and legalized CoPP (certified by UK MHRA and stating free sale in exporting country), detailing ACS Dobfar S.P.A, Italy as manufacturing site & Zambon Switzerland Limited, Switzerland as primary packaging site. As per CoPP, route of administration for product at S.No.1 is **"IV"**
6. Real time Stability Studies upto 48 months. (Chromatograms not provided)
7. Legalized GMP certificates and License of manufacturing site.
8. Legalized GMP certificates and License of primary packaging site (License is valid upto 10-03-2018).
9. Undertakings in the light of M-283 of Reg. Bd.

The firm has further informed regarding a distribution agreement between ICI Pakistan Limited, 5 West Wharf, Karachi, Pakistan and AstraZeneca UK Limited, United Kingdom whereby ICI Pakistan Limited had been authorized to import and distribute various products, including the

above mentioned products, of AstraZeneca in the territory of Pakistan. Later on, Astra Zeneca AB (a company incorporated in Sweden) and AstraZeneca Holdings France SAS (a company incorporated in France) divested their rights to market and sell their product to Pfizer Ireland Pharmaceuticals.

As per evaluation of the dossier/documents submitted by the firm, certain clarifications were sought from the firm. Detail of queries along with firm's response has been placed below:

| Sr. No. | Queries | Response/ Documents Provided By M/S Pfizer, Karachi |
|---|---|---|
| 1. | Document confirming declaration by M/s AstraZeneca regarding divestment of rights in favor of M/s Pfizer, Ireland. | Copy of document confirming delegation of authority (DOA) in favor of M/s Pfizer, issued by Astra Zeneca has been provided. |
| 2. | Clarification regarding provided CoPP, being issued by Pfizer UK whereas the product license holder is Pfizer Ireland Pharmaceuticals as per information provided. Furthermore, if the product is not in free sale in Ireland, provide reasons for the same. | • Pfizer Ireland is only the legal entity that entered into transaction with AstraZeneca on behalf of Pfizer Inc. (Pfizer Group) to acquire the Meronem assets, on global basis.<br>• Whereas, Pfizer UK is the Marketing Authorization/ License holder for Meronem in country of origin and same has been reflected from submitted CoPP.<br>• Copy of letter of authorization from Pfizer UK (authorizing Pfizer Pakistan to submit an application for transfer of registration of Meropenem from M/s ICI to M/s Pfizer) has been provided.<br>• Declaration Letter (along with list of subsidiaries) from Pfizer Inc. (Pfizer Group) has been provided. |
| 3. | CoPP from Pfizer Ireland Pharmaceuticals confirming product license holder. | Same as above. |
| 4. | Clarification regarding secondary packaging site as the firm has only submitted Drug sale license by way of wholesale issued in the name of M/s Pfizer Pakistan Limited, Karachi. | Pfizer Pakistan Limited shall be the secondary packaging site.<br>Copy of DML (No.000025) in the name of Pfizer Pakistan Limited B-2,S.I.T.E., Karachi, Pakistan has been provided. |

RRR Section has communicated that renewal application of the year 2016 received within time. The firm has now requested to consider their request w.r.t change in registration status and addition of primary and secondary sites whereas separate application will be filed for extension in shelf life.

The case was deferred in M-287 as per following details:

*Decision of M-287:*

*The Registration Board deliberated on the matter and deferred the case for submission of following information/documents by the firm:*

i. *Clarification/ details of facilities & protocols for QC release of the finished product.*
ii. *Valid and legalized license of primary packaging site since present authorization as per Swissmedic is valid till 10-03-2018.*

W.r.t the above mentioned decision the firm has now provided Valid and legalized license of primary packaging site i.e valid upto 10-03-2023 along with following information:

**Handling & QC Release Procedure:**

1. Import bulk consignments are receipt at site.
2. Receiving store officer verifies the quantity against invoice.
3. Receiving store officer enters the quantity, manufacturing date and Expiry date in El, which is mentioned on COA/ invoice and generate Inventory receipt report (IRR).

4. Receiving store officer submit IRR to quality representative with relevant documents (COA, Form7 and invoice).
5. Quality representative examined the consignment physically and verified the parent label information's from COA and Form7 during inspection and perform sampling according to SOP- 102789 (Inspection and sampling of Import and local bulk products).
6. After Inspection and sampling, Quality representative change the status of lots in E1 from quarantine to approve on physical basis.
7. Planning Manager creates work order and allocates the quantity in batch for packing in H.
8. Batch packaging document is issued by QA to packaging department.
9. Packaging manager arrange the bulk product in bulk packaging area for secondary packing.
10. QA representative perform in process inspection of packaging and verifies carton information (Art work, price, manufacturing date and expiry date).
11. After completion of bulk packaging, QA representative perform sampling for inspection and retain quantity as reference sample.
12. QA representative release batch in system H after complete audit of batch packaging documents and information received from manufacture.

Furthermore, the firm has submitted Last GMP Inspection report dated 26-06-2018 with following remarks regarding QC Lab:

"The area is found neat & clean. QC Lab is equipped with all instruments required to perform testing of raw materials, packaging materials and products. The QC lab of the firm is organized in four sections i.e. Analytical Lab, Instrument Section, Microbiology Lab and Packaging Lab. The Instrument section is equipped with 10 HPLC units and 02 UV Spectrophotometers. The firm has also Gas Chromatograph for impurities testing of materials and products. The firm is also using Atomic Absorption Spectrophotometer for the analysis of minerals. Total Organic Carbon Analyzer is used for purified water testing. Fourier Transform Infrared Spectrophotometer is used for the identification of materials. Different pharmacopoeias are available in the lab for reference. The firm's Product Development is equipped with 04 stability chambers to carry out stability studies for products. The firm has separate Microbiology Lab and equipped with all required instruments like autoclaves, biological safety cabinets and incubators. Packaging Laboratory is maintaining all approved artworks for all products and perform testing on all incoming packaging materials. Specifications and test method for all materials and products found in-place and testing is performed as per defined testing requirements. Laboratory data handling and documentation found satisfactory and well organized. The sanitary condition and cleanliness were found good."

**Decision: Registration Board decided as follows:**

i. **Cancellation of registration of products at S. No.1 & 2 from the name of M/s. ICI Pakistan Limited, Karachi.**

ii. **Approved registration of products at S.No.1 & 2 in the name of Pfizer Pakistan Limited B-2, S.I.T.E., Karachi, Pakistan (DML No.000025) as per following details:**

| Product License Holder | Manufacturer of Product | Primary Packaging Site (Vial Filling & Primary labelling) | Bulk Import & Secondary Packaging Site (Responsible for QC testing & Batch release of product) |
|---|---|---|---|
| M/s. Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom | ACS Dobfar S.P.A, Viale Addetta, 4/12, TRIBIANO, Milan, I-20067, Italy | Zambon Switzerland Limited Via Industria, N.13, Cadempino, 6814, Switzerland. | Pfizer Pakistan Limited B-2, S.I.T.E., Karachi, Pakistan (DML No.000025). |

iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.3: Verification of Authentication of Stability Data Submitted For Xenase Nasal Spray of M/s Sante (Pvt) Ltd., Karachi.**

Registration Board in its 243rd meeting deferred registration of following products of M/s Sante (Pvt) Ltd., Karachi and decided as recorded in last column.

| | | | | | |
|---|---|---|---|---|---|
| Ear/Nasal drops (General) section vide letter no F.2-12/2006-lic dated 25-02-2011 | Xenase Nasal Spray Each100 micro liter contains: Olopatadine hydrochloride…… ……..665mcg equivalent to 0.6% (600mcg) of base. (Anti Allergic) | Rs.800/15ml Plastic Bottle | 1.Form-5D 2. 23-11-2011 Dy.No.379 Rs.15000/- 3. 08-04-2013 Rs.35,000/- | 1. PATANASE (ALCON PHARMS LTD) SPRAY, METERED;NASAL OLOPATADINE HYDROCHLORIDE 0.665MG/SPRAY (FDA) 2.Acceptable level of GMP (09.05.13) | Deferred for (i) expert opinion (ii) Product Specific Inspection for manufacturing facility. |

According to the decision of 243rd meeting of Registration Board the Product Specific Inspection of premises was conducted by Director DTL (Mr. Abdul Razzaq Jawinda) and Area FID (Syed Hakim Masood) on 16th April, 2015. The panel was of the view to recommend Registration of Xenase Nasal Spray (Olopatadine HCl 0.6% w/v) to the firm subject to the approval of Competent Authority. Regarding expert opinion since product is FDA approved there is no need to take opinion as per M-250 decision of Registration Board.

Registration Board in its 256th meeting approved the request of the firm for grant of registration of above product i.e. Xenase Nasal Spray.

At the time of issuance of registration letter it was observed that the product is new molecule and registration letter was not issued. The firm was asked to provide stability studies as per decision of the Registration Board. Later on, the firm provided stability studies and the case was reconsidered in M-286 with following decision:

*Decision of M-286: Registration Board deferred the case for onsite investigation to confirm genuineness/ authenticity of stability data and associated documents submitted by the firm. The Board further advised that the panel shall be constituted without waiting for confirmation/ finalization of minutes of 286th meeting.*

In line with the decision of M-286, a panel comprising of following members was constituted:

i. Dr. Ghulam Sarwar, Member Registration Board
ii. Mr. Affan Qureshi, Assistant Director, CDL, Karachi
iii. Area FID

**Report on Investigation of Authenticity / Genuineness of data submitted for registration of Xenase (Olopatadine) 0.6% w/v Nasal Spray by M/s. Sante Pharma Pvt. Ltd., Karachi.**

**Reference No:** F.3-9/2018-Reg-II (M-286) (Misc) dated 21st December, 2018.
**Investigation Date and Time:** 28th December, 2018 (Afternoon).
**Investigation Site:** Factory premises of M/s. Sante Pharma, Karachi.

**Background:**

Chairman Registration Board considered the applications of M/s Sante Pharma, Karachi for registration of Xenase (Olopatadine) 0.6% w/v Nasal Spray and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

**Composition of Panel:**

1. Prof Ghulam Sarwar, Dean Faculty of Pharmacy, Jinnah University for Women (Member Registration Board)
2. Mr. Abdul Rasool Shaikh, Area FID, DRAP, Karachi.
3. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

**Scope of investigation:**

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

**Tools for Investigation:**

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

## Xenase (Olopatadine) Nasal Spray

| Sr. No. | Question | Observation by panel |
|---|---|---|
| 1 | Do you have documents confirming the import of API ? | The firm has imported Olopatadine 1kg batch # V0673/0 15030 vide invoice # 20151730 dated 23-12-2015 and obtained approval from DRAP Karachi |
| 2 | What was the rationale behind selecting the particular manufacturers of APIs? | There is proper vendor qualification being implemented by the firm which include a desktop audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF and stability data etc.<br>The manufacturer was evaluated on above mentioned criteria. The same source is being used in another registered eye preparation as well. |
| 3 | Do you have documents confirming the import of API reference standard and impurity standards? | The firm has documents confirming the import of API USP reference standard and impurity standards. |
| 4 | Do you have certificate of Analysis of the API, reference standards and impurity standards? | The firm has certificates of analysis for API, USP reference standard and their impurities. |
| 5 | Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin? | The firm has GMP certificate of Olopatadine Manufacturer M/s Crystal Pharma, Spain issued by Spanish Agency of Medicine and Sanitary Products (AEMPS). |
| 6 | Do you use API manufacturer method of testing? | The firm has used USP method of testing for API. |
| 7 | Do you have stability studies reports on API? | The firm has accelerated stability studies reports of six months and five years real time stability studies reports on Olopatadine. |
| 8 | If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified? | The stability testing has been performed as per SIM method and degradation products have been quantified. |
| 9 | Do you have method for quantifying the impurities in the API? | The firm has USP method for quantifying the impurities in the API. |
| 10 | Do you have some remaining quantities of the API, its reference standard and impurities standards? | The firm has remaining quantities of API and reference standard of API. |

<table>
<tr><th>Sr. No.</th><th>Question</th><th>Observation by panel</th></tr>
<tr><td>11</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used pharmaceutical grade excipients.</td></tr>
<tr><td>12</td><td>Do you have documents confirming the import of the used excipients?</td><td>The firm has documents confirming the procurement of all excipients used.</td></tr>
<tr><td>13</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has test reports and other records on the excipients used.</td></tr>
<tr><td>14</td><td>Do you have written and authorized protocols for the development of API nasal solution?</td><td>The firm has written and authorized protocols for the product development.</td></tr>
<tr><td>15</td><td>Have you performed Drug-excipient compatibility studies?</td><td>Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator “Patanase” manufactured by Alcon Laboratories USA.</td></tr>
<tr><td>16</td><td>Have you performed comparative dissolution studies?</td><td>N/A</td></tr>
<tr><td>17</td><td>Do you have product development (R&D) section</td><td>The firm has R&D section which include facilities for manufacturing.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment available in product development section for development of API Nasal Spray?</td><td>The firm has necessary equipment for product development of API Nasal Spray. The product in question has been developed while using some equipment of commercial manufacturing also. Furthermore, the analytical part has been performed via the routine quality control equipment. Firm has already placed orders for procurement of other equipment for this section.</td></tr>
<tr><td>19</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has SOP for the maintenance/calibration/requalification of equipment used on PD section.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff which include One Chemist and Two Pharmacists in product development section with relevant work experience.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of API nasal solution as required?</td><td>The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Xenase Nasal Spray packed in LDPE bottles of 15ml each.
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg Date</td></tr>
<tr><td>03T</td><td>1000ml</td><td>05-2016</td></tr>
<tr><td>04T</td><td>1000ml</td><td>09-2016</td></tr>
<tr><td>05T</td><td>1000ml</td><td>09-2016</td></tr>
</table></td></tr>
<tr><td>23</td><td>What was the criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of bottles per testing and the number of bottles required for whole stability testing.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. Necessary log books of equipment used has been available with the firm.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocol for stability testing of stability batches in which the stability conditions are:<br>Real Time: 30°C and 65% RH<br>Accelerated: 40°C and 75% RH,</td></tr>
</table>

| Sr. No. | Question | Observation by panel |
|---|---|---|
| | | however, the firm has used LDPE container for the product in question for which ICH guidelines and WHO recommends 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies. |
| 26 | Do you have developed and validated the method for testing of stability batches? | The firm has developed and validated their own method for testing of stability batches in light of USP method for Ophthalmic Solution. The method is supported by impurities standards spiking studies, forced degradation, hence capable of quantifying the degradation products in their nasal spray. |
| 27 | Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab? | Not Applicable |
| 28 | Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug? | The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug. |
| 29 | Do your method of analysis stability indicating? | The firm's method of analytical testing has stability indicating parameters. |
| 30 | Do your HPLC software is 21CFR compliant? | The HPLC software is 21CFR Compliant as per record available with the firm. |
| 31 | Can you show Audit Trail reports on API testing? | The firm showed the audit trail reports on API testing. |
| 32 | Do you have some remaining quantities of degradation products and stability batches? | The firm has completed both accelerated and real time stability studies however a few bottles were available with the firm. |
| 33 | Do you have commitment batches kept on stability testing? | The firm has completed both accelerated and real time stability studies |
| 34 | Do you have valid calibration status for the equipment used in API nasal solutions production in analysis? | The firm has valid calibration status for the equipment used in Xenase Nasal Spray production and analysis. |
| 35 | Do proper and continuous monitoring and control are available for stability chamber? | Continuous power supply and monitoring are available for stability chambers. |
| 36 | Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant? | The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant. |

**Discussion:**

1. On the basis of risk-based approach the genuineness / authenticity of stability data, associated documents, import of API, quality, specification, test analysis, facilities as submitted by the firm for registration of Xenase (Olopatadine) 0.6% Nasal Spray is verifiable to satisfactory level.
2. Furthermore, the firm has conducted the stability studies as per their protocol which is 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies, whereas, the recommended stability conditions for products packed in semi-permeable containers are 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies. However, 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies may be used for semi-permeable containers provided the

calculated water loss multiplied with the corresponding factor may not exceed 5% of initial, which is considered as significant change.

3. In this case the firm has not calculated water loss at any stage, so no comparison can be made between the reference and alternative relative humidity as mentioned in ICH Q1A (R2) (2.2.7.3. Drug products packaged in semi-permeable containers).
4. On risk-based approach the data evaluated during inspection does not show any deviation in the critical tests throughout the study period which may be altered if the water has lost more than the prescribed limits.
5. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Xenase (Olopatadine) 0.6% Nasal Spray.

**Recommendations:**

The firm may be granted necessary registration of Xenase (Olopatadine) 0.6% Nasal Spray in their name with the direction to conduct stability studies on their commitment batches as per ICH guidelines i.e. 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies and submit the data to the Drug Registration Board.

***Decision of M-286:*** *Registration Board deferred the case for submission of stability data at next time point of long term stability studies along with assessment of water loss rate for applied container closure system as per ICH Q1A (R2) guidelines for "Stability Testing of New Drug Substance and Products."*

In line with the above mentioned decision, the firm has now submitted following information:

**General Study of Water loss**
**on Semi permiable Packaging material (LDPE)**
**Product : Xenase Nasal Spray**
**Batch No. 07T**
**Storage condition 40°C / 75% RH**

(1st Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 07-01-2019 | I-F | Diff * 3 |
| 1 | 24.7534 | 24.7445 | 0.0089 | 0.0267 |
| 2 | 25.3129 | 25.3089 | 0.0040 | 0.0120 |
| 3 | 25.1638 | 25.1461 | 0.0177 | 0.0531 |
| 4 | 25.3596 | 25.3501 | 0.0095 | 0.0285 |
| 5 | 25.5955 | 25.5905 | 0.0050 | 0.0150 |

(2nd Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 14-01-2019 | I-F | Diff * 3 |
| 1 | 24.7534 | 24.7432 | 0.0102 | 0.0306 |
| 2 | 25.3129 | 25.3047 | 0.0082 | 0.0246 |
| 3 | 25.1638 | 25.1253 | 0.0385 | 0.1155 |
| 4 | 25.3596 | 25.3447 | 0.0149 | 0.0447 |
| 5 | 25.5955 | 25.5875 | 0.0080 | 0.0240 |

(3rd Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 21-01-2019 | I-F | Diff * 3 |
| 1 | 24.7534 | 24.7414 | 0.0120 | 0.0360 |

| | | | | |
|---|---|---|---|---|
| 2 | 25.3129 | 25.2948 | 0.0181 | 0.0543 |
| 3 | 25.1638 | 25.0919 | 0.0719 | 0.2157 |
| 4 | 25.3596 | 25.3404 | 0.0192 | 0.0576 |
| 5 | 25.5955 | 25.5813 | 0.0142 | 0.0426 |

(4th Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 28-01-2019 | I-F | Diff * 3 |
| 1 | 24.7534 | 24.7398 | 0.0136 | 0.0408 |
| 2 | 25.3129 | 25.2858 | 0.0271 | 0.0813 |
| 3 | 25.1638 | 25.0658 | 0.0980 | 0.2940 |
| 4 | 25.3596 | 25.3359 | 0.0237 | 0.0711 |
| 5 | 25.5955 | 25.5723 | 0.0232 | 0.0696 |

**Storage condition 30°C / 65% RH**

(1st Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 07-01-2019 | I-F | Diff * 3 |
| 1 | 25.1325 | 25.1306 | 0.0019 | 0.0057 |
| 2 | 23.7190 | 23.7164 | 0.0026 | 0.0078 |
| 3 | 25.4003 | 25.3968 | 0.0035 | 0.0105 |
| 4 | 25.5157 | 25.5146 | 0.0011 | 0.0033 |
| 5 | 25.8982 | 25.8977 | 0.0005 | 0.0015 |

(2nd Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 14-01-2019 | I-F | Diff * 3 |
| 1 | 25.1325 | 25.1283 | 0.0042 | 0.0126 |
| 2 | 23.7190 | 23.7135 | 0.0055 | 0.0165 |
| 3 | 25.4003 | 25.3923 | 0.0080 | 0.0240 |
| 4 | 25.5157 | 25.5142 | 0.0015 | 0.0045 |
| 5 | 25.8982 | 25.8974 | 0.0008 | 0.0024 |

(3rd Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 21-01-2019 | I-F | Diff * 3 |
| 1 | 25.1325 | 25.1199 | 0.0126 | 0.0378 |
| 2 | 23.7190 | 23.7051 | 0.0139 | 0.0417 |
| 3 | 25.4003 | 25.3821 | 0.0182 | 0.0546 |
| 4 | 25.5157 | 25.5131 | 0.0026 | 0.0078 |
| 5 | 25.8982 | 25.8920 | 0.0062 | 0.0186 |

(4th Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 28-01-2019 | I-F | Diff * 3 |
| 1 | 25.1325 | 25.1135 | 0.0190 | 0.0570 |
| 2 | 23.7190 | 23.6986 | 0.0204 | 0.0612 |
| 3 | 25.4003 | 25.3736 | 0.0267 | 0.0801 |
| 4 | 25.5157 | 25.5122 | 0.0035 | 0.0105 |
| 5 | 25.8982 | 25.8868 | 0.0114 | 0.0342 |

**Storage condition 30°C / 65% RH**

(1st Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 07-01-2019 | I-F | Diff * 1.9 |
| 1 | 25.1325 | 25.1306 | 0.0019 | 0.00361 |
| 2 | 23.7190 | 23.7164 | 0.0026 | 0.00494 |
| 3 | 25.4003 | 25.3968 | 0.0035 | 0.00665 |
| 4 | 25.5157 | 25.5146 | 0.0011 | 0.00209 |
| 5 | 25.8982 | 25.8977 | 0.0005 | 0.00095 |

(2nd Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 14-01-2019 | I-F | Diff * 1.9 |
| 1 | 25.1325 | 25.1283 | 0.0042 | 0.00798 |
| 2 | 23.7190 | 23.7135 | 0.0055 | 0.01045 |
| 3 | 25.4003 | 25.3923 | 0.0080 | 0.0152 |
| 4 | 25.5157 | 25.5142 | 0.0015 | 0.00285 |
| 5 | 25.8982 | 25.8974 | 0.0008 | 0.00152 |

(3rd Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 21-01-2019 | I-F | Diff * 1.9 |
| 1 | 25.1325 | 25.1199 | 0.0126 | 0.02394 |
| 2 | 23.7190 | 23.7051 | 0.0139 | 0.02641 |
| 3 | 25.4003 | 25.3821 | 0.0182 | 0.03458 |
| 4 | 25.5157 | 25.5131 | 0.0026 | 0.00494 |
| 5 | 25.8982 | 25.8920 | 0.0062 | 0.01178 |

(4th Interval)

| Bottle No. | Initial wt. (I) gm | Final Wt (F) gm | **Difference (gm)** | **Ratio** |
|---|---|---|---|---|
| | Date : 31-12-2018 | Date : 28-01-2019 | I-F | Diff * 1.9 |
| 1 | 25.1325 | 25.1135 | 0.0190 | 0.0361 |
| 2 | 23.7190 | 23.6986 | 0.0204 | 0.0388 |
| 3 | 25.4003 | 25.3736 | 0.0267 | 0.0507 |
| 4 | 25.5157 | 25.5122 | 0.0035 | 0.0066 |
| 5 | 25.8982 | 25.8868 | 0.0114 | 0.0217 |

**Detail of Supporting Documents Provided by the Firm/Observations:**

- As protocol & testing method, the firm has only provided ICH guidelines for stability testing of drug products packaged in Semi-Permeable containers.
- The firm has submitted water loss test results on Real Time storage conditions by multiplying with following 2 different ratios (i.e., Ratio of water loss rates at a given temperature as per ICH guidelines)

"3" (initially)

"1.9" (after clarification sought in the light of ICH guidelines).

- As per ICH guidelines:

**"**A 5% loss in water **from its initial value** is considered a significant change for a product packaged in a semi-permeable container **after an equivalent of 3 months' storage** at 40°C/NMT 25% RH. However, for small containers (1 mL or less) or unit-dose products, a water loss of 5% or more after an equivalent of 3 months' storage at 40°C/NMT 25% RH may be appropriate, if justified".

**Decision:** **Registration Board deliberated the case in the light of ICH Q1A (R2) guidelines for "Stability Testing of New Drug Substance and Products" and decided that the firm shall be directed to submit following information/documents:**

i. **Data to demonstrate that the drug product will not have significant water loss (i.e., 5% loss in water from its initial value) after an equivalent of 3 months' storage.**
ii. **Data to demonstrate linear water loss rate at the alternative relative humidity over the storage period.**

**Item No.IV: Registration-II Section**

**Case No.04: APPEAL FOR RESTORATION OF DRUGS REGISTRATION OF M/S PHARMAWISE Labs, (PVT) LTD, LAHORE.**

The Drug Manufacturing License of M/s PharmaWise Labs, Lahore was cancelled by the Central Licensing Board in its 256th meeting communicated vide letter No.F. 8-5/2017-QA (M-256-CLB) (Pt) dated 03-01-2018. Consequently, **Registration Board in its 280th Meeting held on 15-03-2018 deliberated the matter and decided to cancel the registration of all drugs product registered in the name of M/s PharmaWise Labs, Lahore (DML 000182).**

M/s PharmaWise Labs, Lahore filed an appeal before the Appellate Board against the decision of Central Licensing Board which was considered in 150th & 151st meeting of Appellate Board. The Appellate Board in its 151st meeting held on 16-01-2019 allowed the appeal of the firm. The proceedings of 151st meeting of Appellate Board is as under:-

> "In compliance of decision of the Appellate board in its 150th meeting, the inspection of M/s PharmaWise Labs, (Pvt.) Ltd, Lahore was conducted by the panel on 13-08-2018 and 29-10-2018. The inspection report was received in the secretariat on 17-12-2018. Considering the recommendation of the panel, the Board allowed the appeal and resumed production activities in the following sections, with immediate effect:
>
> i. Oral Liquid section (Syrup/ Suspension)
> ii. Antiseptic External Preparation Section
> iii. Cream / Ointment section
> iv. General Tablet section
>
> The Resumption of production activities in the following sections is allowed subject to installation of 400KVA transformer. The installation and operation of transformer are to be verified by the panel comprising of Dr. Shahid Nasir (Expert member, Appellate Board) and Mr. Asim Rauf (Additional Director E&M), DRAP Lahore):
>
> *i. Sachet section*
> *ii. Repacking section*
> *iii. Capsule section*
> *iv. General Antibiotic Tablet section*
> *v. General Antibiotic Dry powder Suspension*
> *vi. Steroid Section*
>
> The Board did not allow resumption of production activities in Penicillin area."

Now, the firm has requested for restoration of the drug registrations pertaining to above-mentioned four sections in the light of the decision of Appellate Board.

In this regard, Legal Affairs Division, DRAP was requested to furnish legal opinion on subject matter. Legal Affairs Division was also requested to opined on that whether application along with fee is require for restoration of registration or otherwise. The reply of Legal Affairs Division is reproduced as under:-

> ***"Opinion rendered by the Legal Affairs Division in the matter of M/s PharmaWise Labs.(Pvt.) Limited, Lahore.***

*It is submitted that the Drug Manufacturing License (No. 000182) of M/s PharmaWise Labs. (Pvt.) Limited, Lahore was cancelled by the Central Licensing Board (CLB) in its 256th meeting. The decision of the CLB was communicated to the firm on 03.01.2018. Being aggrieved, the firm filed appeal before the Appellate Board on 16.01.2018. The Appellate Board, in its 150th meeting held on 04.04.2018, set-aside the decision of the CLB and constituted a panel for inspection of the firm. It was further decided that the production activities of the firm shall remain suspended till decision of the Appellate Board after considering the panel inspection report. Meanwhile, the Registration Board, in its 280th meeting held on 15.03.2018, cancelled the registration of all drug products registered in the name of the firm. Thereafter, the Appellate Board, in its 151st meeting held on 16.01.2019, considered the recommendations of the panel inspection report and decided to resume production activities in certain sections of the firm as reproduced in para 38/N.*

*Foregoing in view, it is proposed that the Registration Board may be requested to* ***recall*** *its earlier decision taken in 280th meeting held on 15.03.2018 as the appeal of the firm (dated 16.01.2018) was pending before the Appellate Board at the time the Registration Board cancelled the registration of all drug products registered in the name of the firm. Moreover, the decision of CLB which formed basis of the decision of Registration Board was set-aside in 150th meeting of the Appellate Board held on 04.04.2018. In the circumstances, requiring application along with fee for restoration of registration of all drug products would be unreasonable.*

*It is further proposed that the Secretary, Registration Board may kindly confirm the status of appeals, if any, filed in the Secretariat of the Appellate Board before placing the matter of cancelling the drug product registration of any firm on agenda of the Registration Board when the Drug Manufacturing License of any pharmaceutical unit is cancelled by the CLB."*

Matter is submitted for the consideration of Board, please.

**Decision:** **In light of the decision of the Appellate Board and opinion of Legal Affair's Division on the matter, Registration Board deliberated the case and decided to revoke its earlier decision of 280th meeting regarding of M/s PharmaWise Labs, Lahore. The firm may resume production in accordance with the directions of the Appellate Board.**

**Item No.V: Post Registration-I Section**

**Case No.05: Change of Contract Manufacturer of Drug(s) of M/s. Swat Pharmaceuticals, Swat.**

***Previous Case History:***

**"Permission for transfer of contract manufacturing drug along with extension.**

The case of M/s. Swat Pharmaceuticals was discussed in 286th and 287th meeting of Registration Board, the details of whereof are again reproduced hereunder:-

| Sr. No. | Reg. No. | Name of Drug (s) & Composition | Previous Contract manufacturer | Current Contract manufacturer | M-286 decision |
|---|---|---|---|---|---|
| 1 | 029879 | Sanex Injections I.V.<br>Each vial contains:-<br>Ceftriaxone Sodium<br>Eq. to Ceftriaxone …..1gm | M/s. Welwrd Pharmaceuticals Hattar. | M/s EG Pharmaceuticals, Islamabad | Registration Board deferred the case for capacity assessment of M/s EG Pharmaceuticals, Islamabad. |
| 2 | 029880 | Sanex Injection IM<br>Each vial contains:-<br>Ceftriaxone Sodium<br>Eq. to Ceftriaxone..250mg | -do- | | |
| 3 | 029881 | Sanex 500 Injections IM<br>Each vial contains:-<br>Ceftriaxone Sodium<br>Eq. to Ceftriaxone.500mg | -do- | | |

Firm was granted extension in contract manufacturing permission in 250th Meeting of Drug Registration Board which is valid till 30-06-2020.

In this regard firm has submitted following documents: -

i) Application Form.
ii) Fee of Rs.50,000/- for each products vide Challan No.0726140 (Sanex 250mg), 0726139 (Sanex 1gm) and 0726141 (Sanex 500mg).
iii) Copy of Registration letter (250th Meeting).
iv) NOC for CRF Clearance.
v) Photocopy of Agreement between M/s. Sawat Pharmaceuticals and M/s. EG Pharmaceuticals.
vi) GMP inspection report of M/s. EG Pharmaceuticals (Valid Till 03.09.2019).

Moreover, the brand name which was granted to this firm (i.e. Sanex) resembles with already registered brand name Xanax (Reg.No.009822) of M/s. Kurram Chemical Company Kahuta Road, Islamabad.

In furtherance thereto a panel was constituted by Chairman Registration Board which conducted inspection of M/s. EG Pharmaceuticals on 03-12-2018 the panel inspection report endorses that the utilized manufacturing capacity of dry powder injection (Cephalosporin) Section is 22.51% while the available manufacturing capacity of this section of the said pharma is 77.49%.

**Decision of 287th Meeting:**

*"Registration Board discussed the inspection report on assessment and confirmation of manufacturing capacity of M/s EG Pharmaceuticals, Industrial Triangle, Kahuta Road, Islamabad in detail. Deliberations were made on used and available capacity keeping in view registered product, currently applied products. Further Board was apprised that firm has been using UV spectrophotometric methods for most of the products. After thorough deliberation, the Board decided to defer all applied products of contract manufacturing from M/s EG Pharmaceuticals, Islamabad. The Board further directed the M/s EG Pharmaceuticals, Islamabad to review existing methods for their already registered products in light of pharmacopoeal requirements and enhance its analytical capacity of Quality Control Laboratory accordingly."*

**In reference to Case No.: 08** (Miscellaneous cases: Report on assessment and confirmation of manufacturing capacity of M/s EG Pharmaceuticals, Industrial Triangle, Kahuta Road, Islamabad.), **Registration Board decided as under:**

**Decision:** **Registration Board approved the request of M/s. Swat Pharmaceuticals, Swat, for contract manufacturing by M/s EG Pharmaceuticals, Industrial Triangle, Kahuta Road, Islamabad for production of above mentioned three (03) products.**

**Item No.VI: Post Registration-II Section**

**Case No. 06: Transfer of Registered Products from Previous Site (I-10/3) to New Site (National Industrial Zone, Chamber Industrial Area, Rawat, Rawalpindi) of M/s. Benson Pharmaceuticals:**

M/s Benson Pharmaceuticals, Islamabad have requested for transfer of registration of below mentioned products form their previous site i.e. Plot No. 119, Street No.8, I-10/3, Islamabad to new site Plot No. 3, Main Road, National Industrial Zone (Chamber Industrial Area) Rawat, Rawalpindi as per detailed below:-

| S. No. | Product for Registration with Generic Name | Reg. No. | Initial registration date | Renewal Status | Remarks |
|---|---|---|---|---|---|
| 1. | Benifix capsules<br>Each capsule contains:-<br>Cefixime trihydrate eq to Cefixime…….……....400mg<br>(Manufacturer's specifications) | 030462 | 11-06-2003 | 22-3-2018 | The firm has claimed manufacturer's specifications while official monograph of applied formulation exists in JP. |
| 2. | Benkast tablet 10mg<br>Each film coated tablet contains:-<br>Montelukast sodium eq. to Montelukast…….10mg<br>(USP specifications) | 079511 | 23-10-2018 | 22-10-2023 | |
| 3. | Gaboben 50mg capsule<br>Each capsule contains:-<br>Pregabalin……..… 50mg | 087386 | 19-02-2018 | 18-02-2023 | The official monograph of the applied formulation does not exist in any pharmacopoeia. |
| 4. | Unitrate-20 tablets<br>Each tablet contains:-<br>Isosorbide-mononitrate..... 20mg<br>(USP specifications) | 021584 | 02-05-1998 | 22-03-2018 | |

The firm have provided following documents in support of their request as per approved SOP:

a) Application with form 5 and requirement fee amounting to Rs.20,000/-.
b) Copy of registration letter and renewal.
c) Evidence of Section as revealed by the GMP certificate (Tablet General, Capsule General, General Sachet powder, Dry Powder Suspension (Cephalosporin), Capsule Section (Cephalosporin)
d) DML of new site issued on 08-01-2019.
e) Copy of last inspection report: N/A as it is a new manufacturing facility.

**Decision: Registration Board acceded to the request of M/s Benson Pharmaceuticals, Islamabad for transfer of registration of their products from Plot No. 119, Street No.8, I-10/3, Islamabad to new site i.e. Plot No. 3, Main Road, National Industrial Zone (Chamber Industrial Area) Rawat, Rawalpindi and decided as follows:**

**i. Approved the product at sr. No. 1 with "JP specifications" and the product at Sr. No.3 with "as per innovator's specifications".**
**ii. Approved the products at sr. No. 2 and 4.**

**Case No.07: M/s. Danas Pharmaceuticals, Islamabad.**

M/s. Danas Pharmaceuticals, Islamabad has requested for correction of composition and specifications in Registration letter for following product.

| S. No | Reg. No. | Existing Name of Drug(s) & Composition | Desired corrections |
|---|---|---|---|
| 1. | 091941 | Danidol 500mg tablet\<br>Each **film coated** tablet contains:-<br>Paracetamol …….…….500mg<br>(USP Specification) | Danidol 500mg tablet\<br>Each tablet contains:-<br>Paracetamol …….500mg<br>(BP Specification) |

The firm has submitted following documents:

i. Original dossier attached
ii. Notarized attested Copy of Initial Registration Letter dated 09-10-2018
iii. Renewal due: 08-10-2023

Original dossiers have been checked and it is evident that firm has applied **"Each Tablet contains:-Paracetamol ……500mg with BP Specifications**" while in minutes the dosage form is inadvertently recorded as film coated with USP Specifications.

**Decision: Registration Board approved the above product from film coated tablet to "uncoated tablet" and finished product specifications of above product from USP to "BP Specifications".**

**Case No.08: Transfer of Registration from M/s English Pharmaceutical Industries, Lahore to M/s Novamed Pharmaceuticals Pvt. Ltd. Lahore**

M/s Novamed Pharmaceuticals Pvt Ltd. Lahore has requested for Transfer of Registration from M/s English Pharmaceutical Industries for their products as per detailed below.

| Sr. No. | Registration No. | Composition | Pack size | Fee/ Date | Remarks |
|---|---|---|---|---|---|
| 1. | 085858 | Ironone Capsule<br>Each capsule contains<br>Iron polysaccharide complex eq. to elemental iron ……...150mg | 3x5's<br>30's | Rs. 20000/-<br>Dated: 07-12-2018 | The official monograph of the applied formulation does not exist in any pharmacopoeia. |
| 2. | 052921 | Ironone Syrup<br>Each 5ml contains<br>Iron polysaccharide complex 217.4mg eq. to elemental iron ……100mg | 120ml | Rs. 20000/-<br>Dated: 07-12-2018 | The official monograph of the applied formulation does not exist in any pharmacopoeia. |

The firm have provided following documents in support of their request as per approved SOP:

a) Application with form 5 and requirement fee amounting to Rs.20,000/-for each product dated 07-12-2018.
b) Copy of registration letter dated 26-11-2008 and last renewal applied 16-11-2018
c) Copy of approved section by Central Licensing Board or panel inspection report conducted for renewal of DML as evidence of approved sections (in cases of DML before 2005).
d) Copy of last inspection report conducted by DRAP dated 22-01-2019
e) Statement / undertaking that applicant do not have registration of same products. If so, it has to apply for cancellation of product.
f) Undertaking that firm will conduct product development, accelerated and real time stability studies, validation of manufacturing process and method of analysis before sale of drug.

g) An Undertaking that:
   i. Validated method of analysis, master formula and product development data shall be provided.
   ii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.
   iii. Undertaking that the provided information is true & correct.

h) NOC (issued within last 6 Months) from existing manufacturer / registration holder permitting for registration of product to another manufacturer.

**Decision:** **Registration Board decided as follows:**

**i) Cancellation of registration of above products from the name of M/s English Pharmaceutical Industries, Lahore.**

**ii) Grant of registration of above mentioned products in name of M/s Novamed Pharmaceuticals Pvt. Ltd. Lahore.**

**iii) Reference will be sent to Cost & Pricing Division for MRP of the product.**

**Case No.09: Transfer of Registration from M/s English Pharmaceutical Industries, Lahore to M/s Next Pharmaceuticals (Pvt) Ltd, Lahore on contract manufacturing from M/s Novamed Pharmaceuticals (Pvt.) Ltd, Lahore.**

M/s Next Pharmaceuticals (Pvt.) Ltd. Lahore has requested for transfer of registration from M/s English Pharmaceutical Industries, Lahore to M/s Next Pharmaceuticals (Pvt.) Ltd, Lahore for their product Onefer Injection (I.V) 100mg as per detailed below:-

| Sr. No. | Registration No. | Composition | Demanded Pack size / MRP | Fee/Date | Remarks |
|---|---|---|---|---|---|
| 1. | 087943 | Onefer Injection (I.V)<br>Each 5ml contains<br>Iron-III Hydroxide sucrose complex eq. to elemental iron ……100mg | 5mlx5's<br>As per SRO | Rs. 20,000/-<br>Rs. 50,000/-<br>Dated: 07-12-2018 | The official monograph of the applied formulation does not exist in any pharmacopoeia. |

The firm have provided following documents in support of their request as per approved SOP:

a) Application with form 5 and requirement fee amounting to Rs.20,000/- & Rs. 50,000/- dated 07-12-2018.
b) Copy of registration letter and last renewal status.
c) Copy of approved section by Central Licensing Board or panel inspection report conducted for renewal of DML as evidence of approved sections (in cases of DML before 2005).
d) Copy of last inspection report conducted by DRAP dated 27-12-2017
e) Statement / undertaking that applicant do not have registration of same products. If so, it has to apply for cancellation of product.
f) Undertaking that firm will conduct product development, accelerated and real time stability studies, validation of manufacturing process and method of analysis before sale of drug.
g) An Undertaking that:
   i. Validated method of analysis, master formula and product development data shall be provided.

ii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.

iii. Undertaking that the provided information is true & correct.

h) NOC (issued within last 6 Months) from existing manufacturer / registration holder permitting for registration of product to another manufacturer.

**Decision: Registration Board decided as follows:**

**i. Cancellation of registration of above product from the name of M/s English Pharmaceutical Industries, Lahore.**

**ii. Approved registration of above product in the name of M/s Next Pharmaceuticals (Pvt.) Ltd, Lahore and contract manufacturing from M/s.Novamed Pharmaceuticals (Pvt.) Ltd, Lahore.**

**iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

**Case No.10: Transfer of Registration from Import to Local Manufacturing Product of M/s. Himont Pharmaceuticals (Pvt.) Ltd, Lahore.**

M/s. Himont Pharmaceuticals (Pvt.) Ltd, Lahore has requested for transfer of registration from import to local manufacturing of registered product as per detailed below:-

| Sr. No. | Reg. No | Name of product & formulation | Decision of 287th RB | Remarks |
|---|---|---|---|---|
| 1. | 023668 | Gliatilin 1000 injection<br>Each 4ml ampoule contains:-<br>Choline Alfoscerate…….1000mg<br><br>Manufactured by M/s. Italfarmaco S.P.A. Itlay<br>Approved in Italy (AIFA) | Registration board deferred request of M/s. Himont Pharmaceuticals (Pvt.) Ltd, Lahore for latest NOC from Exporter. | Now the firm submitted latest NOC from Manufactured by M/s. Italfarmaco S.P.A. Itlay stating that we have no objection of whatever regarding Himont Pharmaceuticals (Pvt.) Limited, undertaking local production of Choline Alfoscerate Injections and soft Gel capsule **as long as they do not use our brand name i.e. Gliatilin** |

**Decision: Registration Board deferred the case for evaluation of dossier.**

**Item No.VII: Import &Vetrinary Section.**

**Case.No.11: Request of M/s. Boehringer Ingelheim Vetmedica GmBH, Germany for Marketing Authorization Withdrawal of M/s. Marush (Pvt) Ltd, Lahore.**

M/s. Boehringer Ingelheim Vetmedica GmbH, Germany has requested to terminate their distribution agreement and withdraw / cancel the registration of below products registered / submitted with M/s. Marush (pvt) Ltd, Lahore with effect from 31-12-2017

| S.No. | Product Name | Category | Reg. No. |
|---|---|---|---|
| 1. | Ubrolexin Inflammatory suspension | Cattle-Pharmaceutical | 080765 |
| 2. | Calvenza-03 EIV/EHV vaccine | Equine-Biological | 080425 |
| 3. | Elite 9 HS | Cattle-Biological | 080426 |
| 4. | Bar-VAC 10 ways | Cattle-Biological | Dossier Submitted |

They will submit updated registration files of above-mentioned products for new registration through their current authorized distributor i.e. M/s. Saadat International, 17 Habitat Flat Shadman II, Jail Road, Lahore.

**Decision:- Keeping in view the termination of distribution agreement of M/s. Marush (Pvt) Ltd, K-123, Model Town, Lahore by M/s. Boehringer Ingelheim Vetmedica GmbH, Registration Board decided to issued show cause notice to M/s. Marush (Pvt) Ltd, Lahore as to why not the registration of their registered Biological and Non-Biological products may not be cancelled because of termination of their distribution agreement. Furthermore, Board also decided that processing of the submitted dossier i.e "Bar-Vac 10 ways" shall be processed by the concerned Division once fresh/latest authorization is provided by the license holder to any of their authorized agent in Pakistan.**

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**The meeting ended with vote of thanks to and from the Chair.**

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